2015

Adviser's Guide to Health Care, Volume 1: An Era of Reform—The Four Pillars

Robert James Cimasi

Todd A. Zigrang

The Adviser's Guide to Healthcare, Second Edition is a comprehensive resource and reference guide for professionals seeking a working knowledge of the myriad factors involved in consulting with and valuing healthcare practices. Developed by two of the foremost consultants in the healthcare industry, Robert James Cimasi and Todd A. Zigrang, this *Guide* is founded on their seasoned knowledge and industry experience. This 18-chapter, two-volume set is built around a new taxonomy framework for approaching economic value for the healthcare industry—the *Four Pillars* of reimbursement, regulation, competition, and technology. The *Four Pillars* framework is carried throughout each of the two volumes that comprise this book:

Volume I: An Era of Reform—The Four Pillars provides in-depth discussions of the *Four Pillars*, the reimbursement environment, the regulatory environment, the impact of the competitive forces, technology, and the landmark legislation that has contributed to the current healthcare environment.

Volume II: Consulting Services introduces different models of emerging healthcare organizations, details industry subspecialties in terms of the *Four Pillars* framework, and addresses issues related to consulting services for healthcare practices, including valuation services for enterprises, assets, and services.

Keep up with the changing face of healthcare services and consulting practices with *The Adviser's Guide to Healthcare!*

An Era of Reform—The Four Pillars, Volume I of *AICPA's Adviser's Guide to Healthcare, Second Edition*, is your resource for understanding the driving forces that have changed the face of the healthcare system in the United States. You'll receive a detailed understanding of both the short- and long-term effects of the *Patient Protection and Affordable Care Act of 2010* and the *Health Care and Education Reconciliation Act of 2010*, as well as direct insight into the key topics that factor into healthcare industry accounting and valuation activities, making it easy for you to interpret the healthcare reforms that affect your clients or your business.

In addition, *An Era of Reform—The Four Pillars* introduces an in-depth discussion of a new taxonomy framework for approaching healthcare industry issues. This framework serves as a vehicle to analyze the viability, efficiency, efficacy, and productivity of healthcare enterprises in terms of the *Four Pillars*:

- *Reimbursement Environment*
- *Regulatory Environment*
- *Impact of Competitive Forces*
- *Technology Development*

An Era of Reform—The Four Pillars is an essential resource that gives you the tools to provide specialized advice to your clients or your organization in the wake of recent healthcare reform legislation, and for years to come.

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AICPA

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The Adviser's Guide to HEALTH CARE

SECOND EDITION VOLUME I

An Era of Reform—The Four Pillars

Robert James Cimasi, MHA, ASA, MCBA, FRICS, CVA, CM&AA
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Dedication

Dedicated to

Laura M. Baumstark, MBA, CAE

and

Audrey, Peyton, Josephine, and Meredith Zigrang

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Finally, many thanks to David Cohen, Developmental Editor, at the AICPA, who served as our editor on this project.

Foreword

In November 2010, the first edition of "*The Adviser's Guide to Healthcare,*" authored by Robert James Cimasi, MHA, ASA, FRICS, MCBA, CVA, CM&AA, was published by the *American Institute of CPAs* (AICPA). This best-selling, three-volume book established a framework for CPAs, business valuation professionals, healthcare attorneys, c-suite executives, and healthcare providers, to explore the foundational, complex and interrelated issues concerning the reimbursement, regulatory, competition, and technology environments of the healthcare industry.

Since then, much has happened in the healthcare industry that is of great importance to those of us who professionally advise healthcare providers and their c-suite executives. These changes include:

- The implementation of the *Patient Protection and Affordable Care Act of 2010* (ACA), which was signed into law by President Barack Obama on March 23, 2010;
- The affirmation of the constitutionality of the ACA by the *Supreme Court of the United States*, in both *National Federation of Independent Business v. Sebelius* (2012), and *King vs. Burwell* (2015);
- The imposition of a tax on individuals who do not have qualifying health insurance coverage, known as the *Individual Mandate*;
- The expansion of Medicaid to 30 states (including Washington, DC), which covers most individuals up to 138% of the *federal poverty level* (FPL);
- A continuing shift from *volume-based* to *value-based* reimbursement models (through the utilization of evidence-based metrics, bundled payment, shared savings, co-management agreements and other alternative payment methodologies that focus less on productivity and more on quality);
- The advent of *emerging healthcare organizations* (EHOs), such as Medicare/Medicaid and commercial *accountable care organizations* (ACOs) and *clinically integrated networks* (CINs), and the resulting focus of health care providers on population health data and analytics to analyze and drive changes that result in more cost efficient care while maintaining or improving quality;
- The reduction of Medicare reimbursement to hospitals with high readmission rates, as well as to hospitals that have relatively high rates of *hospital acquired conditions* along with the continuing trend of reductions in inpatient hospital service utilization, increases in outpatient service utilization and technology advancements in telehealth;
- The passage of the *Medicare Access and CHIP Reauthorization Act* (MACRA) legislation with the impact of the sustainable growth rate (SGR) fix on future physician quality initiatives and reimbursement and the implementation of ICD-10 and new chronic care management billing codes;
- A significant increase in the number of providers that utilize (and have achieved "*meaningful use*" of) *electronic health records* (EHR) and the advent of internet or electronic physician visits for patient care;
- The increasing purchase of many physician practices by hospitals and subsequent employment of these physicians;

- Health care providers developing their own insurance plans or joint venturing with existing health plans in order to gain direct access to insurance premium dollars;
- Health insurance plans acquiring health care providers;
- The emergence of patient medical information and data hacking and resulting private lawsuits and government enforcement of the *Health Insurance Portability and Accountability Act* (HIPAA) and privacy laws; and
- Finally, because the governments gets a return of approximately 8-9 dollars related to refunds, fines and penalties for every dollar it spends on false claims, Stark and Anti-Kickback Statute enforcement, the continued emphasis on this area of enforcement with more reliance on private *qui tam* actions.

HEALTH CAPITAL CONSULTANTS (HCC) has managed to assemble an authoritative body of information on these rapidly evolving subjects and present their updated findings in an easily understood, yet comprehensive, manner. I have had the pleasure and opportunity to work with both Bob Cimasi and Todd Zigrang, and their colleagues at HCC, over many years and on many different innovative arrangements resulting from the aforementioned health care reform initiatives, and know first-hand the depth of their technical knowledge, creative problem-solving abilities, and overall understanding of the evolving elements of the U.S. healthcare industry. Their signature research resources and capabilities have now been assembled into a comprehensive textbook presented in a concise, organized method—well-sourced and indexed for ease of repeated use. This useful, second edition is a robust text structured as a sourcebook for both CPAs and the clients they serve, as well as a textbook for both aspiring professionals and those pursuing continuing professional education.

Volume I of this two-volume book presents, in six chapters:

(1) An in-depth review of the historical development of medicine in healthcare [Chapter 1];
(2) The *Four Pillars of Healthcare* (i.e., reimbursement, regulatory, competition, and technology) [Chapters 2-5]; and,
(3) Continuing efforts to reform the U.S. healthcare delivery system [Chapter 6].

Volume II of the book explores, in 12 chapters:

(1) The concepts associated with healthcare consulting [Chapter 1] and benchmarking [Chapter 2];
(2) Compensation and income distribution [Chapter 3];
(3) The financial valuation of enterprises, assets, and services [Chapter 4];
(4) Organizational structures [Chapter 5] and emerging models [Chapter 6];
(5) Various types of physician practices [Chapter 7] and mid-level providers practices [Chapter 8];
(6) Technicians and paraprofessionals [Chapter 9], as well as allied health professionals [Chapter 10];
(7) Alternative medicine practices [Chapter 11]; and,
(8) A new paradigm for professional practices [Chapter 12].

Both volumes are structured so that the reader can quickly and efficiently gain a thorough understanding of the healthcare provider medical specialty that he or she has been engaged to value.

This disciplined analysis allows the reader to use this book in a variety of ways. For those who are new to the healthcare industry, they would be well-advised to first read Chapter 1 and Chapter 12, in order to obtain an adequate knowledge basis. Second, I recommend that the reader read the rest of the chapters of Volume I and Volume II for research and reference. In addition, the textbook can be used as a regular sourcebook to return to time and again.

The second edition of "*The Adviser's Guide to Healthcare*" is exhaustively researched and provides keen insight into the trends and value drivers of the healthcare field. With this book, Bob Cimasi and Todd Zigrang have made a significant contribution to the canon of professional literature. It will prove to be an important part of the professional library of healthcare and medical practice consulting professionals.

David W. Grauer, Esq.
Partner, Jones Day

July 31, 2015

Preface

"Tho' much is taken, much abides." (Ulysses) Lord Alfred Tennyson, 1833

Even as recently as the post–World War II era of the 1950s, when an injury or sudden illness required a response by emergency services, the dispatcher would sound the community sirens, signaling the volunteer firemen on duty to radio ahead from their emergency vehicle to the small, four-bed, rural hospital, which would then alert one of the three physicians in the community to rush to the hospital to provide emergency care. In a still largely rural society, when our neighbors developed musculoskeletal conditions from working on the farms or in small manufacturing plants and machine shops, they might visit the town chiropractor, who would perform manipulation and prescribe vitamins and various homeopathic remedies. The local dentist's services were in great demand with the widespread prefluorination incidence of juvenile tooth decay. In the more urban areas, with a greater supply of trained healthcare professionals, access to care was still based, to a great degree, on the ability of patients and their families to pay or on charity care. This was a time in U.S. history when *Marcus Welby*[1] was not only a regular family television drama but was also a reasonable characterization of how healthcare services were perceived to be delivered by professional practices throughout much of the country.

During the 65-year period since 1950, the U.S. population has doubled from just more than 152 million to an estimated 320 million in 2015,[2] and the average life expectancy has increased from approximately 68 years to over 78 years.[3] With the record number of births of the "*baby boomer*" generation from the late 1940s through the early 1960s, the proportion of the U.S. population over the age of 65 increased from 8.1 percent in 1950 to an approximately 15 percent in 2014.[4] This demographic shift is expected to continue, with the proportion of Americans over 65 expected to reach 20 percent of the total population by 2030.[5]

This increased life expectancy and the subsequent "*graying*" of the *baby boomer* population, with the accompanying rise in the incidence and prevalence of the diseases, conditions, and injuries for which the elderly are more at risk, is expected to continue driving demand for healthcare services, as well as a dynamic evolution in the demand for, the supply of, and the very nature of healthcare professional practices.[6]

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1 Marcus Welby was the main character in the television show, Marcus Welby, M.D, portrayed by Robert Young between 1969 and 1976, who portrayed Dr. Welby as an idealized version of the quintessentially altruistic, kindly, and unfailingly non-corporate family physician. "Marcus Welby, M.D." Internet Movie Database, http://www.imdb.com/title/tt0063927/?ref_=ttep_ep_tt (Accessed 7/9/2015).

2 "Historical National Population Estimates: July 1, 1900 to July 1, 1999" U.S. Census Bureau, June 28, 2000, https://www.census.gov/popest/data/national/totals/pre-1980/tables/popclockest.txt (Accessed 4/1/2015); "Monthly Population Estimates for the United States: April 1, 2010 to December 1, 2015" U.S. Census Bureau, http://factfinder.census.gov/faces/tableservices/jsf/pages/productview.xhtml?src=bkmk (Accessed 4/1/2015).

3 "United States Life Tables, 2003," Centers for Disease Control and Prevention, National Vital Statistics Report, Volume 54, Number 14 (April 19, 2006), p. 34; "Health, United States, 2013: With Special Feature on Prescription Drugs" Centers for Disease Control and Prevention: Hyattsville, MD, 2014, p. 2.

4 "Demographic Trends in the 20th Century: Census 2000 Special Reports" By Frank Hobbs and Nicole Stoops, U.S. Census Bureau, November 2002, p. 58; "An Aging Nation: The Older Population in the United States" By Jennifer M. Ortman et al., U.S. Census Bureau, May 2014, http://www.census.gov/prod/2014pubs/p25-1140.pdf (Accessed 2/20/15), p. 2.

5 "An Aging Nation: The Older Population in the United States" By Jennifer M. Ortman et al., U.S. Census Bureau, May 2014, http://www.census.gov/prod/2014pubs/p25-1140.pdf (Accessed 2/20/15), p. 2–3.

6 "The Impact of the Aging Population on the Health Workforce in the United States" Health Resources and Services Administration, December 2005, p. 2; "Health, United States, 2008: With Special Feature on the Health of Young Adults" Centers for Disease Control and Prevention, March 2009, http://www.cdc.gov/nchs/data/hus/hus08.pdf#120 (Accessed 09/11/2009), p. 3–4.

Although age-related population trends are one of the key contributors to the changing demand for health services, other changes in the U.S. demographic and economic climate have significant bearing as well. The accelerated population shift from rural to urban areas during the last 60 years also may have influenced the increased incidence and prevalence of disease. Although the urbanization of the United States was already under way in 1950, this shift accelerated and continued to reshape the population distribution, with the urban population increasing from 64 percent of the U.S. population in 1950 to approximately 81 percent in 2014.[7]

Additionally, the shift from an agrarian into an industrialized society, and once again into a service-driven economy, has affected the American lifestyle and related health trends. The waning of family farms and rise of industrialized agriculture resulted in a shift in the U.S. diet. High-calorie commodities laden with fats, oils, and sugars were mass produced at the expense of farming affordable, fresh, and nutritious produce.[8] With this increased availability, and, consequently, the consumption of high caloric energy, came a decrease in energy expended, arising from the sedentary, high stress, and extended work day practices characteristic of many service industry sectors (for example, finance, legal, insurance and real estate, retail trade, and public utilities), as well as an increased reliance on technology (e.g., television, phones, and computers) as a form of entertainment. The emergence and proliferation of automobile transportation decreased emphasis on the family unit, and sedentary recreational habits led to a decrease in physical activity. These factors further fueled the impact of the fast food industry and processed food consumption on the health of the U.S. population, now plagued by chronic diseases for which obesity and poor diet are often major co-morbidities.[9]

The increased demand for healthcare services, driven by these changes and other economic and demographic variables, may have, in part, fueled the increase in healthcare expenditures from 5 percent of GDP in 1950 to 17.9 percent in 2012.[10] Increased spending also may be a consequence of the surge in technological and other medical advances in the healthcare industry, promulgated at the close of World War II and encouraged by the increase in federal and state funding for healthcare expenditures.[11] Since the adoption of Medicare in 1965, public (government) payors have come to fund more about 40% of all healthcare expenditures.[12]

Also among the driving forces of U.S. healthcare industry trends that impact professional practices are the supply and distribution of various types and multiple levels of healthcare professionals who work within a dynamic framework of myriad competing interests in order to meet the growing needs of an aging and, in many ways, less healthy population. As a result of technological and medical advances, specialized medicine flourished across the healthcare

7 "Table 1. Urban and Rural population: 1900–1990" U.S. Census Bureau, October 1995, http://www.census.gov/population/censusdata/urpop0090.txt (Accessed 03/26/2010); "World Urbanization Prospects: 2014 Revision" United Nations, 2014, http://esa.un.org/unpd/wup/Highlights/WUP2014-Highlights.pdf (Accessed 2/20/15), p. 24.

8 "Obesity and the Economy: From Crisis to Opportunity" By Davis S. Ludwig, MD, PhD and Harold A. Pollack PhD, the Journal of the American Medical Association, Volume 301, Number 5 (February 4, 2009), p. 533.

9 "Obesity and the Economy: From Crisis to Opportunity" By Davis S. Ludwig, MD, PhD and Harold A. Pollack PhD, the Journal of the American Medical Association, Volume 301, Number 5 (February 4, 2009), p. 533.

10 "Health Care Expenditures in the OECD" National Bureau of Economic Research, http://www.nber.org/aginghealth/winter06/w11833.html (Accessed 03/26/2010); "Health Expenditure, Total (% of GDP)" The World Bank, 2015, http://data.worldbank.org/indicator/SH.XPD.TOTL.ZS (Accessed 2/20/15).

11 "Plunkett's Health Care Industry Trends and Statistics 2008 (Summary)" By Jack W. Plunkett, Plunkett Research Ltd., 2007, p. 3.

12 "National Health Expenditure Projections 2013-2023" Center for Medicare & Medicaid Services, September 17, 2014, http://www.cms.gov/Research-Statistics-Data-and-Systems/Statistics-Trends-and-Reports/NationalHealthExpendData/NationalHealthAccountsProjected.html (Accessed 11/19/2014), Table 3.

workforce,[13] growing into a significant trend in the 1950s. One response to the past and present surge in demand associated with these medical advances is the growth in the physician population. The number of physicians has increased from 292,088 in 1965 to 1,045,910 in 2013, and the number of physicians per 100,000 individuals has increased from 148 to 311 over the same period.[14]

Despite these growing workforce trends, it is expected that, with a disproportionate number of physicians retiring or reducing their workload, an inadequate supply of medical graduates, and the expected continuing growth in demand, the present shortage in supply of physician manpower will continue to worsen.[15] As a result, there has been a further increase in diversification of the healthcare workforce, comprised of more than 18 million individuals, with fewer than one million being professionally active physicians.[16] The diversification, specialization, and collaboration of physician and nonphysician practitioners has increased, expanded, and enhanced to meet the compounding demand. This *Guide* addresses not just physician medical practices, but discusses a comprehensive array of professional practice types, as well as the various practitioners that comprise the healthcare workforce, including allied health professionals, mid-level providers, and technicians and paraprofessionals, as well as complementary and alternative medical practitioners.

Although physician, clinical, and other professional services currently account for $667 billion of a $2.9 trillion healthcare market (i.e., 23 percent),[17] recent efforts at regulatory and reimbursement reform suggest that healthcare professional practices may be facing an unprecedented dramatic transition. The evolution and increasing complexity of healthcare reimbursement, regulatory, competitive, and technological environments has made it more difficult for professionals to maintain revenue yield while avoiding running afoul of regulatory edicts.

A notable element of these challenges is an industry transition reflected in the recent increase in the number of hospital-employed physicians, and the dwindling of physician ownership of private, independent practices.[18] A growing number of young physicians, plagued by medical school debt and intent upon achieving a more comfortable work-life balance, are opting out of private, independent practice and pursuing salaried employment with hospitals and health systems.[19]

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13 "Health Care USA: Understanding its Organization and Delivery" By Harry A. Sultz and Kristina M. Young, Sixth Edition, Sudbury, MA: Jones and Bartlett Publishers, 2009, p. 231.

14 "Physician Characteristics and Distribution in the US" American Medical Association, 2015 Edition, 2015, p. 453.

15 "The Complexities of Physician Supply and Demand: Projections from 2013 to 2025" IHS, Inc., Report for Association of American Medical Colleges, March 2015, p. v-viii; "Results and Data: 2013 Main Residency Match," National Resident Matching Program, April 2013, http://www.nrmp.org/wp-content/uploads/2013/08/resultsanddata2013.pdf (Accessed 10/23/2014), p. 1. In 2013, 34,355 applicants competed for fewer than 30,000 graduate medical education positions.

16 "Healthcare Workers" Centers for Disease Control and Prevention, December 12, 2014, http://www.cdc.gov/niosh/topics/healthcare/ (Accessed 2/20/15); "Total Professionally Active Physicians" The Henry J. Kaiser Family Foundation, September 2014, http://kff.org/other/state-indicator/total-active-physicians/ (Accessed 2/20/15).

17 "National Health Expenditure 2013 Highlights" Centers for Medicare & Medicaid Services, http://www.cms.gov/Research-Statistics-Data-and-Systems/Statistics-Trends-and-Reports/NationalHealthExpendData/downloads/highlights.pdf (Accessed 2/20/15).

18 "A Guide to Physician Integration Models for Sustainable Success" American Hospital Association, September 2012, http://www.hpoe.org/Reports-HPOE/guide_to_physician_integration_models_for_sustainable_success.pdf (Accessed 5/19/2014), p 5.

19 "Wanting it All: A New Generation of Doctors Places Higher Value on Work-Life Balance" By Eve Glicksman, Association of American Medical Colleges, May 2013, https://www.aamc.org/newsroom/reporter/336402/work-life.html (Accessed 5/22/2014).

These trends have made it increasingly difficult for older independent practitioners to recruit junior partners,[20] a struggle which, paired with the burden of rising costs, has led many physician-owners to sell their practices to hospitals and enter into salaried employment arrangements as well.[21] This shift further away from the independent practice of medicine as a "*cottage industry*" in the United States may be viewed by patients as both a blessing and a burden of the changing healthcare delivery system. On one hand, the trend away from small, physician- or provider-owned, independent private practices holds the promise of improved quality and cost efficiency for the delivery of better and integrated medical care. Alternately, the "*corporatization*" of healthcare professional practices may result in a weakening of the independent physician- or provider-patient relationship, an intimacy and level of trust that was long a characteristic of the cottage industry healthcare delivery system of old.[22] Given these trends in healthcare professional practices, it may not be far-fetched to believe that "*Marcus Welby is dead!*" (see chapter 2 of *Consulting Services*).

Over the past century, U.S. healthcare reform initiatives have been driven by complex, polarizing, and potentially conflicting market factors, including demographic, socio-political, and economic issues, manifested by increased spending, workforce disruptions, increased prevalence and incidence of chronic and acute medical conditions, a growing and aging population, and inefficient delivery and shortcomings in translating emerging technologies into the delivery of quality and affordable care.

The passage of President Obama's signature healthcare reform initiatives (often referred to as "*Obamacare*") is a landmark event in the history of U.S. healthcare reform. Comprised of the March 23, 2010 enactment of the Patient Protection and Affordable Care Act[23] and the March 25, 2010 passage of the Health Care and Education Reconciliation Act of 2010,[24] the Affordable Care Act (ACA) is neither unique nor is it the first of such reform efforts. The ACA is still in flux, with a multitude of unresolved issues and uncertainties remaining. The first major challenge to the ACA was posed by the *National Federation of Independent Business v. Sebelius* case, where the Supreme Court upheld the ACA's individual mandate, but ruled that the ACA's Medicaid expansion would be optional for states.[25] More recently, the ACA was challenged in the Supreme Court in the *King v. Burwell* case, where the Supreme Court once again upheld the ACA, holding that tax credits provided to individuals who purchased insurance on federally-established health insurance exchanges were, in fact, legal.[26] Despite these victories, there still remain challenges to the implementation of the ACA's provisions.[27] The resolution of these issues, both within the political and market environments, will have a significant impact on the operation of healthcare organizations, as well as on the value of those enterprises, assets, and services.

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20 "2012 Review of Physician Recruiting Incentives" Merritt Hawkins, 2012, http://www.merritthawkins.com/uploadedFiles/MerrittHawkins/Pdf/mha2012survpreview.pdf (Accessed 4/1/2015), p. 4.

21 "A Guide to Physician Integration Models for Sustainable Success" American Hospital Association, September 2012, http://www.hpoe.org/Reports-HPOE/guide_to_physician_integration_models_for_sustainable_success.pdf (Accessed 5/19/2014), p. 5.

22 "More Doctors Giving Up Private Practices" By Gardiner Harris, New York Times, March 25, 2010, http://www.nytimes.com/2010/03/26/health/policy/26docs.html?pagewanted=print (Accessed 5/25/2010); "The Social Transformation of American Medicine" By Paul Starr, Basic Books Inc. 1982, p. ix.

23 "Patient Protection and Affordable Care Act" Pub. L. No. 111-148, 124 Stat. 119 (March 23, 2010).

24 "Health Care and Education Reconciliation Act of 2010" Pub. L. No. 111-152, 124 Stat. 1029 (March 25, 2010).

25 "National Federation of Independent Business et al. v. Sebelius et al." 132 S. Ct. 2566, 2600-2604 (2012).

26 "King et al. v. Burwell, Secretary of Health and Human Services, et al" No. 14-114 (U.S. June 25, 2015), Slip Opinion, p. 21.

27 See Chapter 6, Healthcare Reform, for a further discussion regarding further challenges to the ACA.

The volatility of the U.S. healthcare delivery system, with its continuing uncertainty, impacts suppliers, payors, and providers alike. In addition to navigating through the turbulence of healthcare reform, suppliers, payors, and providers must reckon with capricious capital markets and challenging economic conditions. The direction and ultimate consequence of this process of change on investor perceptions of growth, risk, and capital demands is, in many ways, simply a recasting of failed reform efforts from the 1990s. President Harry S. Truman once said, *"The only thing new in the world is the history you don't yet know."*

A continued and unsustainable rise in healthcare expenditures followed the failed cost reform efforts of the 1990s and served as one of several catalysts that precipitated the need for national healthcare reform initiatives, e.g., the ACA. Other forces that may have driven the passage of some kind of national healthcare reform legislation include:

(1) Declining reimbursement for physician services and provider manpower shortages;
(2) The growing and aging "*baby boomer*" patient demographic;
(3) The amount of the population that remains uninsured and is increasingly underinsured and/or unable to access care; and,
(4) The increasing public demand for transparency, disclosure, and awareness as the burden of healthcare costs shifts from insurance companies to patients.

These circumstances, together with the aftermath of the recent economic recession, an unprecedented intensity and political discourse regarding U.S. government deficit and debt, and an increasing political polarization (especially related to asserting states' rights in opposing federal initiatives), have created a *"perfect storm"* that may fuel real changes to the current system of healthcare delivery in the United States.

These dramatic and ongoing changes, as well as the sheer size and complexity of the healthcare delivery system, have provided new opportunities in healthcare consultancy. Responding to the expanding market in the current era of reform, many financial and management consulting firms have extended their service line to include healthcare advisory services. Accounting firms, which traditionally have served as primary business and financial advisors for their clients, also have steadily increased the scope of their healthcare professional practice advisory services.

The persistent volatility of the healthcare industry landscape can be difficult to navigate. To be effective in offering services to healthcare professional practice clients, consulting professionals should possess an understanding of the history and background of professional practice enterprises, as well as the market mechanisms at work in the current healthcare environment—in particular, how those forces interact to shape the future direction of professional practices in the healthcare delivery system under pending legislative reform.

Although consultancy for healthcare professional practices may present an attractive business development opportunity for consultants, it is not an area that lends itself to ad hoc, generic advisory services. In light of the increasingly complex, diverse, and ever-changing scope and volume of information that contributes to a comprehensive understanding of the healthcare industry, consulting professionals who possess a more general background and expertise and

pursue providing services to healthcare professional practices may endeavor to become better informed to avoid being viewed, in some regard, as jacks of all trades and masters of none.

This two-volume book set is designed to serve as a reference guide for those seeking a more in-depth knowledge of the healthcare marketplace; a working and applied understanding of the forces that affect the industry within which healthcare providers operate; and a primer regarding how consulting services may be offered to these enterprises specifically, healthcare professional practices, in an ever-changing reimbursement, regulatory, competitive, and technological healthcare environment. Such industry-specific knowledge should serve as a catalyst for these consulting professionals to better serve their existing clients and expand their services for potential new engagements.

This *Guide* may also prove useful to the licensed healthcare professionals who own independent practices, as well as their professional advisors, managers, and administrators. Providing these stakeholders with in-depth background information and a context within which to view professional practice enterprises as part of a dynamic healthcare marketplace may enhance their ability to assist their organizations in surviving and thriving in the future.

With the second edition of this *Guide*, we earnestly solicit reader comments, criticisms, and suggestions for improvements in future editions.

Sincerely,

Robert James Cimasi
MHA, ASA, FRICS, MCBA, CVA, CM&AA
Chief Executive Officer
HEALTH CAPITAL CONSULTANTS

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About the Authors

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Robert James Cimasi serves as Chief Executive Officer of **HEALTH CAPITAL CONSULTANTS** (HCC), a nationally recognized healthcare financial and economic consulting firm headquartered in St. Louis, MO, serving clients in 49 states since 1993. Mr. Cimasi has over thirty years of experience in serving clients, with a professional focus on the financial and economic aspects of healthcare service sector entities including valuation consulting and capital formation services; healthcare industry transactions, including joint ventures, mergers, acquisitions, and divestitures; litigation support & expert testimony; and certificate-of-need and other regulatory and policy planning consulting.

Mr. Cimasi holds a Master in Health Administration from the University of Maryland, as well as several professional designations: Accredited Senior Appraiser (ASA—American Society of Appraisers); Fellow Royal Institution of Chartered Surveyors (FRICS—Royal Institution of Chartered Surveyors); Master Certified Business Appraiser (MCBA—Institute of Business Appraisers); Certified Valuation Analyst (CVA—National Association of Certified Valuators and Analysts); and Certified Merger & Acquisition Advisor (CM&AA—Alliance of Merger & Acquisition Advisors). He has served as an expert witness on cases in numerous courts, and has provided testimony before federal and state legislative committees. He is a nationally known speaker on healthcare industry topics and the author of several nationally published books, the latest of which include: "*Accountable Care Organizations: Value Metrics and Capital Formation*" [2013—Taylor & Francis, a division of CRC Press]; "*The Adviser's Guide to Healthcare*"—Vols. I, II & III [2010—AICPA]; "*The U.S. Healthcare Certificate of Need Sourcebook*" [2005—Beard Books]; and, his most recent book, "*Healthcare Valuation: The Financial Appraisal of Enterprises, Assets, and Services*" [2014 - John Wiley & Sons].

Mr. Cimasi is the author of numerous additional chapters in anthologies textbooks, and legal treatises; has published articles in peer reviewed and industry trade journals, research papers, and case studies; and is often quoted by healthcare industry press. Additionally, Mr. Cimasi has served as faculty before numerous professional and academic certification and continuing education classes, including: the CPA Leadership Institute; the American Health Lawyers Association (AHLA); the American Bar Association (ABA); the American Institute of CPAs (AICPA); the American Society of Appraisers (ASA); the National Association for Certified Valuators and Analysts (NACVA); and, the Internal Revenue Service (IRS).

In 2006, Mr. Cimasi was honored with the prestigious "*Shannon Pratt Award in Business Valuation*" conferred by the Institute of Business Appraisers. In 2013, Mr. Cimasi achieved the Certificate of Completion of the American Society of Appraisers Healthcare Special Interest Group's (ASA HSIG) Multidisciplinary Advanced Education in Healthcare Valuation Program. Mr. Cimasi serves on the Editorial Board of the *Business Appraisal Practice* of the Institute of Business Appraisers, of which he is a member of the College of Fellows; and as *Chair Emeritus* of the ASA HSIG. In 2011, he was named a Fellow of the Royal Institution of Chartered Surveyors (RICS).

Todd A. Zigrang, MBA, MHA, FACHE, ASA

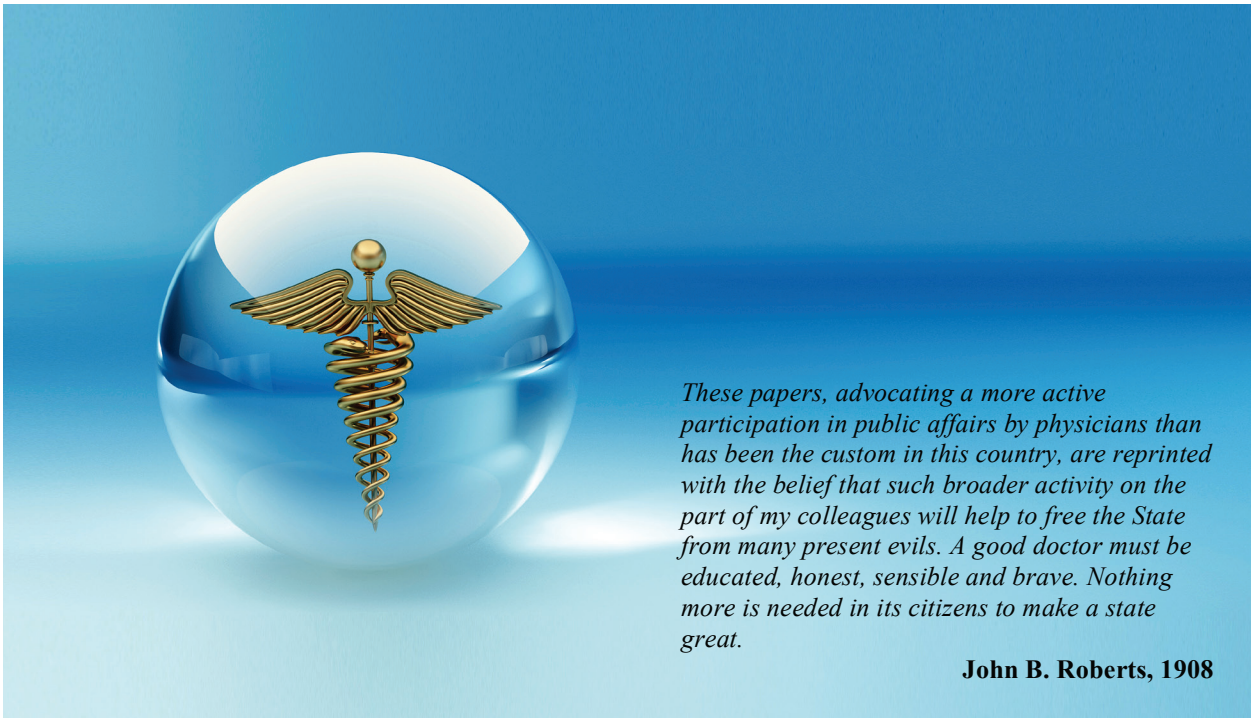
Todd Zigrang is the President of **HEALTH CAPITAL CONSULTANTS** (HCC), where he focuses on the areas of valuation and financial analysis for hospitals, physician practices, and other healthcare enterprises. Mr. Zigrang has over 20 years of experience providing valuation, financial, transaction, and strategic advisory services nationwide in over 1,000 transactions and joint ventures involving acute care hospitals and health systems; physician practices; ambulatory surgery centers; diagnostic imaging centers; accountable care organizations, managed care organizations, and other third-party payors; dialysis centers; home health agencies; long-term care facilities; and numerous other ancillary healthcare service businesses. Mr. Zigrang is also considered an expert in the field of healthcare compensation for physicians, executives, and other professionals.

Mr. Zigrang holds a Master of Science in Health Administration (MHA) and a Master of Business Administration (MBA) from the University of Missouri at Columbia. He is a Fellow of the American College of Healthcare Executives (FACHE) and holds the Accredited Senior Appraiser (ASA) designation from the American Society of Appraisers, where he has served as President of the St. Louis Chapter, and currently serves as Chair of the ASA Healthcare Special Interest Group (HSIG).

Mr. Zigrang is the author of numerous chapters in legal treatises and anthologies and peer-reviewed and industry articles such as *The Accountant's Business Manual* (AICPA); *Valuing Professional Practices and Licenses* (Aspen Publishers); *Valuation Strategies*; *Business Appraisal Practice*; and *NACVA QuickRead*.

Additionally, Mr. Zigrang has served as faculty before professional and trade associations such as the ASA; the American Bar Association (ABA); the National Association of Certified Valuators and Analysts (NACVA); Physician Hospitals of America (PHA); the Institute of Business Appraisers (IBA); the Healthcare Financial Management Association (HFMA); and, the CPA Leadership Institute.

Introduction



THE FOUR PILLARS OF THE HEALTHCARE INDUSTRY

When developing an understanding of the forces and stakeholders that have the potential to drive healthcare markets, it is useful to examine professional practice enterprises as they relate to the "Four Pillars" of the healthcare industry: reimbursement, regulatory, competition, and technology (see the following figure I-1). These four elements shape the professional practice and provider dynamic, while serving as a framework for analyzing the viability, efficiency, efficacy, and productivity of healthcare enterprises. The four pillars, discussed briefly in this introduction, will be further addressed in subsequent chapters devoted to each of these four topics.

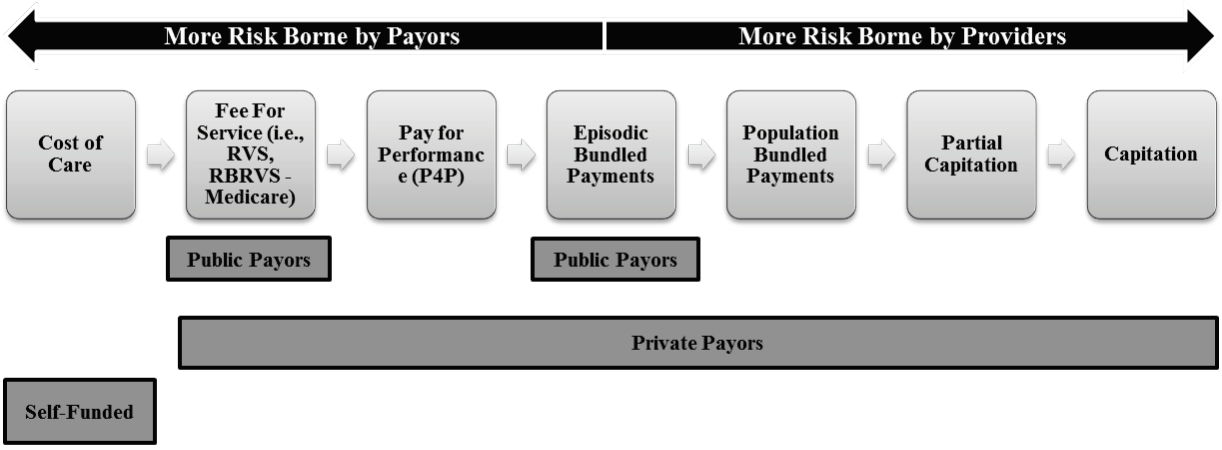
Figure I-1: Four Pillars of Healthcare Value

REIMBURSEMENT

Chapter 2, *Reimbursement Environment,* provides an overview of current and future trends in healthcare reimbursement. In the current era of healthcare reform, it is vital for providers to maintain an applied understanding of healthcare payment sources (e.g., Medicare, Medicaid, State Children's Health Insurance Program); revenue and billing procedures (e.g., the resource-based relative value scale payment system, relative value units and their components); Current Procedural Terminology (CPT) codes; and, payment plans (e.g., fee-for-service plans, performance-based payment plans, and consumer driven health plans).

As healthcare expenditures rise, proponents of reform advocate for both a reduction in service costs and increases in quality of care. To achieve these goals, the healthcare industry has generally moved toward models that shift the risk toward providers, such as managed care, pay-for-performance programs, gainsharing arrangements, and patient-centered models of medical practice (e.g., boutique medicine, the medical home model, accountable care organizations). In addition, reimbursement for physician services has become a highly contested issue; repeated annual congressional overrides of reductions to physician payment rates for services under the sustainable growth rate system have created a large gap in current healthcare spending and target (sustainable) expenditures. To combat these rising costs, for example, the high expenditures for imaging services, billing codes have, during the past decade, been "bundled." Bundling has been utilized to reduce the overall payment for certain interrelated services by billing for them under one, combined code, rather than under independent codes. The emergence of bundled codes, among other trends, is evidence of the rapidly changing reimbursement environment within the U.S. healthcare delivery system.

Figure I-2: U.S. Health Insurance Reimbursement Options



REGULATORY

The U.S. healthcare industry is governed by a network of ever-changing state and federal regulations, relating to both physician and nonphysician professionals. Chapter 3, *Regulatory Environment*, contains a detailed overview of the general provisions that apply to the various practitioners and providers in the healthcare industry.

Various key regulatory issues may influence the healthcare climate. For example, in recent years, there has been increased government scrutiny of regulatory violations of fraud and abuse laws, particularly as the violations relate to acquisition and compensation transactions between hospitals and physicians. Failure to comply with valuation standards for physician and executive compensation arrangements (for example, fair market value and commercial reasonableness) may result in liability under the False Claims Act, the Antikickback Statute, and the Stark law. Chapter 3, *Regulatory Environment* includes a discussion of these concepts and regulations along with the definitions, applications, implications, and trends of additional federal and state healthcare laws and regulations (for example, Certificate of Need programs).

COMPETITION

Additionally, rapid changes in the healthcare competitive market may be attributed to the ever-increasing demand for care from the aging baby boomer population; the influx of newly insured individuals as a result of the ACA; and, the continuous development of new technologies, the latter which may enhance the quality and efficiency of the healthcare delivery system.

The changing demographics of the patient population (i.e., the "baby boomer" population) and the physician workforce also may have a lasting impact on the healthcare competitive environment. There has been an increase in concern related to the shortage of physician manpower and the limited number of available residency slots that restrict physician entry into the healthcare market. Among the most notable concerns is the perceived shortage of primary care physicians; with many medical students opting for careers in higher-paying medical

specialties, primary care physicians are pressed more than ever to meet patient demand for services. Additionally, women and minorities make up a much higher percentage of the physician workforce than they have in the past (in most specialties), effectively diversifying the traditionally Caucasian male physician demographic. Although they provide patients with more choices for care, they also are presenting challenges related to the demands of achieving a practice—lifestyle balance. However, one factor which may help alleviate the physician manpower shortage is the increasing supply and autonomy of mid-level providers such as nurse practitioners and physician assistants, who can provide a specific scope of services independent of physician oversight.

These issues and numerous others, such as healthcare and insurance reform, shape the unique and dynamic healthcare competitive environment. Chapter 4, *Impact of Competitive Forces*, includes a more detailed examination of these issues within the context of Porter's five forces of competition.

TECHNOLOGY

Significant technological advances during the past few decades have had a notable impact on the U.S. healthcare delivery system. Electronic health record technologies gradually have been integrated into medical records maintenance systems, replacing traditional paper files. Similarly, computerized physician order entry has streamlined the process of ordering prescriptions and minimized error caused by handwritten orders. Although these new electronic approaches to healthcare delivery are saving employers money, physician unwillingness to adopt these new technologies has impeded their widespread emergence into the healthcare market. Regardless, new and improved management technology is has become an important facet of the healthcare industry.

Progress in clinical technology also has flourished in recent years, including highly controversial practices such as stem cell research. However, one of the various genres of medical services that may have drawn the most attention is *imaging*; services that utilize the technology, such as the various types of magnetic resonance imaging, computed tomography (for example, positron emission tomography-computed tomography, single photon emission computed tomography, and picture archiving and communications systems), and teleradiology services, have become a staple in modern diagnostic radiology practice.

Oncologists and surgeons also have seen major advancements in the treatment and detection of cancer and in minimally invasive or noninvasive surgery, respectively. For oncologists, radiation therapy methods are improving continuously, and their use of innovative alternative and supporting technologies, such as image-guided radiation therapy, which is used during intensity-modulated radiation therapy; gamma knives; and stereotactic radiosurgery, is increasing. The use of robotics has become a rapidly advancing trend, and surgeons with robotics experience are sought after for their skills. Robotic technologies have been used for urologic, gynecologic, and cardiothoracic procedures, among others. Although expensive, robotic technology minimizes the degree of invasiveness, shortens recovery time, and improves patient outcomes.

These advancements in medical technology have helped to revolutionize modern medicine. The cost of implementing and maintaining these new devices and procedures, however, may counterbalance efforts to control healthcare expenditures. The future of healthcare may well depend on a compromise between the advancement of medical technological capabilities and the cost of supporting those technologies that allows practitioners to provide the best quality care possible. Chapter 5, *Technology Development* includes a more detailed discussion of the impact of technology on healthcare practices.

STRUCTURE OF THIS *GUIDE*

This *Guide* serves as a resource for consulting professionals who provide services to professional practices and related healthcare providers. It is divided into two books:

1. *An Era of Reform—The Four Pillars*, consisting of 6 chapters, begins with an abridged history of healthcare, from the origins of medicine to the transformation of modern healthcare in the twentieth and twenty-first centuries (chapter 1). The next several chapters (chapters 2–5) provide a more comprehensive look at the reimbursement, regulatory, competitive, and technological environments as they apply to healthcare practice. Chapter 6 provides an overview of the healthcare environment and related healthcare reform bills, at the time of the submission of this *Guide*.
2. *Consulting Services*, consisting of twelve chapters, the first four of which provide a descriptive overview for consultants advising professional practice clients on matters related to healthcare consulting (chapter 7); benchmarking strategies related to healthcare and valuation (chapter 8); compensation and income distribution (chapter 9); and, the financial valuation of healthcare enterprises, assets, and services (chapter 10). The next chapters describe a myriad of practice structures (chapter 5), medical specialties, and professionals seen in healthcare to date. This discussion includes emerging models of healthcare enterprises, physicians, mid-level providers, technicians and paraprofessionals, allied health professionals, alternative medicine practitioners, and a new paradigm for professional practices (chapters 6–11, respectively), as well as information regarding the scope of subspecialties, types of providers, and practitioners of each service type.

It should be noted that *Consulting Services* focuses on the professional practice component of the U.S. healthcare delivery system and does not directly address other healthcare sectors, including inpatient (for example, hospitals), outpatient and ambulatory (for example, ambulatory surgery centers and diagnostic imaging centers), long term care (for example, nursing homes and hospice), and home health sectors. However, many of the concepts and much of the content in the aforementioned sections of this *Guide* may be applicable to consulting projects in these other healthcare sectors, as well.

READER TOOLS: SIDEBARS, TABLES, AND FIGURES

To enhance the utility of this *Guide* as a navigable source for readers of various backgrounds, certain tools have been developed and appear throughout:

1. **Sidebars.** These supplemental features have been integrated into the content of each chapter and have been grouped as follows:
   a. **Key terms.** Key terms are important words used in text that may need to be defined for the reader. This tool can be found at the beginning of each chapter and serves to identify those terms that appear within the text of corresponding chapters as well as in the glossary at the end of this book. Key terms may be discussed, or, at least, mentioned in multiple chapters.
   b. **Key concepts.** Similar to key terms, key concepts are the important concepts mentioned in text that may require further elaboration or emphasis and a list of key concepts can be found at the beginning of each chapter. This tool serves a bimodal role, to further stress important ideas discussed in the chapter and to further discuss ideas that may have only been mentioned in passing.
   c. **Key sources.** This feature points to significant sources, both used within this *Guide* and fundamental to the chapter content. These sources serve as chapter-specific bibliographies, and, therefore, may be found in multiple chapters. Key sources can be found at the end of each chapter.
   d. **Associations.** A brief list of topic-relevant associations provides the reader with contact information for associations referenced within a chapter. A list of related associations can be found at the end of each chapter.
   e. **Factoids.** These are brief, related facts of interest either mentioned in text or supplemental to a topic discussed in a particular chapter that help build a contextual framework for the reader that may aid in explaining the material. You will find factoids located close to the content that they address within each chapter.
2. **Tables.** Tables are used to display benchmark data, to demonstrate numerical trends, and to draw comparisons. They are referenced in text, but they may be used to display extra information not discussed in the content of the chapter.
3. **Figures.** Pictorial and graphical depictions have been used to complement the text and enhance the reader's comprehension of the material. These figures are referenced and discussed in text.

PROFESSIONAL PRACTICE TAXONOMY

Healthcare reform is driven by complex, polar, and potentially conflicting market factors, such as increased spending; a growing and graying demographic; workforce shortages and inefficiencies; problematic chronic and acute health indicators; and shortcomings in the delivery of efficient, quality care. The subsequent chapters detail these issues, their implications, and the reform initiatives proposed to delicately counterbalance the U.S. healthcare delivery system on the nation's scale of justice. However, before delving into the complexities of healthcare

reimbursement, regulation, competition, and technology, the dynamic healthcare provider workforce should be addressed.

Provider versatility has been growing and changing to complement an evolving healthcare industry.[1] The diverse healthcare workforce is instrumental to improving efficacy, quality of care, financial efficiency, patient satisfaction, workforce productivity, and professional satisfaction.[2] In order to capitalize on this potential, institutions adopt models that strategically allocate physician and nonphysician manpower resources on the basis of scope and skill set—ensuring that the right care is provided by the right provider at the right time and place."[3] Implementation models are characterized by (1) the site of service (for example, hospital, clinic, or community); (2) the guidelines that regulate provider practice and compensation within an intraprofessional care model; (3) the system by which scope of practice is defined for each provider classification; (4) the degree to which providers are liable for their professional actions; and, (5) the degree to which they model efficacy and efficiency.[4]

The intraprofessional care models that have been implemented most successfully stem from several provider taxonomies, which were intended to mirror the complex relationships within the existing healthcare workforce. The most influential provider taxonomies (detailed in tables I-1[A-D] and I-2) are each based on a different system of classification that focuses on a portion of the industry dynamic and include those developed by (1) the Human Resources and Services Administration, which utilizes a four-tiered hierarchal system and aggregates specific occupations based on the degree of training and type of services provided (table I-1A); (2) the Centers for Medicare and Medicaid Services, which classifies professionals based on the specialized area of medical practice under which they provide their services (table I-1B); and (3) the American Medical Association, which categorizes professionals based on how they bill these professionals for services (table I-1C). Although these taxonomies are based on key structural considerations, they each neglect certain industry facets, and discrepancies arise due to the limitations that this unilateral rationale presents. The models used to enhance the delivery of intraprofessional care face similar limitations, as institutions typically focus on only one, highly customized model, foregoing a more industrywide perspective by neglecting models that represent the other industry sectors.[5]

Alternately, multiple models can be synthesized to represent an industrywide, intrapersonal dynamic.[6] Elements from three models, the physician extender model, the triage model, and the

1 "Coming Together, Moving Apart: A History of the Term Allied Health in Education, Accreditation, and Practice" By Fred G. Donini-Lenhoff, Journal of Allied Health, Vol. 37, No. 1 (2008), p. 47; "Interprofessional Healthcare: A Common Taxonomy to Assist with Understanding" By Alice B. Aiken, PT, PhD and Mary Ann McColl, PhD, Journal of Allied Health, Vol. 38, No. 3 (Fall 2009), p. e-92.

2 "Coming Together, Moving Apart: A History of the Term Allied Health in Education, Accreditation, and Practice" By Fred G. Donini-Lenhoff, Journal of Allied Health, Vol. 37, No. 1 (2008), p. 47; "Interprofessional Healthcare: A Common Taxonomy to Assist with Understanding" By Alice B. Aiken, PT, PhD and Mary Ann McColl, PhD, Journal of Allied Health, Vol. 38, No. 3 (Fall 2009), p. e-92.

3 "Interprofessional Healthcare: A Common Taxonomy to Assist with Understanding" By Alice B. Aiken, PT, PhD and Mary Ann McColl, PhD, Journal of Allied Health, Vol. 38, No. 3 (Fall 2009), p. e-92.

4 "Coming Together, Moving Apart: A History of the Term Allied Health in Education, Accreditation, and Practice" By Fred G. Donini-Lenhoff, Journal of Allied Health, Vol. 37, No. 1 (2008), p. 47; "Interprofessional Healthcare: A Common Taxonomy to Assist with Understanding" By Alice B. Aiken, PT, PhD and Mary Ann McColl, PhD, Journal of Allied Health, Vol. 38, No. 3 (Fall 2009), p. e-92.

5 "Coming Together, Moving Apart: A History of the Term Allied Health in Education, Accreditation, and Practice" By Fred G. Donini-Lenhoff, Journal of Allied Health, Vol. 37, No. 1 (2008), p. 47; "Interprofessional Healthcare: A Common Taxonomy to Assist with Understanding" By Alice B. Aiken, PT, PhD and Mary Ann McColl, PhD, Journal of Allied Health, Vol. 38, No. 3 (Fall 2009), p. e-92.

6 "Interprofessional Healthcare: A Common Taxonomy to Assist with Understanding" By Alice B. Aiken, PT, PhD and Mary Ann McColl, PhD, Journal of Allied Health, Vol. 38, No. 3 (Fall 2009), p. e-92-e-93.

parallel model, were used to derive the taxonomical system for classifying healthcare professionals that is utilized in this *Guide* (detailed in tables I-1D and I-2).

Traditionally, all nonphysician clinicians are referred to as "*allied health professionals*."[7] However, advances in technology and capability paired with the change in healthcare demand during the course of medical history have rendered this system of classification far too rudimentary for the diversity that the workforce now holds. As the healthcare industry continues to change and market demand for primary, preventative, and rehabilitative care increases, the varying degrees of responsibility, expertise, and autonomy afforded to the increasingly diverse nonphysician healthcare workforce is reassessed and the scope of practice continues to expand.[8] By creating a taxonomy based on these three representative models, allied health professionals may be partitioned into appropriate substrata of nonphysician providers, because they would function within the ideal intraprofessional workforce dynamic.

Under the physician extender model, the scope of nonphysician professional practice lies entirely within the scope of physician practice.[9] These *physician extenders* (hereinafter "*technicians and paraprofessionals*") supplement physician care, either as highly technical or technological support or as manpower support.[10] Specifically, one subset of the professionals defined within this model is trained in a highly specialized technical or technological field and provides services that physicians rely upon but are incapable of providing independently. The other subset of professionals, physician extenders, provides routine medical and administrative services to relieve physicians of a portion of their workload, allowing them to focus on more difficult and complex tasks. From an official standpoint, these professionals may or may not be licensed or certified (depending on which subset of the provider population they belong to or which role they tend to fill most appropriately).

The original rationale behind the classification of "*mid-level providers*," as defined for the purposes of this *Guide*, derives from the *triage model*.[11] Under this model, nonphysician professionals are trained to provide a specific subset of physician services, and they traditionally serve as a source of physician relief by providing triage care and enhancing patient throughput.[12] Historically, these providers could only practice under direct or indirect supervision of a physician.[13] As demand has increased, namely for the provision of primary care services, the supply and autonomy of mid-level providers (e.g., nurse practitioners and physician assistants) have increased.[14] To date, these professionals are relied upon for the provision of specialized

7 "Interprofessional Healthcare: A Common Taxonomy to Assist with Understanding" By Alice B. Aiken, PT, PhD and Mary Ann McColl, PhD, Journal of Allied Health, Vol. 38, No. 3 (Fall 2009), p. e-92.
8 "The Impact of Nonphysician Clinicians: Do They Improve the Quality and Cost-Effectiveness of Health Care Services?" By Miranda Laurant; Mirjam Harmsen, Hub Wollersheim, Richard Grol, Marjan Faber, and Bonnie Sibald, Medical Care Research and Review, Vol. 66, No. 6 (December 2009), p. 36S.
9 "Interprofessional Healthcare: A Common Taxonomy to Assist with Understanding" By Alice B. Aiken, PT, PhD and Mary Ann McColl, PhD, Journal of Allied Health, Vol. 38, No. 3 (Fall 2009), p. e-93.
10 "Interprofessional Healthcare: A Common Taxonomy to Assist with Understanding" By Alice B. Aiken, PT, PhD and Mary Ann McColl, PhD, Journal of Allied Health, Vol. 38, No. 3 (Fall 2009), p. e-93.
11 "Interprofessional Healthcare: A Common Taxonomy to Assist with Understanding" By Alice B. Aiken, PT, PhD and Mary Ann McColl, PhD, Journal of Allied Health, Vol. 38, No. 3 (Fall 2009), p. e-94.
12 "Interprofessional Healthcare: A Common Taxonomy to Assist with Understanding" By Alice B. Aiken, PT, PhD and Mary Ann McColl, PhD, Journal of Allied Health, Vol. 38, No. 3 (Fall 2009), p. e-94.
13 "Interprofessional Healthcare: A Common Taxonomy to Assist with Understanding" By Alice B. Aiken, PT, PhD and Mary Ann McColl, PhD, Journal of Allied Health, Vol. 38, No. 3 (Fall 2009), p. e-94.
14 "Interprofessional Healthcare: A Common Taxonomy to Assist with Understanding" By Alice B. Aiken, PT, PhD and Mary Ann McColl, PhD, Journal of Allied Health, Vol. 38, No. 3 (Fall 2009), p. e-94.

services that are *incident to* physician services, but also exercise a certain measure of independence, because they can autonomously provide a specific scope of services in lieu of physicians.[15] The services which mid-level providers are authorized to provide in lieu of physicians typically are limited to a portion of primary care practice healthcare services, and, consistent with the triage model, complex cases are handed off to physicians, because they may fall outside that predetermined scope of service.[16]

The *parallel model* lies on the opposite end of the spectrum. Under this model, the scope of the allied health professional practice is separate, distinct, and, essentially, parallel to the scope of physician practice.[17] These allied health professionals are nonphysician practitioners who practice independently and offer services that, despite some overlap with physician care, are largely outside the scope of physician practices.[18] Although allied health professionals (as defined in this *Guide*) and physicians sometimes may compete due to shared patient populations and practice objectives, the specific services they provide typically have distinct differences.

Table I-1A: Healthcare Professional Practices Provider Taxonomies

Organization: Human Resources and Services Administration
Classification System: A six-digit hierarchal structure resulting in four levels of aggregation (categories): Category 1=Major Group, Category 2=Minor Group, Category 3=Broad Occupation, Category 4=Detailed Occupation.

Category	Definition	Subcategories	
Healthcare Practitioners and Technical Occupations	Major Occupational Group A—Professional occupations concerns with the study, application, and/or administration of medical practices or theories. Some occupations are concerned with interpreting, informing, expressing, or promoting ideas, products, etc. by written, artistic, sound, or physical medium. This category also includes technical occupations, involved in carrying out technical and technological functions in health. May perform research, development, testing, and related activities. May operate technical equipment and systems. **,†	**Health Diagnosing Occupations**	
		Chiropractors	
		Dentists	
		Dentists, General	Prosthodontists
		Oral and Maxillofacial Surgeons	Dentists, All Other Specialties
		Orthodontists	
		Optometrists	
		Physicians and Surgeons	
		Podiatrists	
		Veterinarians	

(continued)

15 "Special Issues in Physician Compensation," in "Physician Compensation Plans: State-of-the-Art Strategies" By Bruce A. Johnson, JD, MPA and Deborah Walker Keegan, PhD, FACMPE, Englewood, CO: Medical Group Management Association, 2006, p. 193-194.
16 "Special Issues in Physician Compensation," in "Physician Compensation Plans: State-of-the-Art Strategies" By Bruce A. Johnson, JD, MPA and Deborah Walker Keegan, PhD, FACMPE, Englewood CO: Medical Group Management Association, 2006, p. 193-194; "Interprofessional Healthcare: A Common Taxonomy to Assist with Understanding" By Alice B. Aiken, PT, PhD and Mary Ann McColl, PhD, Journal of Allied Health, Vol. 38, No. 3 (Fall 2009), p. e-94-e-95.
17 "Interprofessional Healthcare: A Common Taxonomy to Assist with Understanding" By Alice B. Aiken, PT, PhD and Mary Ann McColl, PhD, Journal of Allied Health, Vol. 38, No. 3 (Fall 2009), p. e-94-e-95.
18 "Interprofessional Healthcare: A Common Taxonomy to Assist with Understanding" By Alice B. Aiken, PT, PhD and Mary Ann McColl, PhD, Journal of Allied Health, Vol. 38, No. 3 (Fall 2009), p. e-94-e-95.

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		Dietitians and Nutritionists	
		Pharmacists	
		Physician Assistants	
		Therapists	
		Occupational Therapist	Respiratory Therapists
		Physical Therapist	Speech-Language Pathologist
		Radiation Therapists	Exercise Physiologists
		Recreational Therapists	Therapists, All Other
		Registered Nurses	
		Nurse Anesthetists	
		Nurse Midwives	
		Nurse Practitioners	
		Miscellaneous Health Diagnosing/Treating Practitioners	
		Health Technologists and Technicians	
		Clinical Laboratory Technologists/Technicians	
		Medical and Clinical Laboratory Technologists	Medical and Clinical Laboratory Technicians
		Dental Hygienists	
		Diagnostic Related Technologists and Technicians	
		Cardiovascular Technologists and Technicians	Radiologic Technologists
		Diagnostic Medical	Magnetic Resonance Imaging Technologists
		Sonographers	
		Nuclear Medicine Technologists	
		Emergency Medical Technicians/Paramedics	
		Health Practitioner Support Technologists/Technicians	
		Dietetic Technicians	Surgical Technicians
		Pharmacy Technicians	Veterinary Technicians
		Psychiatric Technicians	Ophthalmic Medical Technicians
		Respiratory Technicians	
		Licensed Practical and Licensed Vocational Nurses	
		Medical Records and Health Information Technicians	
		Opticians, Dispensing	
		Miscellaneous Health Technologists/Technicians	
		Orthotists and Prosthetists	Other
		Hearing Aid Specialists	

<table>
<tr><th>Category</th><th>Definition</th><th colspan="2">Subcategories</th></tr>
<tr><td rowspan="6">Healthcare Practitioners and Technical Occupations</td><td rowspan="6">Major Occupational Group A—Professional occupations concerns with the study, application, and/or administration of medical practices or theories. Some occupations are concerned with interpreting, informing, expressing, or promoting ideas, products, etc. by written, artistic, sound, or physical medium. This category also includes technical occupations, involved in carrying out technical and technological functions in health. May perform research, development, testing, and related activities. May operate technical equipment and systems. **,†</td><td colspan="2">Other Healthcare Practitioners/Technical Occupations</td></tr>
<tr><td colspan="2">Occupational Health and Safety Specialists/Technicians</td></tr>
<tr><td>Occupational Health and Safety Specialists</td><td>Occupational Health and Safety Technicians</td></tr>
<tr><td colspan="2">Miscellaneous Health Practitioners/Technical Workers</td></tr>
<tr><td>Athletic Trainers</td><td>Other</td></tr>
<tr><td rowspan="13">Healthcare Support Occupations</td><td rowspan="13">Major Occupational Group K - Occupations concerned with other healthcare services for children and adults, and mainly cater to the provision of support services. **,†</td><td colspan="2">Nursing, Psychiatric, and Home Health Aides*</td></tr>
<tr><td>Home Health Aides*</td><td>Nursing Assistants*</td></tr>
<tr><td>Psychiatric Aides*</td><td>Orderlies*</td></tr>
<tr><td colspan="2">Occupational Therapy/Physical Therapist Assistants/Aides</td></tr>
<tr><td colspan="2">Occupational Therapy</td></tr>
<tr><td>Occupational Therapy Assistants</td><td>Occupational Therapy Aides</td></tr>
<tr><td colspan="2">Physical Therapy</td></tr>
<tr><td>Physical Therapy Assistants</td><td>Physical Therapy Aides</td></tr>
<tr><td colspan="2">Other Healthcare Support Occupations</td></tr>
<tr><td colspan="2">Massage Therapists</td></tr>
<tr><td colspan="2">Miscellaneous Healthcare Support Occupations</td></tr>
<tr><td>Dental Assistants</td><td>Medical Equipment Preparers</td></tr>
<tr><td colspan="2">Medical Assistants</td></tr>
</table>

Notes:

* *"Chapter 6. Occupation and Industry Classification Systems," in "Nursing Aides, Home Health Aides, and Related Health Care Occupations: National and Local Workforce Shortages and Associated Data Needs" U.S. Department of Health and Human Services, Health Resources and Services Administration, February 2004, http://bhpr.hrsa.gov/healthworkforce/reports/rnhomeaides.pdf (Accessed 2/20/15).*

** *"2010 Standard Occupational Classification" U.S. Bureau of Labor Statistics, January 2009, p. 16-19.*

† *"MOG—Level Definitions," in "Occupational Classification System Manual" U.S. Bureau of Labor Statistics, National Compensation Survey, http://www.bls.gov/ncs/ocs/ocsm/comMOGADEF.htm#mogaanchor (Accessed 1/27/15).*

Table I-1B: Healthcare Professional Practices Provider Taxonomies

Organization: Centers for Medicare and Medicaid Services
Classification System: Based on System for Billing for Services

Category	Definition	Subcategories	
Physician	As stated in Section 1861(r) SSA to include the professionals listed here	N/A	
		*MDs**	*Doctor of Optometry**
		*DOs**	*Chiropractor**
		Doctor of Dental Surgery/	Interns and Residents*
		Dental Medicine*	
		Doctor of Podiatric Medicine*	
Allied Health Providers	As stated in 42 USC Section 295p to include those professionals: "(A) who [have] received a certificate, an associate's degree, a bachelor's degree, a master's degree, a doctoral degree, or postbaccalaureate training, in a science relating to health care; (B) who shares in the responsibility for the delivery of health care services or related services, including- (i) services relating to the identification, evaluation, and prevention of disease and disorders; (ii) dietary and nutrition services; (iii) health promotion services; (iv) rehabilitation services; or (v) health systems management services; and (C) who has not received a degree of doctor of medicine, a degree of doctor of osteopathy, a degree of doctor of dentistry or an equivalent degree, a degree of doctor of veterinary medicine or an equivalent degree, a degree of doctor of optometry or an equivalent degree, a degree of doctor of podiatric medicine or an equivalent degree, a degree of bachelor of science in pharmacy or an equivalent degree, a degree of doctor of pharmacy or an equivalent degree, a graduate degree in public health or an equivalent degree, a degree of doctor of chiropractic or an equivalent degree, a graduate degree in health administration or an equivalent degree, a doctoral degree in clinical psychology or an equivalent degree, or a degree in social work or an equivalent degree or a degree in counseling or an equivalent degree.	*Mid-Level Provider—also known as: Non-Physician*	
		Practitioner/Physician Extender—Health professionals who may deliver covered Medicare services if the services are incident to a physician's service or if there is specific authorization in the law	
		Physician Assistant/Advanced Practice Nurses	
		Physician Assistant,**,†*	*Certified Registered Nurse*
		Anesthetists,**,†*	
		Nurse Practitioners,**,†*	*Certified Nurse Midwives*,**,†*
		Other	
		Qualified Clinical Psychologists*,**,†	Respiratory Therapy Workers††,‡,‡‡,§
		Clinical Social Workers*,**,†	Speech Pathologist/Audiologists††,‡,‡‡,§
		Dieticians/Dietetic	Dietetic Assistants††,‡,‡‡,§
		Technicians,**,†,††,‡,‡‡,§*	
		Dental Hygienists/Assts/Lab Techs††,‡,‡‡,§	*Genetic Assistants††,‡,‡‡,§*
		EMT/Paramedic††,‡,‡‡,§	*Operating Room Technicians††,‡,‡‡,§*
		Health Information Admin/Tech††,‡,‡‡,§	*Ophthalmic/Optometric Medical*
			Assistants††,‡,‡‡,§
		Occupational Therapists††,‡,‡‡,§	Medical Transcriptionists††,‡,‡‡,§
		Orthotists and Prosthetists††,‡,‡‡,§	*Vocational Rehab Counselors††,‡,‡‡,§*
		Physical Therapists††,‡,‡‡,§	Other Rehabilitation Workers††,‡,‡‡,§
		Radiologic Service Workers††,‡,‡‡,§	*Other Social and Mental Health Workers††,‡,‡‡,§*

Notes:
** "Physicians" in "The Public Health and Welfare" 42 U.S.C. § 1395x(r).*
*** "Ratio of Physician to Physician Extenders (Resolution 303, I-97)" By Kay K. Hanley, MD, December 1998, CMS Report 10-1-98.*
† "'Incident to' Services" MLN Matters, SE0441.
†† "Definitions, Federal Health Insurance for the Aged and Disabled, Center for Medicare and Medicaid Services, Department of Health and Human Services" 42 CFR § 405.400.
‡ "Chapter 6A: Definitions, General Provisions, Health Professions Education, Public Health Service, The Public Health and Welfare" 42 U.S.C. § 295.
‡‡ "Civil Remedies Decision CR1961" Departmental Appeals Board, Department of Health and Human Services, June 16, 2009, p. 3.
§ "Interdisciplinary, Community-Based Linkages, Title VII, Part D, Public Health Service Act" Advisory Committee on Interdisciplinary, Community-Based Linkages, 2006, Fifth Annual Report to the Secretary of the U.S. Department of Health and Human Services and to the Congress.

Table I-1C: Healthcare Professional Practices Provider Taxonomies

Organization: American Medical Association
Classification System: As utilized in the Health Care Careers Directory 2012-2013

Category	Definition	Subcategories	
Physician	There are two types of physicians: MD—Doctor of Medicine—and DO-Doctor of Osteopathic medicine. Both MDs and DOs may legally use all accepted methods of treatment, including drugs and surgery.	N/A	
		*MDs**	*DOs**
Optometry	Examine, diagnose, treat, and manage diseases, injuries, and disorders of the visual system, the eye, and associated structures as well as identify systemic conditions affecting the eye	*Optometrist*,***	
Complementary and Alternative Medicine	A group of diverse medical and health care systems, practices, and products that are not presently considered to be part of conventional medicine	Chiropractic*,**	
Dentistry	Diagnose, prevent, and treat problems with teeth or mouth tissue	Dentist*,**	
Pharmacy	Provide information to patients about medications and their use and distribute drugs prescribed by physicians and other health practitioners	Pharmacist*,**	
Podiatry	"Specialize in diagnosing and treating disorders, diseases, and injuries of the foot, ankle, and lower leg"	*N/A*	
		Podiatrist,***	
Veterinary Medicine	Provide healthcare professional and support services for the care of pets, livestock, and zoo, sporting, and laboratory animals	*N/A*	
		Veterinarian,***	
Nursing		*Registered Nurses*,***	*Licensed Vocational Nurses***
		*Licensed Practical Nurses***	
		Mid-Level Provider - also known as: Non-Physician Practitioner/Physician Extender - Health professionals who may deliver covered Medicare services if the services are incident to a physician's service or if there is specific authorization in the law	
		Advanced Practice Nurses	
		Nurse Practitioners†,††,‡	Certified Nurse Midwives†,††,‡
		Certified Registered Nurse Anesthetists†,††,‡	
Psychology	Psychologists in health service provider fields provide mental health care in hospitals, clinics, schools, or private settings.	*Clinical Psychologists*	
		Clinical Psychologists†,††,‡	

(continued)

Category	Definition	Subcategories	
Allied Health Professional	Participate in the delivery of health care, diagnostic, and rehabilitation services, therapeutic treatments, or related services," and excludes "the MODVOPP professions: medicine (allopathic), osteopathic medicine, dentistry, veterinary medicine, optometry, podiatry, and pharmacy—as well as chiropractic, clinical psychology, any level of nursing education, and graduate degrees in public health or health administration.	*Physician Assistant*	
		Physician Assistant†,††,‡	*Physician Assistant†,††,‡*
		Clinical Social Workers†,††,‡	Clinical Social Workers†,††,‡
		Dietetics	
		Dietitian/Nutritionist*,**	Dietitian/Nutritionist*,**
		Dentistry and Related Fields	
		Dentist*,**	Dentist*,**
		Dental Assistant*,**	Dental Assistant*,**
		Communication Sciences	
		Audiologist*,**	Speech-Language Pathologist*,**
		Complementary and Alternative Medicine	
		Massage Therapist*,**	
		Counseling	
		Counselor*,**	Rehabilitation Counselor*,**
		Genetic Counselor*,**	
		Expressive/Creative Art Therapies	
		Art Therapist*,**	Music Therapist*,**
		Dance/Movement Therapist*,**	
		Health Information and Communication	
		Cancer Registrar*,**	Medical Coder*,**
		Health Information Administrator*,**	Medical Librarian*,**
		Health Information Technician*,**	Medical Transcriptionist*,**
		Laboratory Science	
		Blood Bank Technology-Specialist*,**	Clinical Laboratory Technician/
			Medical Laboratory Technician*,**
		Clinical Assistant*,**	Cytogenetic Technologist*,**
		Clinical Laboratory Scientist/Medical	Cytotechnologist*,**
		Technologist*,**	
		Medical Imaging	
		Diagnostic Molecular Sonographer*,**	Magnetic Resonance Technologist*,**
		Histotechnician*,**	Medical Dosimetrist*,**
		Histotechnologist*,**	Nuclear Medicine Technologist*,**
		Pathologists' Assistant*,**	Radiation Therapist*,**

Category	Definition	Subcategories	
Allied Health Professionals	Participate in the delivery of health care, diagnostic, and rehabilitation services, therapeutic treatments, or related services," and excludes "the MODVOPP professions: medicine (allopathic), osteopathic medicine, dentistry, veterinary medicine, optometry, podiatry, and pharmacy—as well as chiropractic, clinical psychology, any level of nursing education, and graduate degrees in public health or health administration.	Phlebotomist*,**	Radiographer*,**
		Diagnostic Medical Sonographer*,**	Registered Radiologist Assistant*,**
		Vision-Related Professions	
		Ophthalmic Assistant/Technician/	Orthoptist*,**
		Technologist*,**	
		Ophthalmic Dispensing Optician*,**	Teacher of the Visually Impaired*,**
		Optometrist*,**	Vision Rehabilitation Therapist*,**
		Orientation and Mobility Specialist*,**	
		Therapy and Rehabilitation	
		Occupational Therapist*,**	Physical Therapist Assistant*,**
		Occupational Therapy Assistant*,**	Therapeutic Recreation Specialist*,**
		Physical Therapist*,**	
		Other	
		Anesthesiologist Assistant*,**	Nursing Aides, Orderlies, Attendants*,**
		Anesthesia Technologist/Technician*,**	Occupational Health and Safety Technician*,**
		Athletic Trainer*,**	Orthotists and Prosthetists*,**
		Cardiovascular Technician/Technologist*,**	Orthotics and Prosthetics Technicians*,**
		Electroneurodiagnostic Technologist*,**	Perfusionist*,**
		Emergency Medical Technician-Paramedic*,**	Pharmacy Technician*,**
		Exercise Science (Personal Fitness Trainer, Exercise Physiologist, and Exercise Science Professional)*,**	Polysomnographic Technologist*,**
		Home Health, Personal Care, and Psychiatric Aides*,**	Psychiatric Aides/Technicians*,**
		Kinesiotherapist*,**	Respiratory Therapist*,**
		Medical Assistant*,**	Respiratory Therapy Technicians*,**
		Medical Equipment Preparer*,**	Surgical Assistant*,**
		Medical Illustrator*,**	Surgical Technologist*,**

Notes:
** "Health Care Careers Directory 2012-2013" American Medical Association, 2012, p. iii-iv.*
*** "Coming Together, Moving Apart: A History of the Term Allied Health in Education, Accreditation, and Practice" By Fred G. Donini-Lenhoff, MA, Journal of Allied Health, Vo. 37, No 1 (Spring 2008), p. 46-49.*
† "Physicians" in "The Public Health and Welfare" 42 U.S.C. § 1395x(r).
†† "Ratio of Physician to Physician Extenders (Resolution 303, I-97)" By Kay K. Hanley, MD, December 1998, CMS Report 10-I-98.
‡ "'Incident to' Services" Centers for Medicare & Medicaid Services, MLN Matters, SE0441.

Table I-1D: Healthcare Professional Practices Provider Taxonomies

Organization: Health Capital Consultants
Classification System: N/A

Category	Definition	Subcategories	
Physicians	Doctors of allopathic or osteopathic medicine. Both allopathic and osteopathic physicians may specialize in many of the same areas, though the process required to achieve specialization certifications occasionally differs between the two forms of medicine.	*N/A*	
		MDs	*DOs*
Allied Health Professionals	Non-physician providers of health services who provide primary healthcare services. Allied health professionals may work with physicians, mid-level providers, paraprofessionals and technicians, but they are professionally licensed to work autonomously in the provision of services.	*N/A*	
		Dentists	Psychologists
		Optometrists	Podiatrists
		Chiropractors	
Midlevel Providers	Non-physician providers who may or may not provide healthcare services independently of a superior licensed provider. Depending on state licensing criteria, mid-level provides (e.g. nurse practitioners, physicians' assistants, dental hygienists) may work independently in the provision of services, or may need to be supervised by a licensed physician or allied health professional.	*Clinical Service Providers*	
		Therapists	Occupational
		Physical	Audiologists/Speech
		Physician Assistants	
		Registered Nurses	
		Registered Nurses	Nurse Practitioners
		APRNS	Nurse Midwives
		Certified Registered Nurse Anesthetists	Dieticians & Nutritionists
		Technical Service Providers	
		Dental Hygienists	Opticians
		Dental Assistants	Dental Assistants
Technicians & Paraprofessionals	Non-physician providers who may never provide healthcare services independently of a supervising licensed provider. This category of provider is divided between licensed and unlicensed paraprofessionals.	*Assistants*	
		Social and Human Service Assistants	Physical Therapist Assistants
		Anesthesiologists Assistants	Dental Assistants
		Occupational Therapist Assistants	Medical Assistants
		Aides	
		Personal Care Aides	Psychiatric Aides
		Home Health Aides	Physical Therapist Aides
		Nursing Aides, Orderlies,	Pharmacy Aides
		Attendants	

Category	Definition	Subcategories	
Technicians & Paraprofessionals	Non-physician providers who may never provide healthcare services independently of a supervising licensed provider. This category of provider is divided between licensed and unlicensed paraprofessionals.	*Therapists*	
		Radiation Therapists	Respiratory Therapists
		Technologists	
		Medical and Clinical	Nuclear Medicine
		Laboratory Technologists	
		Cardiovascular	Surgical
		Radiologic Technicians	
		Cardiovascular	Psychiatric
		Medical and Clinical Laboratory	Respiratory Therapy
		Radiologic	Medical Records and Health Information
		Emergency Medical	Occupational Health and Safety
		Dietetic	Orthotics and Prosthetics
		Pharmacy	
		Nurses	
		Licensed Vocational Nurses	Licensed Practical Nurses
		Other	
		Medical Dosimetrist	Medical Equipment Preparers
		Diagnostic Medical	Medical Transcriptionists
		Sonographers	Athletic Trainers
Alternative Medicine Providers	Providers who may or may not be physicians, but who practice forms of therapy and treatment outside the mainstream practice of medicine, e.g. homeopathic medicine. Alternative medicine practitioners may provide primary or secondary care, and are generally licensed to work independently of supervision by another licensed provider.	*Whole Medical Systems*	
		Eastern Whole Medical Systems	
		Traditional Chinese Medicine	Ayurvedic Medicine
		Western Whole Medical Systems	
		Homeopathic	Naturopathic
		Mind-Body Medicine	
		Aromatherapy	Mental Healing
		Cognitive Behavioral Theory	Expressive/Creative Arts Therapy
		Meditation & Prayer	
		Biologically Based Practices	
		Dietary Supplements	Herbal Remedies
		Manipulative & Body-Based Practices	
		Massage Therapy	Chiropractic Medicine
		Energy Medicine	
		Biofield Therapy	Reiki
		Bioelectromagnetic-Based Therapy	Therapeutic Touch

Table I-2: Healthcare Professional Practices Provider Taxonomies Comparison Chart

Profession	Health Capital Consultants	BLS[1, 2, 3]	CMS[4, 5, 6, 7, 8, 9, 10, 11, 12]	AMA[11, 12, 13, 14, 15]
Chiropractors	Allied Health	Health Diagnosing Occupations	Physician	Complementary and Alternative Medicine
Dentists	Allied Health	Health Diagnosing Occupations	Physician	Dentistry and Related Fields
Psychologists	Allied Health	Social Scientists and Urban Planners	Mid-Level Provider*	Mid-Level Provider*
Podiatrists	Allied Health	Health Diagnosing Occupations	Physician	Podiatrists
Optometrists	Allied Health	Health Diagnosing Occupations	Physician	Optometry
Aromatherapy	Alternative Medicine	Other Health Diagnosing/Treating Practitioners	Auxiliary personnel—not covered for therapy services	Allied Health
Ayuredic Medicine	Alternative Medicine	Miscellaneous Health Diagnosing/Treating Practitioners	Auxiliary personnel—not covered for therapy services	Allied Health
Bioelectromagnetic-Based Therapy	Alternative Medicine	Other Health Diagnosing/Treating Practitioners	Complementary and Alternative Medicine	Allied Health
Biofield Therapy	Alternative Medicine	Other Health Diagnosing/Treating Practitioners	Complementary and Alternative Medicine	Allied Health
Cognitive Behavioral Theory	Alternative Medicine	Other Health Diagnosing/Treating Practitioners	Auxiliary personnel—not covered for therapy services	Allied Health
Dietary Supplements	Alternative Medicine	Other Health Diagnosing/Treating Practitioners	Auxiliary personnel—not covered for medical services	Allied Health
Expressive Creative Arts Therapy	Alternative Medicine	Other Health Diagnosing/Treating Practitioners	Complementary and Alternative Medicine	Allied Health
Herbal Remedies	Alternative Medicine	Other Health Diagnosing/Treating Practitioners	Auxiliary personnel—not covered for medical services	Allied Health
Homeopathic	Alternative Medicine	Miscellaneous Health Diagnosing/Treating Practitioners	Auxiliary personnel—not covered for medical services	Allied Health
Massage Therapy	Alternative Medicine	Other Health Diagnosing/Treating Practitioners	Auxiliary personnel—not covered for therapy services	Allied Health
Meditation & Prayer	Alternative Medicine	Other Health Diagnosing/Treating Practitioners	Complementary and Alternative Medicine	Allied Health
Mental Healing	Alternative Medicine	Other Health Diagnosing/Treating Practitioners	Auxiliary personnel—not covered for medical services	Allied Health
Naturopathic	Alternative Medicine	Miscellaneous Health Diagnosing/Treating Practitioners	Auxiliary personnel—not covered for medical services	Allied Health
Reiki	Alternative Medicine	Other Health Diagnosing/Treating Practitioners	Auxiliary personnel—not covered for medical services	Allied Health

Profession	Health Capital Consultants	BLS[1, 2, 3]	CMS[4, 5, 6, 7, 8, 9, 10, 11, 12]	AMA[11, 12, 13, 14, 15]
Therapeutic Touch	Alternative Medicine	Other Health Diagnosing/Treating Practitioners	Complementary and Alternative Medicine	Allied Health
Traditional Chinese Medicine	Alternative Medicine	Other Health Diagnosing/Treating Practitioners	Auxiliary personnel—not covered for medical services	Allied Health
Prosthetists & Orthotists	Mid-Level	Health Technologists and Technicians	Allied Health—Professionals/ Qualified Auxiliary Personnel	Allied Health
Audiologists/ Speech-Language Pathologists	Mid-Level	Health Assessment and Treating Occupations	Allied Health—Professionals/ Qualified Auxiliary Therapy Personnel	Allied Health
Dental Hygienists	Mid-Level	Health Technologists and Technicians	Allied Health—Professionals/Qualified Auxiliary Personnel	Allied Health
Dieticians & Nutritionists	Mid-Level	Health Assessment and Treating Occupations	Allied Health—Professionals/Qualified Auxiliary Personnel	Allied Health
Certified Registered Nurse Anesthetists	Mid-Level	Health Assessment and Treating Occupations	Mid-Level Provider[16]	Mid-Level Provider[16]
Nurse Midwives	Mid-Level	Health Assessment and Treating Occupations	Mid-Level Provider[16]	Mid-Level Provider[16]
Nurse Practitioners	Mid-Level	Health Assessment and Treating Occupations	Mid-Level Provider[16]	Mid-Level Provider[16]
Physician Assistants	Mid-Level	Health Assessment and Treating Occupations	Mid-Level Provider[16]	Mid-Level Provider[16]
Registered Nurses	Mid-Level	Health Assessment and Treating Occupations	Allied Health—Professionals/Qualified Auxiliary Personnel	Nursing
Pharmacists	Mid-Level	Health Assessment and Treating Occupations	Pharmacists	Pharmacy
Occupational Therapists	Mid-Level	Health Assessment and Treating Occupations	Allied Health—Professionals/Qualified Auxiliary Therapy Personnel	Allied Health
Physical Therapists	Mid-Level	Health Assessment and Treating Occupations	Allied Health—Professionals/Qualified Auxiliary Therapy Personnel	Allied Health
Opticians	Mid-Level	Health Assessment and Treating Occupations	Allied Health—Professionals/Qualified Auxiliary Personnel	Allied Health
DOs	Physician	Health Diagnosing Occupations	Physician	Physician
MDs	Physician	Health Diagnosing Occupations	Physician	Physician
Anesthesiologists Assistants	Technicians and Paraprofessionals	Other Healthcare Support Occupations	Allied Health—Professionals/Qualified Auxiliary Personnel	Allied Health
Athletic Trainers	Technicians and Paraprofessionals	Other Healthcare Practitioners/Technical Occupations	Allied Health—Auxiliary Personnel—not covered for therapy services	Allied Health

(continued)

Profession	Health Capital Consultants	BLS[1, 2, 3]	CMS[4, 5, 6, 7, 8, 9, 10, 11, 12]	AMA[11, 12, 13, 14, 15]
Cardiovascular Technicians	Technicians and Paraprofessionals	Health Technologists and Technicians	Allied Health—Professionals/Qualified Auxiliary Personnel	Allied Health
Cardiovascular Technologists	Technicians and Paraprofessionals	Health Technologists and Technicians	Allied Health—Professionals/Qualified Auxiliary Personnel	Allied Health
Emergency Medical Technicians	Technicians and Paraprofessionals	Health Technologists and Technicians	Allied Health—Professionals/Qualified Auxiliary Personnel	Allied Health
Home Health Aides	Technicians and Paraprofessionals	Nursing, Psychiatric, and Home Health Aides	Allied Health—Professionals/Qualified Auxiliary Personnel	Allied Health
Medical Assistants	Technicians and Paraprofessionals	Other Healthcare Support Occupations	Allied Health—Professionals/Qualified Auxiliary Personnel	Allied Health
Medical Equipment Preparers	Technicians and Paraprofessionals	Other Healthcare Support Occupations	Allied Health—Professionals/Qualified Auxiliary Personnel	Allied Health
Nursing Aides, Orderlies, Attendants	Technicians and Paraprofessionals	Nursing, Psychiatric, and Home Health Aides	Allied Health—Professionals/Qualified Auxiliary Personnel	Allied Health
Occupational Health and Safety Technicians	Technicians and Paraprofessionals	Health Technologists and Technicians	Allied Health—Professionals/Qualified Auxiliary Personnel	Allied Health
Orthotics and Prosthetics Technicians	Technicians and Paraprofessionals	Health Technologists and Technicians	Allied Health—Professionals/Qualified Auxiliary Personnel	Allied Health
Personal Care Aides	Technicians and Paraprofessionals	Nursing, Psychiatric, and Home Health Aides	Allied Health—Professionals/Qualified Auxiliary Personnel	Allied Health
Psychiatric Aides	Technicians and Paraprofessionals	Nursing, Psychiatric, and Home Health Aides	Allied Health—Professionals/Qualified Auxiliary Personnel	Allied Health
Psychiatric Technicians	Technicians and Paraprofessionals	Health Technologists and Technicians	Allied Health—Professionals/Qualified Auxiliary Personnel	Allied Health
Respiratory Therapists	Technicians and Paraprofessionals	Health Assessment and Treating Occupations	Allied Health—Professionals/Qualified Auxiliary Personnel	Allied Health
Respiratory Therapy Technicians	Technicians and Paraprofessionals	Health Technologists and Technicians	Allied Health—Professionals/Qualified Auxiliary Personnel	Allied Health
Surgical Technologists	Technicians and Paraprofessionals	Health Technologists and Technicians	Allied Health—Professionals/Qualified Auxiliary Personnel	Allied Health
Social and Human Service Assistants	Technicians and Paraprofessionals	Other Healthcare Support Occupations	Clinical Social Workers are Mid-Level Providers*; others are Allied Health—Professionals/Qualified Auxiliary Personnel	Allied Health
Dental Assistants	Technicians and Paraprofessionals	Other Healthcare Support Occupations	Allied Health—Professionals/Qualified Auxiliary Personnel	Allied Health
Dietetic Technicians	Technicians and Paraprofessionals	Health Technologists and Technicians	Allied Health—Professionals/Qualified Auxiliary Personnel	Allied Health

Profession	Health Capital Consultants	BLS[1, 2, 3]	CMS[4, 5, 6, 7, 8, 9, 10, 11, 12]	AMA[11, 12, 13, 14, 15]
Medical Records and Health Information Technicians	Technicians and Paraprofessionals	Health Technologists and Technicians	Allied Health—Professionals/Qualified Auxiliary Personnel	Allied Health
Medical Transcriptionists	Technicians and Paraprofessionals	Other Healthcare Support Occupations	Allied Health—Professionals/Qualified Auxiliary Personnel	Allied Health
Medical and Clinical Laboratory Technicians	Technicians and Paraprofessionals	Health Technologists and Technicians	Allied Health—Professionals/Qualified Auxiliary Personnel	Allied Health
Medical and Clinical Laboratory Technologists	Technicians and Paraprofessionals	Health Technologists and Technicians	Allied Health—Professionals/Qualified Auxiliary Personnel	Allied Health
Diagnostic Medical Sonographers	Technicians and Paraprofessionals	Health Technologists and Technicians	Allied Health—Professionals/Qualified Auxiliary Personnel	Allied Health
Medical Dosimetrist	Technicians and Paraprofessionals	Health Technologists and Technicians	Allied Health—Professionals/Qualified Auxiliary Personnel	Allied Health
Nuclear Medicine Technologists	Technicians and Paraprofessionals	Health Technologists and Technicians	Allied Health—Professionals/Qualified Auxiliary Personnel	Allied Health
Radiation Therapists	Technicians and Paraprofessionals	Health Assessment and Treating Occupations	Allied Health—Professionals/Qualified Auxiliary Personnel	Allied Health
Radiologic Technicians	Technicians and Paraprofessionals	Health Technologists and Technicians	Allied Health—Professionals/Qualified Auxiliary Personnel	Allied Health
Radiologic Technologists	Technicians and Paraprofessionals	Health Technologists and Technicians	Allied Health—Professionals/Qualified Auxiliary Personnel	Allied Health
Licensed Practical Nurses	Technicians and Paraprofessionals	Health Technologists and Technicians	Allied Health—Professionals/Qualified Auxiliary Personnel	Nursing
Licensed Vocational Nurses	Technicians and Paraprofessionals	Health Technologists and Technicians	Allied Health—Professionals/Qualified Auxiliary Personnel	Nursing
Pharmacy Aides	Technicians and Paraprofessionals	Other Healthcare Support Occupations	Allied Health—Professionals/Qualified Auxiliary Personnel	Pharmacy
Pharmacy Technicians	Technicians and Paraprofessionals	Health Technologists and Technicians	Allied Health—Professionals/Qualified Auxiliary Personnel	Pharmacy
Occupational Therapist Assistants	Technicians and Paraprofessionals	Occupational Therapy/Physical Therapist Assistants/Aides	Allied Health—Professionals/Qualified Auxiliary Personnel	Allied Health
Physical Therapist Aides	Technicians and Paraprofessionals	Occupational Therapy/Physical Therapist Assistants/Aids	Allied Health—Professionals/Qualified Auxiliary Personnel	Allied Health
Physical Therapist Assistants	Technicians and Paraprofessionals	Occupational Therapy/Physical Therapist Assistants/Aids	Allied Health—Professionals/Qualified Auxiliary Personnel	Allied Health

(continued)

Notes

1 *"Chapter 6. Occupation and Industry Classification Systems," in "Nursing Aides, Home Health Aides, and Related Health Care Occupations—National and Local Workforce Shortages and Associated Data Needs" U.S. Department of Health and Human Services, Health Resources and Services Administration, 2004.*
2 *"2010 Standard Occupational Classification" U.S. Bureau of Labor Statistics, January 2009, p. 16-19.*
3 *"MOG—Level Definitions," in "Occupational Classification System Manual" U.S. Bureau of Labor Statistics, National Compensation Survey, http://www.bls.gov/ncs/ocs/ocsm/comMOGADEF.htm#mogaanchor (Accessed 1/27/15).*
4 *"Definitions, Federal Health Insurance for the Aged and Disabled, Center for Medicare and Medicaid services, Department of Health and Human Services" 42 C.F.R. § 405.400.*
5 *"Chapter 6A: Definitions, General Provisions, Health Professions Education, Public Health Service, The Public Health and Welfare" 42 U.S.C. § 295p.*
6 *"CR1961" Departmental Appeals Board, Civil Remedies Division, Department of Health and Human Services, June 16, 2009, p. 3.*
7 *"Interdisciplinary, Community-Based Linkages, Title VII, Part D, Public Health Service Act" Advisory Committee on Interdisciplinary, Community-Based Linkages, 2005, Fifth Annual Report to the Secretary of the U.S. Department of Health and Human Services and to the Congress.*
8 *"Chapter 15—Covered Medical and Other Health Services" in "Medicare Benefit Policy Manual" Centers for Medicare and Medicaid Services, Rev. 109, August 7, 2009.*
9 *"Chapter 5—Definitions," in "Medicare General Information, Eligibility, and Entitlement" Centers for Medicare and Medicaid Services, Rev. 58, March 6, 2009.*
10 *"Medicare National Coverage Determinations" Department of Health and Human Services, Centers for Medicare and Medicaid, Transmittal 2 (Pub. 100-03), October 17, 2003.*
11 *"Physicians" in "The Public Health and Welfare" 42 U.S.C. § 1395x(r).*
12 *"Incident to' Services," MLN Matters, SE0441.*
13 *"Health Care Careers Directory 2012-2013" American Medical Association, 2012, p. iii-iv.*
14 *"Coming Together, Moving Apart: A History of the Term Allied Health in Education, Accreditation, and Practice" By Fred G. Donini-Lenhoff, MA, Journal of Allied Health, Vol. 37, No. 1 (Spring 2008), p. 46–49.*
15 *"Ratio of Physician to Physician Extenders (Resolution 303, I-97)" By Kay K. Hanley, MD, December 1998, CMS Report 10-I-98.*
16 *Also known as: Non-Physician Practitioner/Physician Extender.*

This *Guide* distinguishes among five general types of health professionals. The trifurcation of nonphysician practitioners in mainstream medicine, as described previously, serves as the rationale behind allied health professionals, mid-level providers, and technicians and paraprofessionals, as they are defined herein. In addition to the physician and nonphysician professionals who practice conventional medicine, a class of professionals exists that provides complementary and alternative medical services that, to date, is treated as a parallel (sometimes intertwined) but unconventional subset of the healthcare workforce. In brief, the five taxonomical categories of professional providers, as they are discussed in this *Guide*, are defined as:

(1) *Physicians*—Doctors of allopathic or osteopathic medicine. Both allopathic and osteopathic physicians may specialize in many of the same areas, though the process required to achieve specialization certifications occasionally differs between the two forms of medicine.
(2) *Allied health professionals*—Nonphysician providers of health services who provide primary healthcare services. Allied health professionals may work with physicians, mid-level providers, and paraprofessionals and technicians, but they are professionally licensed to work autonomously in the provision of services. This *Guide* discusses five distinct allied health professions: dentists, optometrists, chiropractors, psychologists, and podiatrists.
(3) *Mid-level providers*—Nonphysician providers who may or may not provide healthcare services independently of a superior licensed provider but are, by in large, moving into increasingly autonomous practice types. These professionals typically provide primary care services in lieu of physicians. Depending on state licensing criteria, mid-level providers (such as nurse practitioners, physicians' assistants, and dental hygienists) may work independently in the provision of services. Mid-level

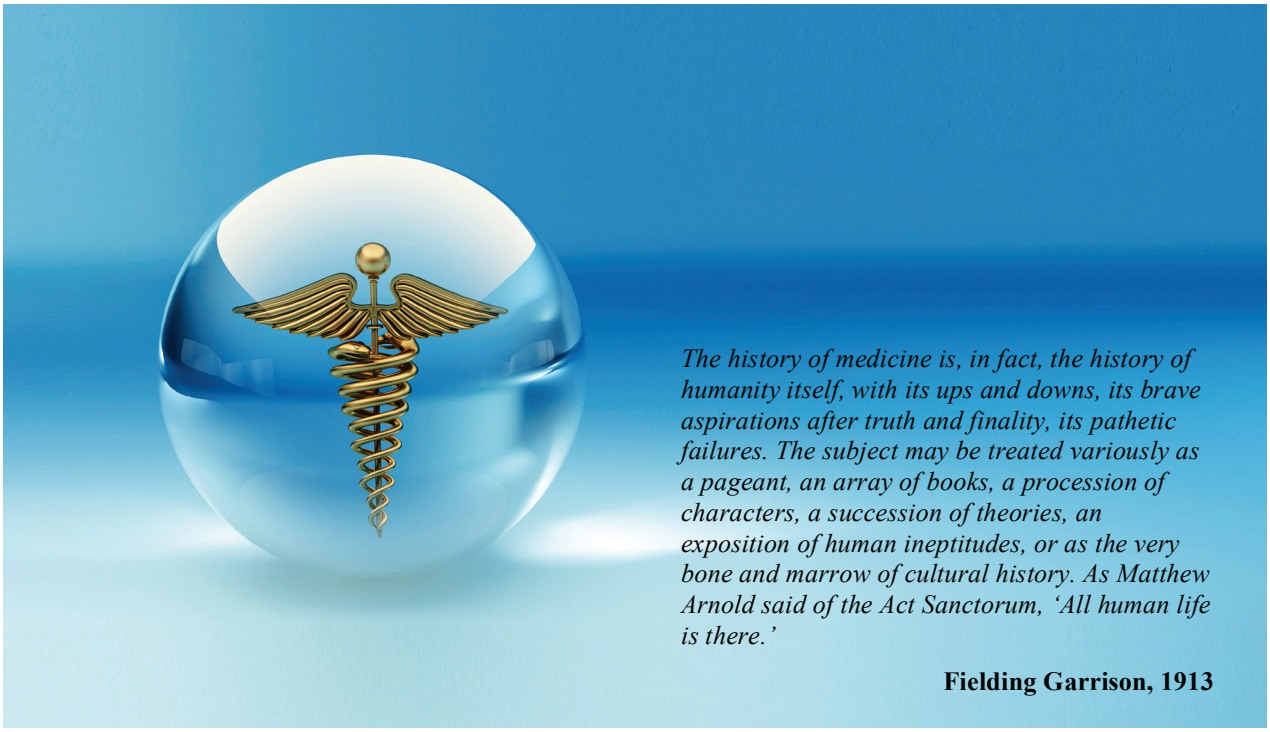
providers are further divided between clinical service providers and technical service providers.

(4) *Technicians and paraprofessionals*—Nonphysician providers who may never provide healthcare services independently of a supervising licensed provider. These individuals either serve to alleviate a manpower deficit or to contribute to the technological sophistication, efficiency, and quality of physician services; in either case, their scope of practice is contingent upon the scope of their physician's practice and nonexistent otherwise. On the basis of these two types of physician extenders, this category of provider is divided between licensed and unlicensed technicians and paraprofessionals.

(5) *Alternative medicine practitioners*—Providers who may or may not be physicians but who practice forms of therapy and treatment outside the mainstream practice of medicine, for example, homeopathic medicine. Alternative medicine practitioners may provide primary or secondary care, and they generally are licensed to work independently of supervision by another licensed provider.

Chapter 1

Historical Development



The history of medicine is, in fact, the history of humanity itself, with its ups and downs, its brave aspirations after truth and finality, its pathetic failures. The subject may be treated variously as a pageant, an array of books, a procession of characters, a succession of theories, an exposition of human ineptitudes, or as the very bone and marrow of cultural history. As Matthew Arnold said of the Act Sanctorum, 'All human life is there.'

Fielding Garrison, 1913

KEY TERMS

Allopathic Medicine
Chiropractic
Corpus
Customary Prevailing and Reasonable
Diagnostic Related Groups
Eclectic Medicine
Health Maintenance Organization
Homeopathic Medicine
Industrial Hygiene
Legal Medicine
Medicaid
Medicare
Medicare Part A
Medicare Part B
Naturopathic Medicine
Osteopathic
Pasteurization
Physiotherapy
Preferred Provider Organization (PPO)
Prospective Payment System
Public Health
Resource Based Relative Value System
Studium Generale

Key Concept	Definition	Citation	Mentioned on Page #
Assyro-Babylonian Medicine	Established in 4 BC by the people of southern Mesopotamia; regarded medicine as an abstraction to be treated with priestly reverence.	"Chapter III: Antiquity," in "The Greatest Benefit to Mankind: A Medical History of Humanity" By Roy Porter, New York: NY: HarperCollins Publishers Ltd., 1997, p. 46–47. "A History of Medicine" By Arturo Castiglioni, New York, NY: Alfred A. Knopf, Inc., 1947, p. 32.	28
The Rod and Serpent in Assyro-Babylonian Medicine	First seen as the symbol attributed to the Babylonian lord of physicians, Ninazu, and his son. The serpent represented the healing god, Sachan.	"The Rod and Serpent of Asklepios. Symbol of Medicine" By J. Schouten, London: Elsevier, 1967, p. ix, 260.	28
Galenic Medicine	Based on the findings of Claudius Galen and his followers. Pioneered the fields of anatomy and physiology, methods of animal dissection, and an understanding of the circulation of blood. Although this generation of medicine was significant to developments in scientific inquiry, false assumptions about animal-to-human anatomic translation and hematology served in the medical world's disfavor as time progressed.	"Chapter 3: The Reawakening," in "Doctors: The Illustrated History of Medical Pioneers" By Sherwin B. Nuland, New York, NY: Black Dog & Leventhal Publishers, Inc., 2008, p. 71; "The Western Medical Tradition 800 BC to AD 1800" By Lawrence I. Conrad et al., Cambridge University Press, 1995, p. 225.	34
The Rod and Serpent in Galenic Medicine	Reappeared in depictions of the Greek god of healing, Asklepios, in which he is seen holding a staff with a snake coiled around it.	"The Rod and Serpent of Asklepios. Symbol of Medicine" By J. Schouten, London: Elsevier, 1967, p. ix, 260.	29
Types of Roman Universities	(1) community-funded, (2) state-funded, and (3) ecclesiastically funded.	"A History of Medicine," by Arturo Castiglioni, Alfred A. Knopf, Inc., 1947, p. 325.	35
The Rod and Serpent in Roman Civilization	Reappeared in depictions of the Roman god of healing, Asclepius, in which he is seen holding a staff with a snake coiled around it.	"The Rod and Serpent of Asklepios. Symbol of Medicine," by J. Schouten. (Pp. 260+ix; illustrated. 65s.) London: Elsevier, 1967.	29
Greco-Arabian Medicine	The solution to shortcomings of the medical education of the Middle Ages; involved incorporation of Arabian medical texts, as introduced by scholars and physicians who infused Arabian medicine, with the scholarship of philosophy, and attempted to compromise their differences.	"Chapter IV: Medicine and Faith," in "The Greatest Benefit to Mankind: A Medical History of Humanity" By Roy Porter, New York: NY: HarperCollins Publishers Ltd., 1997, p. 98–99; "A History of Medicine," by Arturo Castiglioni, Alfred A. Knopf, Inc., 1947, p. 325–329.	35
The Rod and Serpent Today	Used as the modern symbol for medicine.	"The Rod and Serpent of Asklepios. Symbol of Medicine" By J. Schouten, London: Elsevier, 1967, p. ix, 260.	29
Reason for a Resource-Based Relative Value Scale	Was intended to bring medical practice more in line with a prospective payment system in which payments are made based on set fees for types of procedures or diagnosis. Medicare payments are based on the relative value assigned to each procedure's work, practice expense, and malpractice costs with payment adjusted by a geographic and a universal conversion factor. Every physician uses the same payment schedule under the Medicare program.	"A Guide to Consulting Services for Emerging Healthcare Organizations" By Robert James Cimasi, CBI, CBC, New York, NY: John Wiley and Sons, Inc., 1999, p. 24–25.	60

OVERVIEW

Modern medicine is the product of continuous (if sometimes sporadic) advances in scientific, sociopolitical, and philosophic thought throughout many centuries. Paul Starr[1] addresses this evolution of medical thought and practice in his book, *The Social Transformation of American Medicine*, examining "first, the rise of professional sovereignty; and second, the transformation of medicine into an industry and the growing, though still unsettled, role of corporations and the state."[2] This chapter describes the chronological progression of medicine in accordance with this bimodal transformation, specifically, the centuries of progress in healthcare practitioner and professional practice credibility.

ORIGINS OF MEDICINE

The original concept of the practice of medicine derived from the concern for human pain. From this source, a sequence of facts, ideas, and discoveries resulted in the development and evolution of medical thought, knowledge, study, and practice.[3] Without an understanding of the basic origins and principles of medicine, one can neither understand the modern practice of medicine nor anticipate developments related to healthcare professional practice.

> *Because it deals with the vital interests of both individuals and societies—with life and death, and with so much that matters in between—medicine has long had an unusually complex and intimate relationship to social and cultural developments at large . . . In other words, medical history involves social and economic as well as biologic content and presents one of the central themes in human experience. After all, what is more basic in the life of any people than life itself?*
>
> **Richard Harrison Shryock, 1966**

The original concept of medicine derived from the concern for human pain

Arturo Castiglioni, 1947

1 Paul Starr is a reputed scholar of Sociology and Public Affairs, and known for his writings on the development of American medicine.
2 "The Social Transformation of American Medicine: The Rise of a Sovereign Profession and the Making of a Vast Industry" By Paul Starr, New York, NY: Basic Books Inc., 1982, p. ix.
3 "A History of Medicine" By Arturo Castiglioni, Second Edition, New York, NY: Alfred A. Knopf, Inc., 1947, p. 3, 12.

MEDICINE AND RELIGION AND ASTROLOGY

The Mediterranean region gave rise to civilizations that heavily influenced the advance of human knowledge, innovation, and society.[4] The region endured five thousand years of war, politics, development, and demise, fostering not only the origin and intensive development of art and science, but also the birth of monotheistic religion.[5] Therefore, the evolution of medicine is inherently linked to the civilizations that rose and fell in the Fertile Crescent, as well as the religions and spiritualties on which these societies relied.[6] In 4 BC, the people of southern Mesopotamia attempted to establish a systematic medical concept. The outcome of their effort became known as Assyro-Babylonian Medicine.[7]

For the Sumerians, Babylonians, and Assyrians, medicine was a highly revered abstraction treated with magical and priestly reverence.[8] These civilizations intently studied astronomy, and the assumed relationships between physiology and celestial findings led to the development of medical concepts.[9] As astronomy evolved to include stories, divinities, and beliefs, the concepts developed into religious systems.[10] The reliance on divine healing became a concept of medical practice: the Assyrians relied on the healing god, Nabu, and the Babylonians turned to the lord of magicians, Marduk, and the god of medicine, Ea, to sustain and restore health.[11] Further, the Babylonian caste of physicians was led by Ninurta, a god who served as their chief. Ninazu, the lord of physicians, and his son, Ningischzida, are known most notably for their symbol, the rod and serpent (the serpent representing the healing god Sachan).[12]

> Sumerian, Assyrian, and Babylonian civilizations intently studied astronomy, and medical concepts developed as a result of the assumed relationships between physiology and celestial findings.
>
> ***Arturo Castiglioni, Inc., 1947***

4 "A History of Medicine" By Arturo Castiglioni, Second Edition, New York, NY: Alfred A. Knopf, Inc., 1947, p. 31-32; "The Greatest Benefit to Mankind: A Medical History of Humanity" By Roy Porter, New York: NY: HarperCollins Publishers Ltd., 1997, p. 44-45.
5 "A History of Medicine" By Arturo Castiglioni, Second Edition, New York, NY: Alfred A. Knopf, Inc., 1947, p. 31-32.
6 "The Greatest Benefit to Mankind: A Medical History of Humanity" By Roy Porter, New York: NY: HarperCollins Publishers Ltd., 1997, p. 46-47.
7 "A History of Medicine" By Arturo Castiglioni, Second Edition, New York, NY: Alfred A. Knopf, Inc., 1947, p. 32; "The Greatest Benefit to Mankind: A Medical History of Humanity" By Roy Porter, New York: NY: HarperCollins Publishers Ltd., 1997, p. 46-47.
8 "A History of Medicine" By Arturo Castiglioni, Second Edition, New York, NY: Alfred A. Knopf, Inc., 1947, p. 31-44.
9 Ibid., p. 33.
10 Ibid., p. 33-41.
11 Ibid., p. 38.
12 Ibid.

Askleopios (left) and Caduceus (right).

The Greek god of healing, Asklepios, was also depicted holding a staff with a snake coiled around it, similar to the symbol attributed to the Babylonian gods Ninazu and Ningischzida.[13] (Aesculapios, his Roman counterpart, carried a rod as well). This single-serpent symbol image in Greek and Roman cultures was attributed to their healing and medical deities, and it serves as a modern symbol of medicine in most countries. Note, however, that the United States uses both the single-serpent symbol, Asklepian, and the double-serpent symbol, Caduceus, to represent medicine (see preceding photo).[14]

The people of Israel, dating back to 1500 BC, recognized the practice of medical healing as attributed to "the one God."[15] This idea was reaffirmed through the traditions of Christianity, which emerged from a disease-plagued society.[16] Jesus Christ's depiction as a healer translated not only into spiritual salvation, but also into his divine ability to miraculously heal physical ailments.[17] Christianity centers on "a different valuation of human life, a fraternal concept of equality and charity which imposed on all the faithful the most severe sacrifices in order to lessen the suffering of others."[18] This concept influenced attitudes toward medicine in areas where people were simultaneously adopting religion and fighting widespread disease. Intellectuals collaborated almost exclusively on religious issues with underlying ethical implications, and medicine was commonly among the most pressing issues discussed.[19] Despite

13 "Rod and Serpent" By Edwin Clarke, Book Review of "The Rod and Serpent of Asklepios. Symbol of Medicine" British Medical Journal, Vol. 3, No. 5561 (August 5, 1967), p. 358.

14 "The Symbol of Modern Medicine: Why One Snake Is More Than Two" By Robert A. Wilcox and Emma M. Whitham, Annals of Internal Medicine, Vol. 138, No. 8 (April 15, 2003), p. 673-674; History of the American Medical Writer's Association Part 5" By Cynthia Haggard, Clarifying, April 8, 2009, http://clarifying.wordpress.com/2009/04/08/history-of-the-american-medical-writers-association-part-5/ (Accessed 2/17/10); "Physician Payment Reform, a California Lesson?" By Steve Sweetman, Healthcare Updates from Steve Sweetman: Regional Contracts Director for The Scooter Store, September 15, 2009, http://stevesweetman.wordpress.com/2009/09/15/physician-payment-reform-a-california-lesson/ (Accessed 2/17/10).

15 "A History of Medicine" By Arturo Castiglioni, Second Edition, New York, NY: Alfred A. Knopf, Inc., 1947, p. 32, 72.

16 Ibid., p. 73-77; "The Greatest Benefit to Mankind: A Medical History of Humanity" By Roy Porter, New York: NY: HarperCollins Publishers Ltd., 1997, p. 85-87.

17 "The Greatest Benefit to Mankind: A Medical History of Humanity" By Roy Porter, New York: NY: HarperCollins Publishers Ltd., 1997, p. 85-87; "The Western Medical Tradition 800 BC to AD 1800" By Lawrence I. Conrad, et al., Cambridge University Press, 1995, p. 73-74.

18 "A History of Medicine" By Arturo Castiglioni, Second Edition, New York, NY: Alfred A. Knopf, Inc., 1947, p. 245-246.

19 Ibid., p. 246.

stages of resistance, the church ultimately acknowledged the importance of medicine, namely when it recognized Claudius Galen (see *Galenic Medicine*) as a canonical authority.[20]

Table 1-1 summarizes key early religious figures, places, and medical concepts.

Table 1-1: Early Medical Figures, Places, and Concepts

Deities and Religious Figures*,**,†		
Name	**Location**	**Claim to Fame**
Nabu	Mesopotamia	Assyrian god of healing
Marduk	Mesopotamia	Babylonian lord of magicians
Ea	Mesopotamia	Babylonian god of medicine
Ninurta	Mesopotamia	Babylonian god who led the caste of physicians
Ninazu	Mesopotamia	Babylonian lord of the physicians, represented by rod and serpent symbol
Ningischzida	Mesopotamia	Son of Ninazu, also represented by rod and serpent symbol
Askleopios	Greece	Greek god of healing
Aesculapios	Rome, Italy	Roman god of healing
Buddha (Siddhartha Gautama)	Kapilavastu, Nepal	A spiritual leader and the founder of Buddhism
Jesus Christ	Nazareth, Israel	Son of God, thought to have a divine ability to heal physical ailments
Places§		
Fertile Crescent	Western Asia, including the fertile regions of present-day Iraq and Syria	Medicine rooted in both religious and empirical treatments evolved from the Mesopotamian civilization
Medical Concepts and Symbols*,§§,‡		
Name	**Description**	
Rod and Serpent	Representation of the healing god Sachan in Babylonia	
Asklepian	The staff of Asklepios around which a serpent or serpents are wrapped to symbolize medicine	
Caduceus	Double serpent winding around a staff; a symbol for medicine	
Vedas	A collection of doctrinal Ayurvedic medical texts	
Ayurvedic Sages	Educated by the medical deity prior to transcription of the Vedas	
Palatine Archiaters	Court physicians	

* *"A History of Medicine" By Arturo Castiglioni, Alfred A. Knopf, Inc., 1947.*
** *"Rod and Serpent" By Edwin Clarke, Book Review of "The Rod and Serpent of Asklepios. Symbol of Medicine" By J. Schouten. (p. 260+ix; illustrated. 65s.) London: Elsevier, 1967, in the British Medical Journal, Vol. 3, No. 5561 (August 5, 1967).*
† *"The Western Medical Tradition 800 BC to AD 1800" By Lawrence I. Conrad, et al., Cambridge University Press, 1995.*
§ *"The Greatest Benefit to Mankind: A Medical History of Humanity" By Roy Porter, New York: NY: HarperCollins Publishers Ltd., 1997.*
§§ *"The Symbol of Modern Medicine: Why One Snake Is More Than Two" By Robert A. Wilcox and Emma M. Whitham, Annals of Internal Medicine, Vol. 138, No. 8 (April 15, 2003).*
‡ *"A History of Medicine" By Louis N. Magner, Marcel Dekker, Inc., 1992.*

PHILOSOPHY AND SCIENCE OF MEDICINE

Following from ancient tradition, religion shaped the way early Greeks perceived medicine.[21] The dawn of Greek philosophy influenced the origins of a much more scientific approach to

20 "A History of Medicine" By Arturo Castiglioni, Second Edition, New York, NY: Alfred A. Knopf, Inc., 1947, p. 244-247.
21 "A History of Medicine" By Arturo Castiglioni, Second Edition, New York, NY: Alfred A. Knopf, Inc., 1947, p. 51-53; "The Greatest Benefit to Mankind: A Medical History of Humanity" By Roy Porter, New York: NY: HarperCollins Publishers Ltd., 1997, p. 44-45.

medicine, spurring a pursuit for cures through "critical thought based on observation and experience."[22] Philosophers of both Western (for example, Thales of Miletus, Plato, Aristotle, Anaximander, and Anaximenes) and Eastern (for example, Zoroaster, Confucius, Buddha, and Pythagoras) origins contributed to a mathematical, cosmic, and physiological concept of nature and the biologic system.[23]

> Ancient philosophers, including Thales of Miletus, Plato, Aristotle, Anaximander, Anaximenes, Zoroaster, Confucius, Buddha, and Pythagoras, contributed to a mathematical, cosmic, and physiological concept of nature and the biologic system.
>
> ***Arturo Castiglioni, 1947***

Similar to their Western counterparts, the people of the Orient viewed medicine as inherently intertwined in religious tradition. Buddhism and Hinduism were instrumental to ancient Chinese and Indian medicine.[24] Although both Eastern and Western medical traditions stemmed from the similar religious origins and progressed into parallel eras of proliferative philosophy, they diverged as a result of the differing roles that religion would play in the centuries that followed. Hinduism has a profound impact on Indian medicine (known as Ayurvedic Medicine), as does Buddhism on traditional Chinese medicine (see Chapter 11 of *Consulting Services*).[25] In fact, it is believed that the Vedas, a collection of doctrinal Ayurvedic medical texts, is inspired by the teachings of the Hindu divinity Dhanvantari.[26] According to Indian tradition, the medical deity transcribed the Vedas only after educating many Ayurvedic sages.[27] Unlike Eastern medicine, and despite centuries of ecclesiastic resistance, philosophic (and later, scientific) foundations for Western medicine formed, solidified, and, over time, replaced religion as drivers of medical practice.

Table 1-2 outlines the key philosophers and locations in the history of early medicine.

Table 1-2: Early Medical Figures, Places, and Concepts

Name	Birth/Death	Location	Claim to Fame
Eastern Philosophers*,**			
Zoroaster	660–583 BC	Iran	Philosopher and religious reformer; founder of Zoroastrianism, or Parsiism
Confucius	551–479 BC	State of Lu (present-day Shandong province, China)	Most famous Chinese philosopher/teacher/political theorist
Western Philosophers§			
Plato	428–347 BC	Greece	Renowned philosopher and author
Aristotle	384–322 BC	Greece	Student of Plato, renowned for knowledge of art, science, and philosophy
Thales of Miletus	639–544 BC	Miletus (present-day Turkey)	The first philosopher in the Greek tradition

(continued)

22 "A History of Medicine" By Arturo Castiglioni, Second Edition, New York, NY: Alfred A. Knopf, Inc., 1947, p. 55, 130; "The Greatest Benefit to Mankind: A Medical History of Humanity" By Roy Porter, New York: NY: HarperCollins Publishers Ltd., 1997, p. 44-45.
23 "A History of Medicine" By Arturo Castiglioni, Second Edition, New York, NY: Alfred A. Knopf, Inc., 1947, p. 129-133, 135-142.
24 "A History of Medicine" By Louis N. Magner, New York, NY: Marcel Dekker, Inc., 1992, p. 38-39.
25 Ibid.
26 Ibid.
27 Ibid,

Name	Birth/Death	Location	Claim to Fame
Eastern Philosophers*,**			
Anaximander	610–546 BC	Miletus (present-day Turkey)	Pupil of Thales, who focused on the cyclical rhythm of generation and corruption
Anaximenes	570–500 BC	Miletus (present-day Turkey)	Follower of Thales, who thought the essential substance of life was air
Pythagoras	580–489 BC	Croton, Italy	Founder of Italic School of Philosophy, who connected math, music, and medicine
Places§§			
Place	**Location**	**Role in Medical History**	
Fertile Crescent	Western Asia, including the fertile regions of present-day Iraq and Syria	Medicine evolved from the Mesopotamian civilization	

HIPPOCRATES

> "A physician who is a lover of wisdom is the equal to a god."
>
> ***Hippocrates***

During its golden age, Greece prospered in countless social aspects, wisdom, knowledge, development, beauty, literature, and culture, so that "it seemed as if an impulse to grandeur and glory and a striving for liberty and beauty pervaded all Greece."[28] Among the unmatched intellectuals of this era was Hippocrates, recognized as "the wisest and the greatest practitioner of his art."[29] Born in 460 BC, Hippocrates served as both a priestly and empirical authority of medicine, and he authored the Corpus with his students, which includes works on medical specialties and pathologies, the practice of medicine, and medical ethics.[30] Several influential philosophers and intellectuals in the area of medicine (for example, Galen and Erotius) published commentaries on Hippocrates and his teachings.[31] Additionally, many of his contemporaries, including Plato, praised his efforts as an author and inspirer of important medical texts.[32]

> Hippocrates served as both a priestly and empirical authority of medicine during the golden age of Greece; he was responsible for compiling the Oath of Hippocrates, as well as writing and inspiring works that became part of the Corpus.
>
> ***Roy Porter, 1997 and Arturo Castiglioni, 1947***

The first of Hippocrates' ethical texts was the Oath of Hippocrates, "which covers the duty of the physician to his teacher, his pupils, and his patients, clearly shows that a relationship existed between Hippocratic medicine and priestly medicine; but it raises medicine to a height and

28 "A History of Medicine" By Arturo Castiglioni, Second Edition, New York, NY: Alfred A. Knopf, Inc., 1947, p. 148.
29 Ibid.
30 "A History of Medicine" By Arturo Castiglioni, Second Edition, New York, NY: Alfred A. Knopf, Inc., 1947, p. 55, 148-149, 153; "The Greatest Benefit to Mankind: A Medical History of Humanity" By Roy Porter, New York: NY: HarperCollins Publishers Ltd., 1997, p. 55-56.
31 "A History of Medicine" By Arturo Castiglioni, Second Edition, New York, NY: Alfred A. Knopf, Inc., 1947, p. 150-153.
32 "A History of Medicine" By Arturo Castiglioni, Second Edition, New York, NY: Alfred A. Knopf, Inc., 1947, p. 150-51; "The Greatest Benefit to Mankind: A Medical History of Humanity" By Roy Porter, New York: NY: HarperCollins Publishers Ltd., 1997, p. 62-63, 71.

human dignity that assures it its own position as a science."[33] Figure 1-1 contains an excerpt from the classic Oath of Hippocrates.

Medical students commonly take the Hippocratic Oath (or a modification thereof) to demonstrate a commitment to uphold ethical standards as they practice medicine.[34] Although many attribute the physician's commitment to "first do no harm" (translated from the Latin phrase *primum non nocere*) to Hippocrates, the true origins of the phrase are unknown and arguably not of Hippocratic origin.[35] Table 1-3 outlines the three most influential figures and their works during this time period.

Figure 1-1: Excerpt From the Classic Hippocratic Oath*

I swear by Apollo Physician and Asclepius and Hygieia and Panaceia and all the gods and goddesses, making them my witnesses, that I will fulfill according to my ability and judgment this oath and this covenant:

To hold him who has taught me this art as equal to my parents and to live my life in partnership with him, and if he is in need of money to give him a share of mine, and to regard his offspring as equal to my brothers in male lineage and to teach them this art—if they desire to learn it—without fee and covenant; to give a share of precepts and oral instruction and all the other learning to my sons and to the sons of him who has instructed me and to pupils who have signed the covenant and have taken an oath according to the medical law, but no one else.

I will apply dietetic measures for the benefit of the sick according to my ability and judgment; I will keep them from harm and injustice.

I will neither give a deadly drug to anybody who asked for it, nor will I make a suggestion to this effect. Similarly I will not give to a woman an abortive remedy. In purity and holiness I will guard my life and my art.

I will not use the knife, not even on sufferers from stone, but will withdraw in favor of such men as are engaged in this work.

Whatever houses I may visit, I will come for the benefit of the sick, remaining free of all intentional injustice, of all mischief and in particular of sexual relations with both female and male persons, be they free or slaves.

What I may see or hear in the course of the treatment or even outside of the treatment in regard to the life of men, which on no account one must spread abroad, I will keep to myself, holding such things shameful to be spoken about.

* "Hippocratic Oath" Johns Hopkins University, http://guides.library.jhu.edu/content.php?pid=23699&sid=190555 (Accessed 9/10/09).

Table 1-3: Influential Figures During the Time of Hippocrates*

Name	Birth/Death	Location	Claim to Fame
Hippocrates	460–370 BC	Greece	Thought to be one of the wisest authorities on medicine at the time; authored medical books on specialties and pathologies, the practice of medicine, and ethics, including the Oath of Hippocrates, which is still used today to swear in graduating medical students
Julius Caesar	100–44 BC	Rome, Italy	Granted Roman citizenship to physicians, elevating their social status
Claudius Galen	AD 138–201	Pergamon (Asia Minor)	A physician and author best known for his study of anatomy and theories on the circulation of the blood, in his best known work, *Ars Parva*

** "A History of Medicine" By Arturo Castiglioni, Alfred A. Knopf, Inc., 1947.*

33 "A History of Medicine" By Arturo Castiglioni, Second Edition, New York, NY: Alfred A. Knopf, Inc., 1947, p. 177.
34 "The White Coat Ceremony: A Contemporary Medical Ritual" By S. J. Huber, Journal of Medical Ethics, Vol. 29 (2003), p. 364.
35 "'Primum Non Nocere' and the Principle of Non-Maleficence" By Raanan Gillon, British Journal of Medicine, Vol. 21 (July 13, 1985), p. 130.

PROFESSIONAL PRACTICE AND STATUS OF THE PHYSICIAN

The practice of medicine originated in Greece and spread slowly throughout the Roman Empire.[36] People regarded medical practice as a trade of foreigners, and Greek physicians were regarded with little, if any, respect.[37] Many people assumed the title of *physician* without obtaining the proper training, which further contributed to the defamation of the profession.[38] However, in 46 BC, Julius Caesar granted physicians the right to Roman citizenship, an honor that elevated the reputation of physicians in Roman society.[39] Soon thereafter, it became necessary to establish medical schools to repel the invasion of unqualified *pseudo-physicians* seeking easy profit in Rome.[40] The number of medical schools approved by the Roman Empire increased, the most celebrated of which could be found in Marseille, Lyon, Saragossa, Antioch, Athens, and Alexandria.[41] A medical licensure process was mandated, and both private and public libraries were developed to preserve the valued texts and manuscripts.[42] Court physicians, called *palatine archiaters*, played an essential role in politics and legal affairs and designated celebrated physicians in the empire.[43] As the practice of medicine became systemized, so did the social position of physicians.[44] Although the medical advances made by the Roman Empire were minimal, Rome was first to incorporate a system of medicine that became an important part of its intricate system of laws.[45]

> The Roman Empire was first to incorporate a system of legal medicine, which was an important part of Rome's intricate system of laws.
>
> ***Arturo Castiglioni, 1947***

GALENIC MEDICINE

Solidifying Hippocratic theories through dissection and experimentation helped reduce the mystery and doubt that surrounded physicians and helped enhance the quality of medical care in the Roman Empire.[46] The first influential strides in this direction were made by Galen of Pergamon in Asia Minor (AD 129–200), a student of Hippocrates, who published fifteen commentaries to Hippocrates' work.[47] He was appointed physician of the gladiators, an

36 "A History of Medicine" By Arturo Castiglioni, Second Edition, New York, NY: Alfred A. Knopf, Inc., 1947, p. 232-233; "The Greatest Benefit to Mankind: A Medical History of Humanity" By Roy Porter, New York: NY: HarperCollins Publishers Ltd., 1997, p. 69.
37 "The Greatest Benefit to Mankind: A Medical History of Humanity" By Roy Porter, New York: NY: HarperCollins Publishers Ltd., 1997, p. 69-70.
38 "A History of Medicine" By Arturo Castiglioni, Second Edition, New York, NY: Alfred A. Knopf, Inc., 1947, p. 232-233.
39 Ibid., p. 233.
40 Ibid.
41 Ibid.
42 Ibid., p. 233-234.
43 Ibid., p. 233-235.
44 Ibid.
45 Ibid., p. 232-241.
46 Ibid., p. 217-218.
47 "A History of Medicine" By Arturo Castiglioni, Second Edition, New York, NY: Alfred A. Knopf, Inc., 1947, p. 218-219; "The Western Medical Tradition 800 BC to AD 1800" By Lawrence I. Conrad, et al., Cambridge University Press, 1995, p. 58, 63, 65-69, 81.

honorable and sought after position.[48] Galen quickly became known as an extraordinary practitioner, writer, and student.[49]

A student of philosophy and medicine, Galen was a pioneer in the field of anatomy, translating his findings from animal dissection to human application.[50] His philosophical background drove many of his hypotheses, chiefly those related to the physiological explanation for human blood circulation.[51] Though Galenic medicine represented a huge step forward for evidence-based medicine, it also impeded advances in anatomy and physiology due to its inherent flaws and blind adoption by the medical and religious communities.[52]

> Drawbacks of Galenic Medicine: findings based entirely on animal dissection and false perceptions regarding the circulation of human blood.
>
> ***Sherwin B. Nuland, 1988 and Lawrence I. Conrad, 1995***

RISE OF THE MEDICAL UNIVERSITY

The oldest universities, though originating from the ancient Latin schools and persevering through the Roman Empire, did not flourish until the end of the thirteenth century.[53] As academia increased in sophistication, three kinds of universities emerged: community-funded, state-funded, and ecclesiastically-funded.[54] Although some schools focused entirely on medicine, others (termed *Studium Generale*) also incorporated law, theology, and philosophy in their curricula.[55]

The church's influence on medical curricula often slowed the advance of anatomical and physiological understanding due to its resistance to findings of clinical and experimental research.[56] The Christian belief that disease was a consequence of sin left healing to the devices of nature.[57] Through the translation of Arabian medical texts, scholars developed Greco-Arabian medicine, which confronted the shortcomings of medical education in the early Middle Ages.[58] The physician Abu Ali al-Husayn Abdallah ibn Sinna (known in the West as *Avicenna*) compiled

48 "A History of Medicine" By Arturo Castiglioni, Second Edition, New York, NY: Alfred A. Knopf, Inc., 1947, p. 218, 239; "The Western Medical Tradition 800 BC to AD 1800" By Lawrence I. Conrad, et al., Cambridge University Press, 1995, p. 61.

49 "A History of Medicine" By Arturo Castiglioni, Second Edition, New York, NY: Alfred A. Knopf, Inc., 1947, p. 218-219; "The Western Medical Tradition 800 BC to AD 1800" By Lawrence I. Conrad, et al., Cambridge University Press, 1995, p. 79.

50 "A History of Medicine" By Arturo Castiglioni, Second Edition, New York, NY: Alfred A. Knopf, Inc., 1947, p. 218-19, 221-223; "The Greatest Benefit to Mankind: A Medical History of Humanity" By Roy Porter, New York: NY: HarperCollins Publishers Ltd., 1997, p. 74-75, 76-77.

51 "A History of Medicine" By Arturo Castiglioni, Second Edition, New York, NY: Alfred A. Knopf, Inc., 1947, p. 220-222; "The Greatest Benefit to Mankind: A Medical History of Humanity" By Roy Porter, New York: NY: HarperCollins Publishers Ltd., 1997, p. 74-77.

52 "Doctors: The Illustrated History of Medical Pioneers" By Sherwin B. Nuland, New York, NY: Black Dog & Leventhal Publishers, Inc., 2008, p. 71; "The Western Medical Tradition 800 BC to AD 1800" By Lawrence I. Conrad, et al., Cambridge University Press, 1995, p. 79-80.

53 "A History of Medicine" By Arturo Castiglioni, Second Edition, New York, NY: Alfred A. Knopf, Inc., 1947, p. 325.

54 Ibid., p. 326.

55 Ibid., p. 325-327.

56 "A History of Medicine" By Arturo Castiglioni, Second Edition, New York, NY: Alfred A. Knopf, Inc., 1947, p. 326, 329; "Doctors: The Illustrated History of Medical Pioneers" By Sherwin B. Nuland, New York, NY: Black Dog & Leventhal Publishers, Inc., 2008, p. 71.

57 "The Greatest Benefit to Mankind: A Medical History of Humanity" By Roy Porter, New York: NY: HarperCollins Publishers Ltd., 1997, p. 110.

58 "A History of Medicine" By Arturo Castiglioni, Second Edition, New York, NY: Alfred A. Knopf, Inc., 1947, p. 325-329; "The Greatest Benefit to Mankind: A Medical History of Humanity" By Roy Porter, New York: NY: HarperCollins Publishers Ltd., 1997, p. 98-99.

the first comprehensive medical text in Arabic.[59] His work, *Kitab al-Qanun* (*The Canon of Medicine*), synthesized the philosophies and teachings of Hippocrates, Galen, Dioscorides, and Alexandrian physicians.[60] His mastery of medical science became legendary, and ibn Sinna became known as the "Galen of Islam."[61] One of the most famous scholars following Avicenna was Moses Maimonides,[62] a Jewish physician who is attributed with authoring the "Prayer for Physicians."[63] In his efforts to reconcile scientific reasoning and religious faith, Maimonides combined elements of philosophy, logic, theology, and astronomy,[64] and published numerous works, including the *Regimen of Health* and the *Book of Precepts*, many of which contained sound advice regarding diet, hygiene, and first aid.[65]

Despite the barriers posed by the Inquisition, scholars, philosophers, and physicians, such as Pietro d'Abano, infused Arabian medicine into the scholarship of philosophy while attempting to compromise their differences.[66] This movement gave rise to the University of Padua, which pioneered public dissections of human cadavers and gave rise to revolutionary work in dentistry and medieval medicine and to publications, including Galen's *Ars Parva* (a commentary of Torrigiani), and Aphorisms of Hippocrates.[67] Greco-Arabian medicine also gave rise to the University of Bologna, the first literary collection of clinical cases, and the work of Ugo Borgognoni of Lucca, the latter of which set the foundation of modern surgery.[68] The University of Montpellier was the first institution to award a doctorate degree, and at one point, Bologna and Montpellier had the most stringent dissection requirements.[69] However, the University of Montpellier lost its prominence when the popes retreated from Avignon and religious warfare decimated the area.[70]

EASTERN MEDICAL TRADITIONS

The contrast between the evolution of western and eastern medicine resulted from western medicine's evolution through the development of hypothetical deductions, while eastern medicine developed by utilizing more inductive methods, where every individual was thought to possess a balance between internal defenses and external insults, a lack of which balance resulted in disease.[71] Underlying the practice of eastern medicine was the emphasis on the laws of nature

59 "The Greatest Benefit to Mankind: A Medical History of Humanity" By Roy Porter, New York: NY: HarperCollins Publishers Ltd., 1997, p. 98-99.
60 "The Canon of Medicine" By Laleh Bakhtiar, Great Books of the Islamic World, Inc., 1999, p. xxxvii; "The Greatest Benefit to Mankind: A Medical History of Humanity" By Roy Porter, New York: NY: HarperCollins Publishers Ltd., 1997, p. 98-99.
61 "A History of Medicine" By Arturo Castiglioni, Second Edition, New York, NY: Alfred A. Knopf, Inc., 1947, p. 220-222; "The Greatest Benefit to Mankind: A Medical History of Humanity" By Roy Porter, New York: NY: HarperCollins Publishers Ltd., 1997, p. 74-75, 76-77.
62 "Medicine: An Illustrated History" By Albert S. Lyons and R. Joseph Petrucelli, New York, NY: Harry N. Abrams, Inc., 1978, p. 313.
63 "The Oxford Illustrated Companion to Medicine" Edited by Stephen Lock, et al., 3rd Edition, New York, NY: Oxford University Press, 2001, p. 573. Note, however, that some commentators dispute Maimonides' authorship of the Prayer for Physicians. "Medicine: An Illustrated History" By Albert S. Lyons and R. Joseph Petrucelli, New York, NY: Harry N. Abrams, Inc., 1978, p. 315.
64 "Medicine: An Illustrated History" By Albert S. Lyons and R. Joseph Petrucelli, New York, NY: Harry N. Abrams, Inc., 1978, p. 315; "The Greatest Benefit to Mankind: A Medical History of Humanity" By Roy Porter, New York: NY: HarperCollins Publishers Ltd., 1997, p. 101.
65 "Medicine: An Illustrated History" By Albert S. Lyons and R. Joseph Petrucelli, New York, NY: Harry N. Abrams, Inc., 1978, p. 315; "The Greatest Benefit to Mankind: A Medical History of Humanity" By Roy Porter, New York: NY: HarperCollins Publishers Ltd., 1997, p. 101.
66 "A History of Medicine" By Arturo Castiglioni, Second Edition, New York, NY: Alfred A. Knopf, Inc., 1947, p. 329-333.
67 "A History of Medicine" By Arturo Castiglioni, Second Edition, New York, NY: Alfred A. Knopf, Inc., 1947, p. 326, 330, 332-333; "Doctors: The Illustrated History of Medical Pioneers" By Sherwin B. Nuland, New York, NY: Black Dog & Leventhal Publishers, Inc., 2008, p. 70-73.
68 "A History of Medicine" By Arturo Castiglioni, Second Edition, New York, NY: Alfred A. Knopf, Inc., 1947, p. 333-335.
69 "A History of Medicine" By Arturo Castiglioni, Second Edition, New York, NY: Alfred A. Knopf, Inc., 1947, p. 338-339; "The Greatest Benefit to Mankind: A Medical History of Humanity" By Roy Porter, New York: NY: HarperCollins Publishers Ltd., 1997, p. 110.
70 "A History of Medicine" By Arturo Castiglioni, Second Edition, New York, NY: Alfred A. Knopf, Inc., 1947, p. 338-339.
71 "Eastern and Western Approaches to Medicine" By Julia J. Tsuei, Western Journal of Medicine, Vol. 128, No. 6 (June 1978), p. 551-553.

as a parallel to bodily phenomena, leading to traditional concepts that "man is nothing but a creature living between heaven and earth,"[72] the duality of the Yin and Yang, Buddhist philosophy, and the teachings of Ayurvedic medicine (the science of life).[73]

Although the practices of western and eastern medicine evolved through different methods, and on significantly different timelines, their progression was somewhat similar, as both practices grew from religious roots and ancient texts. In India, the Vedas, a set of ancient texts revered by Hindus as sacred, referenced medical lore through tales of demons and charms. These teachings gave way to the science of life, or Ayurvedic medicine, which applied the theory of humors[74] to bodily health. The Ayurvedic system was slightly different from the similar Greek teachings regarding humors, as the Ayurvedic system also considered the five elements, five winds, two souls, as well as blood, in the assessment of health. Ancient Indian medicine also encompassed early forms of surgery, hospitals, and medical colleges.[75]

Chinese medicine is arguable the oldest practice of medicine, with the Huang-ti Nei Ching (The Inner Canon of the Yellow Emperor), published during the T'ang Dynasty (618-907). This work was based on the balance between the Yin and the Yang, which generate the five phases (wood, fire, earth, metal, and water) that affect health. The Huang-ti Nei Ching influenced folk healing practices for over 2,500 years. Theories on anatomy, illness, and diagnosis were all founded on the duality of the Ying and the Yang, espoused by the Huang-ti Nei Ching, and, accordingly, the focus of Chinese healing became more preventative than reactionary.[76]

Eastern medicine shows a significant similarity to its origins in India and China, unlike western medicine, which has changed dramatically throughout its development. Currently utilized alternative medical techniques, such as acupuncture, were discussed in the ancient Chinese Cannon of Medicine and aim, even today, are thought to restore the flow of Yin and the Yang in the body.[77]

RENAISSANCE: REVIVAL OF ANATOMY AND PHYSIOLOGY

Liberation from Galenic medicine and the scholasticisms encouraged by the church began with the work of early Renaissance Anatomists in the late 1400s and early 1500s.[78] Artist-anatomists such as Andrea Verrochio and Leonardo da Vinci were pioneers in the field.[79] Da Vinci

72 From the ancient Chinese Nei Ching (Cannon of Medicine) published at the end of the Chou Dynasty (1121-249 BC) and beginning of the Chin Dynasty (221-207 BC). "Eastern and Western Approaches to Medicine" By Julia J. Tsuei, Western Journal of Medicine, Vol. 128, No. 6 (June 1978), p. 553; "A History of Medicine" By Lois N. Magner, Second Edition, New York, NY: Informa Healthcare, Inc., 2007, p. 53-56.

73 "Eastern and Western Approaches to Medicine" By Julia J. Tsuei, Western Journal of Medicine, Vol. 128, No. 6 (June 1978), p. 552-553; "A History of Medicine" By Lois N. Magner, Second Edition, New York, NY: Informa Healthcare, Inc., 2007, p. 53-56.

74 The three humors (i.e., wind, bile, and phlem) compose the bodily systems and must remain in balance to ensure good health. "A History of Medicine" By Lois N. Magner, Second Edition, New York, NY: Informa Healthcare, Inc., 2007, p.59.

75 "A History of Medicine" By Lois N. Magner, Second Edition, New York, NY: Informa Healthcare, Inc., 2007, p. 55-65.

76 Ibid., p. 66-71.

77 Ibid., p. 76.

78 "A History of Medicine" By Arturo Castiglioni, Second Edition, New York, NY: Alfred A. Knopf, Inc., 1947, p. 408-413, 416-417; "Doctors: The Illustrated History of Medical Pioneers" By Sherwin B. Nuland, New York, NY: Black Dog & Leventhal Publishers, Inc., 2008, p. 70-72.

79 "A History of Medicine" By Arturo Castiglioni, Second Edition, New York, NY: Alfred A. Knopf, Inc., 1947, p. 410-413; "Doctors: The Illustrated History of Medical Pioneers" By Sherwin B. Nuland, New York, NY: Black Dog & Leventhal Publishers, Inc., 2008, p. 72; "The Greatest Benefit to Mankind: A Medical History of Humanity" By Roy Porter, New York: NY: HarperCollins Publishers Ltd., 1997, p. 176-177.

performed dissections of human cadavers and made drawings of his observations.[80] He also refuted many of the statements made by his Galenic predecessors; due to his objective perspective of anatomy, his work was not immediately recognized with the respect it deserved.[81]

Andreas Vesalius also refuted aspects of Galen's work, claiming that Galen's anatomical knowledge applied only to animals and was incredibly flawed when applied to humans.[82] His discoveries in anatomy, released in the mid-1500s, are medical landmarks.[83] By contradicting Galen's deductions from animal dissection and philosophical conjecture, Vesalius was the first to describe the vasculature and anatomy of the human heart.[84] By daring to question the doctrinal teachings of their honored predecessors, these and other artists, anatomists, philosophers, and scientists heralded an era of enlightenment, through which "the sluices of objective inquiry and experiment had been opened."[85] Table 1-4 indicates the most influential figures and important locations in the history of healthcare during the Renaissance and Inquisition.

Table 1-4: Influential Figures and Important Places During the Time of the Renaissance and Inquisition*,**

Influential Figures			
Name	**Birth/Death**	**Location**	**Claim to Fame**
Abu Ali al-Husayn (Abdallah ibn Sinna or "Avicenna")	AD 980–1037	Bukhara, Persia	Compiled first comprehensive medical text in Arabic, *Kitab al-Qanun* (*The Canon of Medicine*)
Pietro d'Abano	AD 1250–1315	Padua, Italy	Infused Arabian medicine into the scholarship of philosophy
Ugo Borgognoni of Lucca	Second half of the twelfth century–1252	Bologna, Italy	A Bolognese surgeon during the Crusades, he simplified the treatment of lesions of the extremities and fractures; none of his works exist today, but he has been quoted by his son, Theodoric of Lucca (AD 1205–1258)
Andrea Verrochio	AD 1435–1488	Florence, Italy	Painter and anatomist; teacher of Leonardo da Vinci; his students examined cadavers
Leonardo da Vinci	AD 1452–1519	Florence, Italy	Greatest artist anatomist; revolutionized anatomy with his anatomical sketches based on actual cadavers
Andreas Vesalius	1515–1564	Brussels, Belgium	First to describe vasculature and anatomy of the human heart; refuted Galen's theories of anatomy
Important Places			
Place	**Location**	**Role in Medical History**	
University of Padua	Padua, Italy	Pioneered public dissection of human cadavers	
University of Bologna	Bologna, Italy	Held the first literary collection of clinical cases	
University of Montpellier	Montpellier, France	Became the first institution to award doctorate degrees	

* *"A History of Medicine" By Arturo Castiglioni, Alfred A. Knopf, Inc., 1947.*
** *"The Greatest Benefit to Mankind: A Medical History of Humanity" By Roy Porter, New York: NY: HarperCollins Publishers Ltd., 1997.*

80 "A History of Medicine" By Arturo Castiglioni, Second Edition, New York, NY: Alfred A. Knopf, Inc., 1947, p. 413; "The Greatest Benefit to Mankind: A Medical History of Humanity" By Roy Porter, New York: NY: HarperCollins Publishers Ltd., 1997, p. 176-177.
81 "A History of Medicine" By Arturo Castiglioni, Second Edition, New York, NY: Alfred A. Knopf, Inc., 1947, p. 413-417.
82 "A History of Medicine" By Arturo Castiglioni, Second Edition, New York, NY: Alfred A. Knopf, Inc., 1947, p. 418-419, 422-423; "The Greatest Benefit to Mankind: A Medical History of Humanity" By Roy Porter, New York: NY: HarperCollins Publishers Ltd., 1997, p. 179-181.
83 "A History of Medicine" By Arturo Castiglioni, Second Edition, New York, NY: Alfred A. Knopf, Inc., 1947, p. 420-423.
84 Ibid., p. 422-423.
85 "The Growth of Medicine" By Frederick Stenn, Springfield, IL: Charles C. Thomas Publisher, 1967, p. 78-79.

SEVENTEENTH CENTURY: THE DAWN OF SCIENTIFIC LIBERTY

ANATOMICAL ADVANCES

Countless influential figures significantly contributed to the overhaul of Galenic medicine, laying the foundation for the modern school of medical thought. The work of da Vinci and Vesalius prompted advances in anatomy and physiology.[86] Michael Servetus's breakthroughs in pulmonary circulation, Fabrecius's discovery of the valves in veins, and William Harvey's revelations on the enigmatic circulation of the blood gave mathematical, mechanical, and methodical meaning to the sciences of physiology and pathological anatomy.[87] These findings prompted a contagion of anatomical investigations like Adrien Spigelius's studies of the liver, Giulio Casseri's inquiries of the anatomy of abdominal organs, and Antonio Maria Valsalva's observation of the human ear.[88]

In the early 1670s, microscopes were developed by Marcello Malpighi and Antoni van Leeuwenhoek, which triggered the interest in the molecular implications of human anatomy.[89] The microscope was originally developed by a Dutch spectacle-maker named Zacharias Janssen, however, Janssen's early model could only magnify objects ten times.[90] Van Leeuwenhoek's microscopes could magnify up to 270 times, which allowed him to discover red blood corpuscles and the structure of skeletal muscles.[91]

The conceptualization of toxicology, knowledge of contagious diseases, and developments in surgery were furthered by brilliant minds, including Marcello Malpighi, Jean-Baptiste van Helmont, and Francois Mauriceau.[92]

PROGRESS IN HYGIENE

A series of devastating epidemics terrorized Europe from the fourteenth century through beginning of the eighteenth century. During this period, Europeans suffered from scurvy, malaria, typhus, smallpox, diphtheria, influenza, and, perhaps most notably, the various

86 "A History of Medicine" By Arturo Castiglioni, Second Edition, New York, NY: Alfred A. Knopf, Inc., 1947, p. 410-425; "Doctors: The Illustrated History of Medical Pioneers" By Sherwin B. Nuland, New York, NY: Black Dog & Leventhal Publishers, Inc., 2008, p. 70-73; "The Greatest Benefit to Mankind: A Medical History of Humanity" By Roy Porter, New York: NY: HarperCollins Publishers Ltd., 1997, p. 176-177, 179-181.

87 "A History of Medicine" By Arturo Castiglioni, Second Edition, New York, NY: Alfred A. Knopf, Inc., 1947, p. 434-435, 515; "The Greatest Benefit to Mankind: A Medical History of Humanity" By Roy Porter, New York: NY: HarperCollins Publishers Ltd., 1997, p. 183-184.

88 "A History of Medicine" By Arturo Castiglioni, Second Edition, New York, NY: Alfred A. Knopf, Inc., 1947, p. 515, 525-527.

89 "Medicine: An Illustrated History" By Albert S. Lyons and R. Joseph Petrucelli, New York, NY: Harry N. Abrams, Inc., 1978, p. 439.

90 Ibid.

91 Ibid.

92 "A History of Medicine" By Arturo Castiglioni, Second Edition, New York, NY: Alfred A. Knopf, Inc., 1947, p. 519, 522-524, 536, 539-540, 543, 555-556.

infestations of The Black Death.[93] The Black Death decimated Europe from 1320–1420, with mortality counts of barely less than two-thirds the original population.[94] The notable devastation endured through the seventeenth century, prompting the focused study of the causes of disease, the results of which led to the emergence of epidemiology, as well as, perhaps most important, the rise of modern hygiene.[95] Giovanni Maria Lancisi, a renowned clinician and epidemiologist, responded to the influenza epidemic in Italy by proposing a series of hygiene improvements, namely, the need to drain stagnant bodies of water and to purify the air in places where disease ran rampant.[96]

> The epidemic-related devastation of the seventeenth century, which saw outbreaks of scurvy, malaria, typhus, the Bubonic plague, smallpox, diphtheria, and influenza, prompted the dawn of epidemiology, and, more important, modern hygiene.
>
> ***Roy Porter, 1997 and Arturo Castiglioni, 1947***

Because disease was a significant problem in the military, sanitary measures and disease containment within the military became an area of significant focus.[97] The first substantial investigations into military hygiene were conducted by Florentine Orazio Monti and Antonio Porzio.[98] Porzio made notable advances on the subject of epidemic avoidance in armies, demonstrating the detrimental effects of intra-barrack contamination and, ultimately, civilian contamination.[99]

Bernardino Ramazzini of Capri became the father of industrial hygiene and authored the first treatise on occupational disease: *De Morbis Artificum*.[100] Ramazzini compiled research on the diseases of miners and issued a report of his findings that resembled a modern occupational risk assessment.[101] He also studied the harmful effects of metals on artisans, the risks associated with surgeon exposure to mercurial inunctions, and the exposures to lead, antimony, and countless other toxins endured by chemists, pharmacists, gilders, painters, tinners, and colored-glass workers.[102] Not only was Ramazzini the first investigator of occupational disease, but he was also a remarkable general clinician, focusing on the methodical investigation of disease toward the proper course of action.[103]

93 "A History of Medicine" By Arturo Castiglioni, Second Edition, New York, NY: Alfred A. Knopf, Inc., 1947, p. 560-563; "The Black Death and the Transformation of the West" By David Herlihy, Cambridge, MA: Harvard University Press, 1997, p. 17-18.
94 "The Black Death and the Transformation of the West" By David Herlihy, Cambridge, MA: Harvard University Press, 1997, p. 17-18.
95 "A History of Medicine" By Arturo Castiglioni, Second Edition, New York, NY: Alfred A. Knopf, Inc., 1947, p. 560-563; "The Greatest Benefit to Mankind: A Medical History of Humanity" By Roy Porter, New York: NY: HarperCollins Publishers Ltd., 1997, p. 236.
96 "A History of Medicine" By Arturo Castiglioni, Second Edition, New York, NY: Alfred A. Knopf, Inc., 1947, p. 562-563.
97 Ibid., p. 563.
98 Ibid.
99 Ibid.
100 "A History of Medicine" By Arturo Castiglioni, Second Edition, New York, NY: Alfred A. Knopf, Inc., 1947, p. 564; "The Greatest Benefit to Mankind: A Medical History of Humanity" By Roy Porter, New York: NY: HarperCollins Publishers Ltd., 1997, p. 296.
101 "The Greatest Benefit to Mankind: A Medical History of Humanity" By Roy Porter, New York: NY: HarperCollins Publishers Ltd., 1997, p. 296.
102 Ibid.
103 "A History of Medicine" By Arturo Castiglioni, Second Edition, New York, NY: Alfred A. Knopf, Inc., 1947, p. 565.

> Bernardo Ramazzini of Capri became known as the father of industrial hygiene; he authored the first treatise on occupational disease, *De Morbis Artificum*.
>
> ***Roy Porter, 1997 and Arturo Castiglioni, 1947***

Legislators began passing sanitation laws toward the end of the seventeenth century.[104] When the plague broke out in Rome, the city took measures to contain the disease by means of regulatory sanitary controls.[105] For example, the College of Physicians was asked to report all patients who had been treated for certain diseases in the past six months.[106] Physicians took appropriate measures to disinfect victims of the plague, and the city gave physicians permits to euthanize and perform autopsies on any patients dying of contamination.[107] The executions caused uproar among civilians, which brought an end to these measures for disease control.[108] Nonetheless, they prompted more efforts toward military hygiene.[109] From these advances in hygiene, preventative and sanitary control measures became areas of legislative reform that developed throughout the eighteenth and nineteenth centuries.[110]

> Beginning in the seventeenth century and continuing through the eighteenth and nineteenth centuries, advances in hygiene, methods for arriving at pathological conclusions, and preventative and sanitary control measures became areas of legislative reform.
>
> ***Roy Porter, 1997 and Arturo Castiglioni, 1947***

EIGHTEENTH CENTURY: THE SHIFT TOWARD THE "*SCIENCE*" OF MEDICINE

The reformist attitudes of physicians and scientists initiated scientific progress in the eighteenth century. They believed that health improvement was imperative "to human emancipation...from suffering, want, and fear."[111] As the dark age of the ecclesiastic resistance to scientific advance culminated, advocates argued that medicine should be more philosophical and method-based.[112] Although the eighteenth century became known for Immanuel Kant's suggestion "that philosophy is the queen of all the sciences," it is more renowned for landmark progress in the exact sciences.[113] Countless discoveries in chemistry, physics, biology, physiology, anatomy, and pathology yielded a single conclusion: without an applied understanding of each of these areas of

104 "A History of Medicine" By Arturo Castiglioni, Second Edition, New York, NY: Alfred A. Knopf, Inc., 1947, p. 566-567.
105 Ibid.,
106 Ibid., p. 567.
107 Ibid.
108 Ibid.
109 Ibid.
110 "A History of Medicine" By Arturo Castiglioni, Second Edition, New York, NY: Alfred A. Knopf, Inc., 1947, p. 567; "The Greatest Benefit to Mankind: A Medical History of Humanity" By Roy Porter, New York: NY: HarperCollins Publishers Ltd., 1997, p. 397-400, 405-407.
111 "The Greatest Benefit to Mankind: A Medical History of Humanity" By Roy Porter, New York: NY: HarperCollins Publishers Ltd., 1997, p. 374.
112 "The Western Medical Tradition 800 BC to AD 1800" By Lawrence I. Conrad, et al., Cambridge University Press, 1995, p. 374.
113 "A History of Medicine" By Arturo Castiglioni, Second Edition, New York, NY: Alfred A. Knopf, Inc., 1947, p. 580.

science, the practice of medicine is arbitrary.[114] Table 1-5 outlines the most influential figures and a few key events in medical history during the seventeenth and eighteenth centuries.

> According to Immanuel Kant and his followers, "philosophy is the queen of all sciences."
>
> ***Arturo Castiglioni, 1947***

Table 1-5: Influential Figures and Important Events During the Seventeenth and Eighteenth Centuries

Influential Figures*,**,§			
Name	**Birth/Death**	**Location**	**Claim to Fame**
Michael Servetus	1511–1553	Villanueva, Spain	Discovered pulmonary circulation
Hieronymus Fabricius ab Aquapendente	1533–1619	Padua, Italy	The greatest comparative anatomist; published that veins contained valves in his work, *De Venarum Ostiolis* (*On the Valves and the Veins)* in 1603
William Harvey	1578–1657	Folkeston, England	Premier name in the discovery of the modern theories of circulation
Adrian Spigelius	1567–1625	Brussels, Belgium	Studied the liver
Giulio Casseri	1552–1616	Padua, Italy	Studied abdominal organs
Antonio Maria Valsalva	1666–1723	Bologna, Italy	Studied the human ear
Antoni van Leeuwenhoek	1632–1723	Delft, Holland	Invented the microscope in the early 1670s, with which he is believed to have discovered red blood corpuscles and advanced the study of vessel walls
Marcello Malpighi	1628–1694	Crevallcore, Italy	Conceptualized toxicity
Jean-Baptiste van Helmont	1577–1644	Brussels, Belgium	Known for his knowledge of contagious diseases
Francois Mauriceau	1637–1709	Paris, France	A obstetric pioneer renowned for his contribution to surgical medicine
Giovanni Maria Lancisi	1654–1720	Rome, Italy	Renowned epidemiologist, who, in responding to an influenza epidemic, improved public hygiene by draining stagnant bodies of water and purifying the air in disease-ridden areas
Orazio Monti	1724–1787	Vienna, Austria	Conducted the first substantial investigations of military hygiene in his book, *Trattato della Consuetudine, con il Modo do Governare gli Eserciti ed i Naviganti*
Antonio Porzio	1637–1715	Vienna, Austria	Made advances in epidemic avoidance in armies, with his book *De Militum in Castris Sanitate Tuenda* in 1865
Bernardino Ramazzini	1633–1714	Capri, Italy	Father of industrial hygiene
Immanuel Kant	1724–1804	Königsberg, Prussia	Philosopher
Events*,§§			
Name		**Definition**	
Black Death		A plague that decimated two thirds of Europe's population	
De Morbis Artificum		First treatise on occupational disease written by Bernardino Ramazzini	
College of Physicians		Physicians association; by the end of the seventeenth century, reported all patients treated for certain diseases	

* *"A History of Medicine" By Arturo Castiglioni, Alfred A. Knopf, Inc., 1947.*
** *"The Greatest Benefit to Mankind: A Medical History of Humanity" By Roy Porter, New York: NY: HarperCollins Publishers Ltd., 1997.*
§ *"Memorie storico-culturali delle Accademie orcianesi" By Franco Marini, Fondazione Cassa di Risparmio, www.fondazionecarifano.it/EventsDocs/2007/AccademieOrcianesi.htm (Accessed 3/15/10).*
§§ *"The Black Death and the Transformation of the West" By David Herlihy, Harvard University Press, 1997.*

114 Ibid., p. 580-582.

NINETEENTH CENTURY: THE PRACTICE OF MEDICINE

STUDY OF THE MEDICAL SCIENCES

> *The knowledge a man can use is the only knowledge which has life and growth in it and converts itself into practical power. The rest hangs like dust about the brain or dries like raindrops off the stones.*
>
> **(Froude) Sir William Osler, 1899**

The nineteenth century saw an increase in the number of medical schools and efforts to teach the history of scientific advancement in a focused, discipline-centric manner, which heralded the concept of the practice of medicine. The famed text, *Practice*, published in 1843 by Sir Thomas Watson, remained the prominent treatise on general medicine for more than forty years.[115] However, with Watson's work becoming perceived as outdated, in 1891, Sir William Osler wrote his magnum opus—*The Principles and Practice of Medicine: Designed for the Use of Practitioners and Students of Medicine*—while working at Johns Hopkins School of Medicine.[116] Osler's text, first published in 1892, established him as a leading authority on medicine and sold hundreds of thousands of copies; multiple editions were published throughout his life and posthumously.[117]

In the early 19th century, medical licensure was little more than an honorary title and some states chose not to enact medical licensure requirements, despite the opening of several medical schools across the country.[118] Shortly after the American Revolution, the equivalency of a medical license was obtained through membership in a state medical society.[119] Membership in a medical society became a kind of required practice if a physician were to become financially successful. As medical societies became more reputable, and membership within the societies grew, physicians who were not members of a medical society were seen to be "unacceptable by his fellow-workers."[120] Near the end of the 19th century, states began to establish licensing laws and boards of medical examiners, and this popular movement continued for two decades until every state had a medical licensing law.[121]

115 "The Life of Sir William Osler" By Harvey Cushing, Third Impression, Vol. 1, Oxford: The Clarendon Press, 1925, p. 339.
116 Ibid., p. 336, 339.
117 "A History of William Osler's The Principles and Practice of Medicine" By Richard L. Golden, Journal of American Medical Association, Vol. 293, No. 15 (April 20, 2005), p. 1926.
118 "The Social Transformation of American Medicine: The Rise of a Sovereign Profession and the Making of a Vast Industry" By Paul Starr, New York, NY: Basic Books, Inc., 1982, p. 30.
119 "Two Centuries of American Medicine: 1776-1976" By James Bordley III and A. McGehee Harvey, Philadelphia, PA: W.B. Saunders Company, 1976, p. 69.
120 "The Doctor's Duty to the State: Essays on the Public Relations of Physicians" By John B. Roberts, Chicago, IL: American Medical Association Press, 1908, p. 63.
121 "Two Centuries of American Medicine: 1776-1976" By James Bordley III and A. McGehee Harvey, Philadelphia, PA: W.B. Saunders Company, 1976, p. 71.

IMPACT OF THE INDUSTRIAL REVOLUTION ON THE PRACTICE OF MEDICINE

Following a lull attributed to the French and American revolutions and unrest in central Europe, medical progress began gaining momentum.[122] Urban and industrial growth spurred demand for sanitary conditions,[123] and "[t]ogether with the great increase in material and cultural growth, a deeper sense of human dignity was penetrating even to the lowest classes."[124] However, in many countries, a "realistic tendency and the pursuit of materialistic aims" shattered this idealism.[125] Finally, medicine was regarded as a necessary scientific field. Efforts to overcome "transcendental tendencies and to further the progress of the natural sciences" resulted in experimental investigation and observation of all forms of life.[126] Scientists sought to understand complex biological issues that philosophical hypotheses previously disregarded.[127] As a result, various schools of thought emerged and advances in science fostered medical specialization.[128]

DIVERSIFIED SCHOOLS OF MEDICINE

Allopathic Medicine

Since its inception as a mythical abstraction, medicine has transformed into a rational science. Through expansion of logical thought, the study of social value systems,[129] medical knowledge, and technological capabilities, allopathic (traditional) Western physicians adopted "…a method of healing founded on a scientific basis."[130] At the time of its establishment in 1847, the American Medical Association (AMA) was largely comprised of allopathic physicians.[131] The AMA recognized the potency of Western medicine and understood that danger may result from inadequately regulated growth and expansion of biologically based methodologies.[132]

> *As the frontiers of scientific medicine extended, quackery found even broader fields of operation. Scientific explorations into the mysteries of vitamins, hormones, and antibiotics not only provided better medical care for the public, but also opened up new sources of gain for the unscrupulous. While scientific research kindled the imagination of crafty promoters who sought easy ways to riches, its failure to discover cures for various major ailments made the boastful claims of pretending healers all the more impressive.*[133]

122 "A History of Medicine" By Arturo Castiglioni, Second Edition, New York, NY: Alfred A. Knopf, Inc., 1947, p. 667.
123 "A History of Medicine" By Arturo Castiglioni, Second Edition, New York, NY: Alfred A. Knopf, Inc., 1947, p. 668; "The Greatest Benefit to Mankind: A Medical History of Humanity" By Roy Porter, New York: NY: HarperCollins Publishers Ltd., 1997, p. 405.
124 "A History of Medicine" By Arturo Castiglioni, Second Edition, New York, NY: Alfred A. Knopf, Inc., 1947, p. 668.
125 Ibid.
126 Ibid.
127 "A History of Medicine" By Arturo Castiglioni, Second Edition, New York, NY: Alfred A. Knopf, Inc., 1947, p. 668.
128 "A History of Medicine" By Arturo Castiglioni, Second Edition, New York, NY: Alfred A. Knopf, Inc., 1947, p. 668; "The Greatest Benefit to Mankind: A Medical History of Humanity" By Roy Porter, New York: NY: HarperCollins Publishers Ltd., 1997, p. 386-389.
129 "Theory of Valuation" By John Dewey, The University of Chicago Press, Vol. II, No. 4 (1966), p. 1.
130 "The AMA and U.S. Health Policy Since 1940" By Frank D. Campion, Chicago, IL: Chicago Review Press, 1984, p. 468.
131 "Our History, Illustrated Highlights" American Medical Association, 2009, http://www.ama-assn.org/ama/pub/about-ama/our-history/illustrated-highlights.shtml (Accessed 9/10/09); "The AMA and U.S. Health Policy Since 1940" By Frank D. Campion, Chicago, IL: Chicago Review Press, 1984, p. 468.
132 "The AMA and U.S. Health Policy Since 1940" By Frank D. Campion, Chicago, IL: Chicago Review Press, 1984, p. 467-468.
133 "AMA: Voice of American Medicine" By James G. Burrow, Baltimore, MD: The Johns Hopkins Press, 1963, p. 252-253.

As such, the AMA served to scientifically and ethically appraise innovative medical developments, as well as educational standards, and hoped to regain public support and trust.[134]

Alternative Medicine

Allopathic practitioners were skeptical of *cultist* or *sectarian* physicians who practiced unconventional forms of medicine, such as homeopathic, eclectic, naturopathic, chiropractic, and osteopathic medicine.[135] Allopathic sentiments toward alternative medical practices were distrustful and condemning, to say the least. Oliver Wendell Holmes, a prominent physician, attributed with coining the term *anesthesia*, went as far as to call homeopathic practitioners, "a mingled mass of perverse ingenuity, of tinsel erudition, of imbecile credulity, and of artful misrepresentation."[136] Though not as prominent as allopathic medicine, practitioners of alternative medicine exist today. To reduce public aversion and distrust, the alternative medicine field has developed education and training requirements, as well as regulation and licensing measures to legitimize its practices.[137]

One of the two most widely accepted schools of medicine in the United States, apart from allopathic medicine, is osteopathic medicine.[138] Andrew Taylor Still founded osteopathic medicine, treating patients by assessing not only their symptoms but also their overall health and environment.[139] He opened the American School of Osteopathy in 1892 in Kirksville, Missouri.[140] By the 1960s, there were six schools for osteopathy, and, as of 1985, Doctors of Osteopathic Medicine were certified in all specialties.[141] Because osteopathic medicine contributes a great deal to the modern practice of medicine, Chapter 7 of *Consulting Services* addresses in detail the similarities and differences between Doctors of Medicine and Doctors of Osteopathic Medicine.

Homeopathic therapies utilize medicine that would typically induce disease symptoms in healthy individuals to treat individuals with that disease; homeopathy still exists as a school of medicine.[142] Eclectics use herbal medicines and remedies to treat pathologic conditions.[143] Among less threatening therapies, eclectics are known primarily for their use of arsenic and mercury treatments.[144] Naturopathic physicians utilize natural elements like water, heat, and massage in their therapies.[145]

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134 "Two Centuries of American Medicine: 1776-1976" By James Bordley III and A. McGehee Harvey, Philadelphia, PA: W.B. Saunders Company, 1976, p. 45; "The AMA and U.S. Health Policy Since 1940" By Frank D. Campion, Chicago, IL: Chicago Review Press, 1984, p. 467-468.
135 "American Medicine and the Public Interest" By Rosemary Stevens, New Haven, CT: Yale University Press, 1971, p. 43-44; "The AMA and U.S. Health Policy Since 1940" By Frank D. Campion, Chicago, IL: Chicago Review Press, 1984, p. 468.
136 "Medical Essays: 1842-1882" By Oliver Wendell Holmes, New York, NY: Houghton Mifflin Company, 1911, p. 101.
137 "The AMA and U.S. Health Policy Since 1940" By Frank D. Campion, Chicago, IL: Chicago Review Press, 1984, p. 468-469.
138 "An Osteopathic Approach to Diagnosis and Treatment" By Eileen L. DiGiovanna and Stanley Schiowitz, Second Edition, New York, NY: Lippincott–Raven, 1997, p. 1.
139 Ibid., p. 1-3.
140 Ibid., p. 3.
141 Ibid., p. 1-3.
142 "The AMA and U.S. Health Policy Since 1940" By Frank D. Campion, Chicago, IL: Chicago Review Press, 1984, p. 468; "The Greatest Benefit to Mankind: A Medical History of Humanity" By Roy Porter, New York: NY: HarperCollins Publishers Ltd., 1997, p. 390-391.
143 "The AMA and U.S. Health Policy Since 1940" By Frank D. Campion, Chicago, IL: Chicago Review Press, 1984, p. 468.
144 Ibid.
145 Ibid., p. 469.

The practice of chiropractic medicine has transformed from a form of alternative medicine into an allied health profession. The origins of chiropractic medicine involved beliefs that vertebral alignment would serve to remedy diseases; progress in science and medicine cultivated skepticism toward practitioners of this philosophy.[146] Over time, a reduced focus on these abstract chiropractic practices reduced skepticism from medical practitioners; although some chiropractors still employ questionable methods, modern chiropractic practice is mainstream and widely accepted.[147]

> As of April 1985, Doctors of Osteopathy (D.O.) were certified in all specialties.
>
> ***Eileen L. DiGiovanna and Stanley Schiowitz, 1997***

DIVERSIFIED ROLES OF MEDICINE

The practice of medicine in the nineteenth century expanded from strictly clinical practice to include legal medicine, public health, and medical research. Legal medicine involves the implementation of medical expertise for legal and judicial purposes.[148] In the later portion of the century, the scientific and medical communities began to grapple with the social and economic implications of healthcare.[149] As such, medicine transformed itself from an elite and sophisticated trade, and "assume[d] its role as a social science."[150] The national prevalence of infectious disease resulted in an emphasis on community and hygienic medicine.[151]

Public health is an area of science and medicine characterized by a "community health point of view," and was developed as a relationship between human beings and their social environment rather than a relationship between human beings and their doctors.[152] All public health research, policies, and programs stemmed from the same objective: to provide "defen[s]e against disease as a social problem" by way of preventative medicine.[153] Unfortunately, progress in prevention is difficult to quantify, and its value within the healthcare industry is not concrete.[154] As a result, preventative care is dismissed as inferior, and public health has faced significant resistance and alienation from the medical community.[155]

Lastly, growth in holistic medical research paired with paralleled growth in scientific knowledge facilitated the publication of substantial medical literature in serial journals, with the *American Journal of Medical Sciences* entering print in 1838 and the *New England Journal of Medicine*

146 Ibid.
147 "Principles and Practice of Chiropractic" By Scott Haldeman, Third Edition, McGraw-Hill, 2004, p. 112.
148 "A History of Medicine" By Arturo Castiglioni, Second Edition, New York, NY: Alfred A. Knopf, Inc., 1947, p. 742-743.
149 Ibid., p. 762-765.
150 "A History of Medicine" By Arturo Castiglioni, Second Edition, New York, NY: Alfred A. Knopf, Inc., 1947, p. 764.
151 "Two Centuries of American Medicine: 1776-1976" By James Bordley III and A. McGehee Harvey, Philadelphia, PA: W.B. Saunders Company, 1976, p. 47.
152 "A History of Medicine" By Arturo Castiglioni, Second Edition, New York, NY: Alfred A. Knopf, Inc., 1947, p. 901; "The Western Medical Tradition: 800 BC to AD 1800" By Lawrence I. Conrad, et al., New York, NY, Cambridge University Press, 1995, p. 485.
153 "A History of Medicine" By Arturo Castiglioni, Second Edition, New York, NY: Alfred A. Knopf, Inc., 1947, p. 902.
154 "The Greatest Benefit to Mankind: A Medical History of Humanity" By Roy Porter, New York: NY: HarperCollins Publishers Ltd., 1997, p. 405.
155 Ibid.

and Surgery entering print in 1812.[156] This constant flow of new research findings and an increasing knowledge base resulted in the perpetual tendency toward specialization that continues to drive current trends in medicine.

SPECIALIZATION OF THE SCIENCES

The nineteenth century saw the first significant period in technical progress that proved extremely important to the advance of both science and medicine.[157] Through continued advances in chemistry and physics, the disciplines of physiological and pathological chemistry emerged. A more intensive knowledge base was established for biology, chemistry, anatomy, and physiology, which gave rise to fields like biochemistry, cytology, genetics, endocrinology, anthropology, immunology, and microbiology.[158]

Through his investigations of fermentation and pathogenic bacteria, Louis Pasteur pioneered a branch of microbiology now known as bacteriology.[159] Pasteur's work influenced both clinical and laboratory medicine through his discovery of pasteurization, a process widely used today in the preservation of perishable products.[160] Pasteurization involves the strategic application of heat to kill microbes without injuring the quality of its media (for example, wine, beer, etc.).[161] Through the discovery of pasteurization, the development of antirabic treatment, and his observations of anthrax, chicken cholera, staphylococci, and streptococci, Pasteur became recognized as "one of the greatest and noblest pioneers of civilization."[162] Pasteur improved healthcare and enhanced its economic benefits through his contributions to the fields of clinical, hygienic, and social medicine.[163]

SPECIALIZATION OF MEDICINE

Specialized forms of internal medicine emerged contemporaneously with developments in pathology and microbiology.[164] The nineteenth century marked the discovery of anesthesia and asepsis, which resulted in unmatched advances in the study of surgery.[165] Surgical specialization

156 "Two Centuries of American Medicine: 1776-1976" By James Bordley III and A. McGehee Harvey, Philadelphia, PA: W.B. Saunders Company, 1976, p. 71-72.
157 "A History of Medicine" By Arturo Castiglioni, Second Edition, New York, NY: Alfred A. Knopf, Inc., 1947, p. 668; "The Greatest Benefit to Mankind: A Medical History of Humanity" By Roy Porter, New York: NY: HarperCollins Publishers Ltd., 1997, p. 305.
158 "A History of Medicine" By Arturo Castiglioni, Second Edition, New York, NY: Alfred A. Knopf, Inc., 1947, p. 668-672, 765; "The Greatest Benefit to Mankind: A Medical History of Humanity" By Roy Porter, New York: NY: HarperCollins Publishers Ltd., 1997, p. 305.
159 "A History of Medicine" By Arturo Castiglioni, Second Edition, New York, NY: Alfred A. Knopf, Inc., 1947, p. 809; "The Greatest Benefit to Mankind: A Medical History of Humanity" By Roy Porter, New York: NY: HarperCollins Publishers Ltd., 1997, p. 428-431.
160 "A History of Medicine" By Arturo Castiglioni, Second Edition, New York, NY: Alfred A. Knopf, Inc., 1947, p. 810-811.
161 Ibid., p. 811.
162 "A History of Medicine" By Arturo Castiglioni, Second Edition, New York, NY: Alfred A. Knopf, Inc., 1947, p. 813; "The Greatest Benefit to Mankind: A Medical History of Humanity" By Roy Porter, New York: NY: HarperCollins Publishers Ltd., 1997, p. 431-435.
163 "A History of Medicine" By Arturo Castiglioni, Second Edition, New York, NY: Alfred A. Knopf, Inc., 1947, p. 811-812.
164 Ibid., p. 829.
165 "Two Centuries of American Medicine: 1776-1976" By James Bordley III and A. McGehee Harvey, Philadelphia, PA: W.B. Saunders Company, 1976, p. 300-302; "A History of Medicine" By Arturo Castiglioni, Second Edition, New York, NY: Alfred A. Knopf, Inc., 1947, p. 844-845; "The Greatest Benefit to Mankind: A Medical History of Humanity" By Roy Porter, New York: NY: HarperCollins Publishers Ltd., 1997, p. 360, 374.

fostered the inception of plastic surgery, neurosurgery, pathological (namely, cancer-related) surgery, surgical procedures in gynecology and obstetrics, and countless other areas.[166]

The technological advancements in medicine and precise instrumentation in the early 1900s vastly improved the delivery of healthcare and, as a result of this leap forward in technology, physicians increasingly began to specialize in specific areas of medicine.[167] Although the concept of specialization was met with initial hesitation by some medical professionals, pressures of scientific, social, and economic factors eventually led to the widespread acceptance of the compartmentalization of medicine.[168] In 1866, the American Medical Association (AMA) analyzed the benefits and risks of physician specialization.[169] These benefits and risks are set forth below, in Table 1-6: *Benefits and Risks of Specialization According to the AMA*.

Table 1-6: Benefits and Risks of Specialization According to the AMA[170]

Benefits	Risks
Minuteness of observation Acuteness in study Wideness in observation Skill in diagnosis Multiplicity of invention Superior skill in manipulation	Narrowness of view Tendencies of specialists to magnify the effects of their covered disease Tendencies of specialists to undervalue the treatment of the disease by general practitioners Temptation of specialists to utilize unwarranted measures to gain a popular reputation Tendencies of specialists to increase fees

Although physicians began to make claims as to the extent of their skill in a specific area of medicine, there was no formal system in place to validate their claims.[171] In 1908, Derrick T. Vail, Sr. introduced the concept of a medical specialty board, which would establish minimum qualifications for specialist physicians.[172] The establishment of such a system was a slow process, and through the 1930s individual examining boards were still working with specific specialties to advance the specialty board concept. These boards included: the American Board of Ophthalmology; the American Board of Otolaryngology; the American Board of Obstetrics and Gynecology; and the American Board of Dermatology and Syphiology. [173]

The specialty board system of the 1920s and 1930s greatly contributed to the improvement of medical education and physician competence. Specialty boards began to require physicians to obtain additional education through programs approved either by AMA or accredited through the boards and residency review committees.[174] Further still, boards began to require physicians to obtain a certain amount of professional experience and to pass examinations that were established and independently administered by the various specialty boards. Soon, national board

166 "A History of Medicine" By Arturo Castiglioni, Second Edition, New York, NY: Alfred A. Knopf, Inc., 1947, p. 829, 843-845, 847, 852, 853, 861-881.
167 "The Specialty Board Movement" American Board of Medical Specialties, 2012, http://www.abms.org/About_ABMS/ABMS_History/Extended_History/Specialty_Board_Movement.aspx (Accessed 8/6/12).
168 "Medicine: An Illustrated History" By Albert S. Lyons and R. Joseph Petrucelli, New York, NY: Harry N. Abrams, Inc., 1978, p. 538.
169 "American Surgery: An Illustrated History" By Ira M. Rutkow, Philadelphia, PA: Lippicott-Raven Publishers, 1998, p. 173.
170 Ibid.
171 "The Specialty Board Movement" American Board of Medical Specialties, 2012, http://www.abms.org/About_ABMS/ABMS_History/Extended_History/Specialty_Board_Movement.aspx (Accessed 8/06/12).
172 Ibid.
173 Ibid.
174 Ibid.

organizations were able to restrain uneducated physicians from designating themselves as specialists.

Expanding upon the specialty board system, a federation of individual specialty boards, the Advisory Board of Medical Specialties, was established in 1933.[175] In 1970, the Advisory Board of Medical Specialties reorganized into the American Board of Medical Specialties (ABMS). The strong central agency was able to deal with matters common to all specialty boards and act as the public representative of all specialty boards.[176]

Specialty Diagnostics

Physicians in the nineteenth century were among the first to engage in the identification, classification, and reporting of various pathologies and diseases.[177] In order to conduct the necessary laboratory procedures, physicians had to possess a substantial amount of knowledge in a condensed area of medicine.[178] As a result, the range of available specialties grew, became more focused, and ultimately led to more specialized medical research.[179] At the turn of the twentieth century, diagnostic medicine endured a transformation with Wilhelm Conrad Roentgen's discovery of x-rays in 1895, which promulgated the rapid advancement of quantum physics and Antoine Béclère's implementation of the first x-ray machine in 1906.[180] Soon after, these nuances in radiation diagnostics would leak into therapeutics with discoveries in radiation therapy.[181]

Specialty Therapeutics: Pharmacology and Physiology

The practice of medicine has not always been about understanding a problem to arrive at its solution. For much of history, diagnostic medicine was an enigma—frequently neglected, unequivocally lacking, and often hypothetical.[182] The treatment of diseases, however, has always been at the apex of the medical practice.[183] Physician inquiry in specialized areas of medicine allowed for the expansion of diagnostic capabilities in the nineteenth century.[184] Additionally, the nineteenth century brought with it the unparalleled evolution of therapeutic technology.[185] It was not until the 1800s that pharmacology gained scientific credibility through animal and clinical trial investigations.[186] Ancient forms of physiotherapy slowly transformed over time,

175 "Becoming ABMS" American Board of Medical Specialties, http://www.abms.org/About_ABMS/ABMS_History/Extended_History/Becoming_ABMS.aspx (Accessed 8/06/12).
176 Ibid.
177 "A History of Medicine" By Arturo Castiglioni, Second Edition, New York, NY: Alfred A. Knopf, Inc., 1947, p. 698-699; "The Greatest Benefit to Mankind: A Medical History of Humanity" By Roy Porter, New York: NY: HarperCollins Publishers Ltd., 1997, p. 304-316.
178 "A History of Medicine" By Arturo Castiglioni, Second Edition, New York, NY: Alfred A. Knopf, Inc., 1947, p. 701-711; "The Greatest Benefit to Mankind: A Medical History of Humanity" By Roy Porter, New York: NY: HarperCollins Publishers Ltd., 1997, p. 304-316.
179 "A History of Medicine" By Arturo Castiglioni, Second Edition, New York, NY: Alfred A. Knopf, Inc., 1947, p. 701-711.
180 "Early History of X Rays" By Alexi Assmus, Beamline Publication, Summer 1995, p. 10-11, 24.
181 Ibid., p. 10-24.
182 "A History of Medicine" By Arturo Castiglioni, Second Edition, New York, NY: Alfred A. Knopf, Inc., 1947, p. 891.
183 Ibid.
184 "A History of Medicine" By Arturo Castiglioni, Second Edition, New York, NY: Alfred A. Knopf, Inc., 1947, p. 701-711, 891; "The Greatest Benefit to Mankind: A Medical History of Humanity" By Roy Porter, New York: NY: HarperCollins Publishers Ltd., 1997, p. 304-316.
185 "A History of Medicine" By Arturo Castiglioni, Second Edition, New York, NY: Alfred A. Knopf, Inc., 1947, p. 891-899.
186 "A History of Medicine" By Arturo Castiglioni, Second Edition, New York, NY: Alfred A. Knopf, Inc., 1947, p. 891-892; "The Greatest Benefit to Mankind: A Medical History of Humanity" By Roy Porter, New York: NY: HarperCollins Publishers Ltd., 1997, p. 333-334.

only to emerge in various specialized forms including hydrotherapy, massage, mechanotherapy, electrotherapy, and heat therapy.[187]

Rise of the Hospital

As physicians developed competence in a continually growing area of specialties, there was an expectation that their expertise would also apply to the level of care that they administered.[188] This increasing demand for innovative technologies allowed for the provision of services that would require advanced diagnoses. In response to this increased demand, resulting from the desire for advanced technologies, as well as demographic and disease trends, existing technologies evolved to improve the quality and efficiency of services delivered.[189]

Through the 18th and 19th centuries, and in an effort to meet this increased demand, hospitals began opening across the U.S. (the first, The Pennsylvania Hospital, having been established in 1751 by Benjamin Franklin and Dr. Thomas Bond[190]), especially in large, urban areas. These hospitals were plagued by high rates of infection, and in 1859, Florence Nightingale, published *Notes on Hospitals,* in which she described the optimal design for hospitals to prevent infection.[191] Developments in organization and medical knowledge following the Civil War led to increases in hospital hygiene and tidiness.[192]

As hospital functions and procedures changed in response to technological advances and an increased focus on acute care, construction and operating costs also increased, gradually exceeding the capacity of the charities that initially funded these hospitals. [193] These increased costs were eventually passed to patients, and insurance plans became new revenue streams for hospitals, as physician-directed revenues, rather than donations, became the hospital's main source of income. The influence and managerial powers of physicians increased as reliance on charitable donations became less necessary. [194] Table 1-7 summarizes the key people, places, and events of the nineteenth century in medical history.

187 "A History of Medicine" By Arturo Castiglioni, Second Edition, New York, NY: Alfred A. Knopf, Inc., 1947, p. 895-899.
188 Ibid., p. 701-11.
189 "Biomarket Trends: Pharmaceutical Industry Undergoing Transformation" By Steve Arlington and Anthony Farino, Genetic Engineering and Biotechnology News, Vol. 27, No. 15 (September 1, 2007); "Cancer Molecular Diagnostics Take the Stage: CMDS Are at the Forefront of Evolving Healthcare Practices" Genetic Engineering and Biotechnology News, Vol. 29, No. 7 (April 1, 2009), http://www.genengnews.com/articles/chitem_print.aspx?aid=2852&chid=0 (Accessed 7/6/09).
190 "The Cambridge Illustrated History of Medicine" Edited By Roy Porter, Cambridge, England: Cambridge University Press, 1996, p. 214; "In the Beginning: The Story of the Creation of the Nation's First Hospital" University of Pennsylvania, http://www.uphs.upenn.edu/paharc/features/creation.html (Accessed 8/21/12).
191 "Two Centuries of American Medicine: 1776-1976" By James Bordley III and A. McGehee Harvey, Philadelphia, PA: W.B. Saunders Company, 1976, p. 62.
192 "The Social Transformation of American Medicine: The Rise of a Sovereign Profession and the Making of a Vast Industry" By Paul Starr, New York, NY, Basic Books, Inc., 1982, p. 154.
193 Ibid., p. 160.
194 Ibid., p. 160-162.

Table 1-7: Influential Figures, Key Places, and Important Events During the Nineteenth Century

Influential Figures*,**,†,††,‡,‡‡			
Name	**Birth/Death**	**Location**	**Claim to Fame**
Sir Thomas Watson	1792–1882	Devonshire, England	Authored *Practice*, a premier medical text published in 1843
Sir William Osler	1849–1919	Montreal, Canada	Authored *The Principles and Practice of Medicine*, a premier medical text published in 1892
American Medical Association	1847–Present	U.S.	A group of predominantly allopathic physicians that lobbies for physicians rights and supremacy
Oliver Wendell Holmes	1809–1894	U.S.	Prominent physician who coined the term *anesthesia*
Andrew Taylor Still	1828–1917	U.S.	Founder of osteopathic medicine, the practice of treating patients based on symptoms and overall health
Louis Pasteur	1822–1896	Paris, France	Pioneered bacteriology, a subfield of microbiology; also discovered pasteurization
Wilhelm Conrad Roentgen	1845–1923	Germany	Discovered x-rays in 1895
Antoine Béclère	1856–1939	Paris, France	Implemented the first x-ray treatment of glandular tuberculosis
Places‡‡			
Place	**Location**	**Role in Medical History**	
American School of Osteopathy	Kirksville, MO, U.S.	First osteopathic school, founded by Andrew Taylor Still in 1892	
Events*,,‡,§,§§**			
Name	**Definition**		
Anesthesia	A numbing agent		
American Journal of Medical Science	Began printing in 1838 to help the spread of medical information		
New England Journal of Medicine and Surgery	Began printing in 1812 and to facilitate the growth of medical knowledge		
Fermentation	The enzymatic decomposition of an organic substance in the absence of oxygen		
Pathogenic Bacteria	Bacteria that causes disease		
Pasteurization	A process which involves the strategic application of heat to kill microbes		
Antirabic Treatment	A treatment for rabies developed at the Pasteur Institute		
Anthrax	A fatal bacterial infection of warm-blooded animals		
Chicken Cholera	Pasteur's work with the disease led him to discover vaccinations		
Staphylococci	A set of spherical bacteria		
Streptococci	Used to make Streptomycin, an antibiotic		
Asepsis	The state of being free from disease-causing germs		
X-ray	Discovered in 1895, promulgated the rapid advancement of quantum physics		

* *"A History of Medicine" By Arturo Castiglioni, Alfred A. Knopf, Inc., 1947.*

** *"The Greatest Benefit to Mankind: A Medical History of Humanity" By Roy Porter,* New York: NY: HarperCollins Publishers Ltd., 1997.

† *"The Life of Sir William Osler" By Harvey Cushing, Oxford, 1925.*

†† *"Our History, Illustrated Highlights" American Medical Association, 2009, www.ama-assn.org/ama/pub/about-ama/our-history/illustrated-highlights.shtml, (Accessed 9/10/09).*

‡ *"Dr. Holmes at 200—The Spirit of Skepticism" By Charles S. Bryan, MD, and Scott H. Podolsky, MD, New England Journal of Medicine, Vol. 361, No. 9 (August 27, 2009), p. 846.*

‡‡ *"An Osteopathic Approach to Diagnosis and Treatment" By Eileen L. DiGiovanna and Stanley Schiowitz, 1997.*

§ *"Early History of X Rays" By Alexi Assmus, Beamline Publication, Stanford University, Summer 1995.*

§§ *"Two Centuries of American Medicine" By James Bordley III, MD and A. McGehee Harvey, MD, W.B. Saunders Company, 1976.*

As hospitals' reliance on physicians for revenue increased, healthcare professional practitioners became viewed not only as *healers* but also as *businessmen*. Within that context, demand for more sophisticated management technologies to enhance practice efficiency and reliability increased significantly.[195] As the demand for increasingly expensive medical technology grew, the old adage, "No Buck, No Buck Rogers," was often cited to define the cyclical relationship between technological demand and business capital investment.

TWENTIETH AND TWENTY-FIRST CENTURIES: THE TRANSFORMATION OF MODERN HEALTHCARE

> *The twentieth century will be remembered chiefly, not as an age of political conflicts and technical inventions, but as an age in which human society dared to think of the health of the whole human race as a practical objective.*
>
> **Arnold Toynbee, 1931**

By the twentieth and twenty-first centuries, healthcare professionals had earned credibility, and continuing developments in modern medicine only fortified the perpetual growth of their medical authority.[196] Starr noted:

> *The rise of the professionals was the outcome of a struggle for cultural authority as well as for social mobility. It needs to be understood not only in terms of the knowledge and ambitions of the medical profession, but also in the context of broader changes in the culture and society that explains why Americans became willing to acknowledge and institutionalize their dependence on the professions. The acceptance of professional authority was, in a sense America's cultural revolution.*[197]

THE INTRODUCTION OF HEALTH INSURANCE

It is possible to trace aspects of the current U.S. health insurance system to practices arising from large post-Industrial Revolution era mining and railroad companies, which provided medical treatment for employment-related injuries. Accident or casualty insurance, which would replace income in the case of an illness or accident, was available for individuals in that era,[198] but coverage of non-casualty related medical services was not offered. In 1847, the first insurance company began offering casualty insurance for rail and steamboat accidents and by the close of the 19th century, 47 insurance companies offering accident insurance existed in the U.S.[199]

195 "Studies Show Electronic Medical Records Make Financial Sense" By Stacy Lawrence, Posted on CIO Insight, September 14, 2005, http://www.cioinsight.com/c/a/Health-Care/Studies-Show-Electronic-Medical-Records-Make-Financial-Sense/ (Accessed 8/17/12).
196 "The Social Transformation of American Medicine: The Rise of a Sovereign Profession and the Making of a Vast Industry" By Paul Starr, New York, NY: Basic Books, Inc., 1982, p. 17.
197 Ibid.
198 "The U.S. Health System: Origins and Functions" By Marshall W. Raffel, New York, NY: John Wiley & Sons, 1980, p. 394.
199 Ibid.

The delineation between medical care for work-related injuries and worked-acquired diseases (*industrial medicine*, as it came to be known) began to fade as company-employed physicians eventually became more involved in general employee health, with companies beginning to compete for employees through the perceived value of their intra-company medical services.[200] At its core, the multi-goal purpose of these programs was to create goodwill toward the company from their employees and the public by establishing an employee-employer connection and, perhaps most importantly, to reduce tort liability from work-related injuries and accidents. [201]

Ultimately, upon employers realizing the potential benefits associated with providing employee health services, the movement evolved toward programs more closely resembling contemporary *health insurance*. Despite positive reception, the early industrial health programs were one of the first casualties of the massive unemployment of the Great Depression as major industries perceived in-house medical services as an unnecessary expenditure.[202] However, during the Great Depression one of today's largest and most highly publicized insurance conglomerates, Blue Cross Blue Shield, began operation.

The Blue Cross Blue Shield Association (BCBSA) started as two separate entities, with Blue Cross covering hospital services and Blue Shield providing coverage for physician services.[203] The first nonprofit, prepaid hospital plan, which would eventually become the Blue Cross Organization, was first created in 1929 and developed by Justin Ford Kimball, a vice-president of the University Hospital at Baylor University, for Dallas area teachers.[204] The plan initially covered 1,500 teachers who paid $6 per year for 21 days of hospital care at the University Hospital.[205] At that time, the Great Depression resulted in a growing number of patients who could not afford to pay their bills, and prepaid plans similar to the Baylor Plan quickly began to develop at hospitals across the country.[206] These plans, known as Blue Cross, gained formal recognition in 1934 when the American Hospital Association (AHA) and the American College of Surgeons (ACS) expressed their approval of hospital group plans.[207]

Blue Shield developed in response to the public's desire to have prepaid coverage for physician services comparable to what Blue Cross offered for hospital services. Beginning in 1933, Dr. Sidney Garfield offered prepaid physician services to 5,000 aqueduct workers in California, each of whom paid a nickel per day.[208] Admiring this success, Henry J. Kaiser adopted Dr. Garfield's approach in the late 1930s to provide his employees with physician services. The Kaiser Foundation Health Plan prospered and thrives today as the Kaiser-Permanente plan.[209] Since

200 "The Social Transformation of American Medicine: The Rise of a Sovereign Profession and the Making of a Vast Industry" By Paul Starr, New York, NY: Basic Books, Inc., p. 200-209.
201 Ibid., p. 200-201.
202 Ibid., p. 203-204.
203 "The Blues: A History of the Blue Cross and Blue Shield System" By Robert Cunningham III and Robert M. Cunningham Jr., DeKalb, IL: Northern Illinois University Press, 1997, p. viii.
204 Ibid., p. 4.
205 "The Social Transformation of American Medicine: The Rise of a Sovereign Profession and the Making of a Vast Industry" By Paul Starr, New York, NY: Basic Books, Inc., 1982, p. 295.
206 Ibid., p. 295-296.
207 "The Blues: A History of the Blue Cross and Blue Shield System" By Robert Cunningham III and Robert M. Cunningham Jr., DeKalb, IL: Northern Illinois University Press, 1997, p. 19.
208 Ibid., p. 39.
209 Ibid.

their formation, Blue Cross and Blue Shield have remained strong forces in the insurance market as the Blue Cross Blue Shield Association (the two companies combined on October 17, 1977).[210] The expansion of the insurance and other healthcare markets increased the need for regulation related to competition.

THE INCEPTION OF MEDICARE AND MEDICAID SERVICES

The economic devastation that plagued a weary middle- and working-class at the dawn of the Great Depression gave rise to the concept of *health security* in the newly urbanized and industrialized United States.[211] Despite resistance from conservative stakeholders, that is, the AMA, the Progressive movement emerged in hopes of relinquishing "inequities and poverty in America."[212] President Franklin D. Roosevelt (FDR) attempted to implement a national health insurance program, first in 1935 through the Social Security Bill, a part of The New Deal, and again through the National Health Act of 1939.[213]

The Passage of the Social Security Act

President Roosevelt's action to establish social security in the U.S. began June 8, 1934, and led to the passage of the Social Security Act (SSA) on August 14, 1935, absent a national healthcare program,[214] but providing many of the recommendations of the Committee on Economic Security, and those benefits Roosevelt enumerated in his address to Congress in January, 1935.[215] The SSA has been amended numerous times, with the establishment of Medicare and Medicaid (a part of President Lyndon B. Johnson's *Great Society* initiatives during the 1960s) being the most significant change concerning healthcare.

The National Health Act of 1939, President Roosevelt's second attempt at the establishment of a national health insurance program, met with similar disappointment. The National Health Act of 1939 purported to support a national health program funded by federal grants to states and administered by the states themselves.[216] However, after the conservative revival in the 1938 election, further innovations in public policy stalled.[217]

Accordingly, both of FDR's attempts were in vain, and his sudden, tragic death in 1945 left health reform in the hands of his successor, Harry S. Truman.[218]

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210 Ibid., p. 197.
211 "Harry S. Truman Versus the Medical Lobby: The Genesis of Medicine" By Monte M. Poen, Columbia, MO: University of Missouri Press, 1979, p. 2, 14-15.
212 Ibid., p. 2,-3.
213 "Harry S. Truman Versus the Medical Lobby: The Genesis of Medicine" By Monte M. Poen, Columbia, MO: University of Missouri Press, 1979, p. 2-3; "A Brief History: Universal Health Care Efforts in the U.S." By Karen S. Palmer, Physicians for a National Health Program, Spring 1999, http://www.pnhp.org/facts/a_brief_history_universal_health_care_efforts_in_the_us.php?page=all (Accessed 2/17/10).
214 "A Brief History: Universal Health Care Efforts in the US" By Karen S. Palmer, Physicians for a National Health Program, http://www.pnhp.org/print/facts/a-brief-history-universal-health-care-efforts-in-the-us (Accessed 2/19/15).
215 "FDR's Statements on Social Security" Social Security Administration, https://www.socialsecurity.gov/history/fdrstmts.html (Accessed 4/20/12).
216 "A Brief History: Universal Health Care Efforts in the US" By Karen S. Palmer, Physicians for a National Health Program, http://www.pnhp.org/print/facts/a-brief-history-universal-health-care-efforts-in-the-us (Accessed 2/19/15).
217 Ibid.
218 "Harry S. Truman Versus the Medical Lobby: The Genesis of Medicine" By Monte M. Poen, Columbia, MO: University of Missouri Press, 1979, p. 50-51.

Harry Truman's Efforts to Establish Universal, Comprehensive Coverage

Truman was a zealous proponent of "universal, comprehensive coverage," and actively sought enactment of a program for the entirety of his presidency.[219] However, he faced opposition from the AMA, perceived to be "the country's richest and most influential post-World War II lobby."[220] His stance on healthcare was viewed by the AMA and other conservative stakeholders as "socialistic" and "un-American."[221] Although his vehement support for health reform did not result in the implementation of a national health program during his presidency, Truman did live to see the inception of a program that, though not as ambitious as the ones he or FDR proposed, represented significant progress in the direction of change.[222]

Post-War Technologies

Following World War II (WWII), the U.S. healthcare delivery system saw the rapid advent of new medical technologies, resulting in higher levels of health and an increased life expectancy, accompanied by a significant increase in medical costs. Associated with these rising costs has been a decline in infant and child mortality and increased longevity, which, in turn, led to an increase in the overall population and the number of individuals needing care and treatment.[223] Post-war discoveries of new medical therapies, such as *sulfa drugs* and *penicillin*, quickly reduced infectious disease rates, with these rates decreasing to current levels within two decades.[224] Similarly, longer lifespans resulted in a more aged population, and shifted the focus of medicine toward expensive treatments for *degenerative* age-related diseases, e.g., heart disease; stroke; cancer; and senile dementia, treatment of which increased overall costs due to the long-term nature of the care.[225]

The Hill-Burton Act of 1946

After World War II, the regulation of healthcare resources began with the passage of the Hospital Survey and Construction Act, commonly referred to as the Hill-Burton Act. [226] The passage of the Hill-Burton Act marked the beginning of over four decades of federally funded health policy planning.[227] The Act's federal funding was intended to correct the perceived shortage of healthcare facilities following the Great Depression and World War II by encouraging states to

219 Ibid., p. ix.
220 Ibid.
221 Ibid.
222 Ibid.
223 "Epidemiology in the United States After World War II: The Evolution of Technique" By Mervyn Susser, Epidemiology Reviews, Vol. 7 (1985), p. 149-150.
224 "The Determinants of Mortality" By David Cutler, et al., Journal of Economic Perspectives, Vol. 20, No. 3 (2006), p. 103.
225 "Epidemiology in the United States After World War II: The Evolution of Technique" By Mervyn Susser, Epidemiology Reviews, Vol. 7 (1985), p. 149-150.
226 "Health and Politics: The Impact of Certificate of Need Regulation" By Andrew B. Dunham, Chicago, IL: National Center for Health Service Research, 1981, p. 141.
227 "Cost, Quality, and Access in Health Care: New Rolls for Health Planning in a Competitive Environment" By Frank A. Sloan, et al., San Francisco, CA: Josey-Bass Publishers, 1988, p. 21.

develop hospitals in rural areas.[228] To receive federal funding for hospital construction under the Act, states had to institute health policy planning.[229] In addition to publishing a healthcare plan outlining their healthcare needs, states were required to inventory existing healthcare facilities and designate a single agency that would be responsible for health policy planning.[230] Over the course of three decades, the Act provided financial assistance to nearly 60 percent of all U.S. hospital,[231] while also prohibiting discrimination against the provision of hospital services based on race and religion, and mandating hospitals to provide a reasonable amount of charitable care.[232]

John F. Kennedy, Lyndon Johnson, and the Establishment of Medicare

In the late 1950s and early 1960s, preparations began for the enactment of Medicare and Medicaid. As employer-based health insurance coverage increased, private insurance plans began to set premiums based on previous health costs, and those individuals who were retired and/or disabled found it more and more difficult to obtain affordable coverage. Consequently, health reformers refocused their efforts toward the elderly. In the 1960s, John F. Kennedy's presidential campaign once again targeted the recession, unemployment, and stagnant economy introduced by World War II.[233] Author Paul Starr stated that "[t]he triumph of the liberal agenda in the mid-1960s brought a new generation of programs and policies in health care."[234] Starr also recognized that the need for an increase in *health manpower* would result in an expansion of education programs and initiatives.[235]

Introduced by President Kennedy, Medicare is solely managed by the federal government, and attempts to alleviate the economic hardships of the elderly who encounter rising medical costs, while at the same time experiencing a diminishing income, frequently resulting in dire financial conditions. In the aftermath of President Kennedy's assassination, and following legendary political debates, President Johnson guided the passage of Medicare and signed *House Resolution 6675 o*n July 30, 1965.[236] The bill amended the Social Security Act (SSA) of 1935 and was comprised of two components: Medicare Parts A and B. Medicare Part A is "a hospital insurance plan providing protection against the costs of hospital and related care." Medicare Part B involves "a supplementary medical insurance plan covering payments for physicians' services and other medical and health services to cover certain areas not covered by the hospital insurance

228 "Health and Politics: The Impact of Certificate of Need Regulation" By Andrew B. Dunham, Chicago, IL: National Center for Health Service Research, 1981, p. 141.
229 "Cost, Quality, and Access in Health Care: New Rolls for Health Planning in a Competitive Environment" By Frank A. Sloan, et al., San Francisco, CA: Josey-Bass Publishers, 1988, p. 30.
230 "Health and Politics: The Impact of Certificate of Need Regulation" By Andrew B. Dunham, Chicago, IL: National Center for Health Service Research, 1981, p. 141.
231 "Special Analyses: Budget of the United States Government: Fiscal Year 1978" United States Office of Management and Budget, Washington, DC: Government Printing Office, 1978, p. 215.
232 "Timeline: History of Health Reform in the U.S." Kaiser Family Foundation, http://healthreform.kff.org/flash/health-reform-new.html (Accessed 8/20/12).
233 "The Social Transformation of American Medicine: The Rise of a Sovereign Profession and the Making of a Vast Industry" By Paul Starr, New York, NY: Basic Books, Inc., 1982, p. 363.
234 Ibid.
235 Ibid., p. 364.
236 "History of SSA During the Johnson Administration 1963-1968, The Development of Medicare" Social Security Administration, http://www.ssa.gov/history/ssa/lbjmedicare1.html (Accessed 4/27/12).

plan."[237] Part A, which provides hospital insurance, is funded through the Medicare Hospital Insurance (HI) Trust Fund, which is comprised of payroll taxes paid by both employers and employees; enrollees who have not met the requisite requirements for automatic enrollment; a Social Security benefits tax; interest on Federal securities; and government credits. [238] Medicare Part B is funded through the Supplementary Medical Insurance (SMI) Trust Fund and draws the bulk of its resources from premiums paid by Medicare Part B enrollees; general revenue; and payments from the disabled enrollees with chronic renal disease. [239]

Although the passage of Medicare was the result of a longtime congressional interest in social health insurance for elderly Americans, discontent at Medicare's original suggestion ultimately prompted a central figure in the law's passage, Representative Wilbur Mills, a member of the House Ways and Means Committee, to combine the original proposal with two additional components.[240] The AMA lobbied for increased coverage of physician services under the program and even went as far to suggest an Eldercare program, their own version of what eventually became Medicare. Representative Mills placated all involved parties by integrating portions of each program into the final legislative package.[241] The original Medicare proposal (i.e., Part A), coupled with the Republican suggestion to cover physician services, was eventually supplemented by an additional program, prompting some commentators to classify the program as a "three-layer cake" containing Medicare Parts A and B, as well as a social insurance for the healthcare of impoverished Americans – Medicaid.[242]

Creation of Medicaid

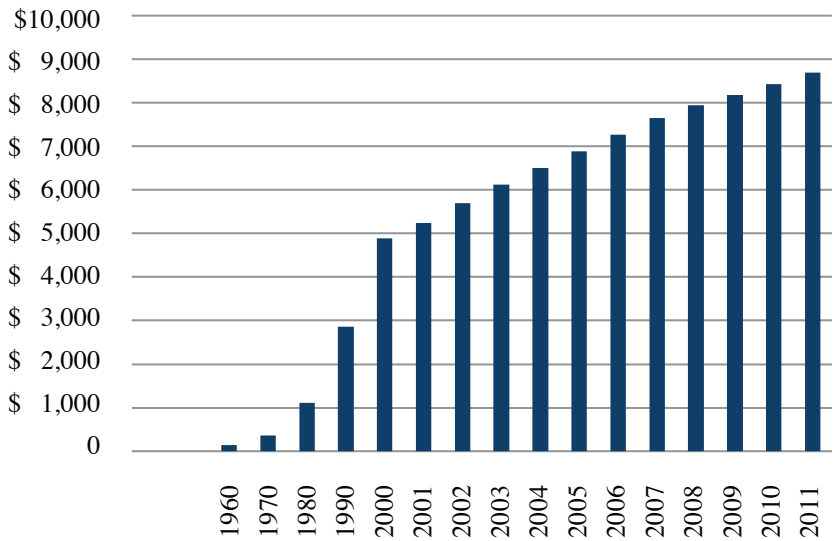
The SSA amendment passed in 1965 (which is discussed above) also included the establishment of the Medicaid program. Medicaid, which was part of President Lyndon B. Johnson's *Great Society* initiative, delivered healthcare insurance coverage for poor individuals who met the requirements of their states of residence. Unlike Medicare, which is a federal initiative, Medicaid is a collaborative program between both the federal and state governments, with individual states setting the criteria for eligible residents. Compared to Medicare, Medicaid was seen as a welfare program and did not enjoy the widespread acclaim and admiration as its oft-cited companion.[243]

237 Ibid.
238 "Section 2 - Medicare" U.S. House Ways and Means Committee, "WMCP 108-6 - Background Material and Data on Programs Within the Jurisdiction of the Committee on Ways and Means (Green Book)" Washington, DC: U.S. Government Printing Office, 2004, p. 2-10.
239 Ibid., p. 2-14.
240 "The Social Transformation of American Medicine: The Rise of a Sovereign Profession and the Making of a Vast Industry" By Paul Starr, New York, NY: Basic Books, p. 368-371.
241 Ibid.
242 Ibid.
243 "Annual Statistical Supplement, 2011: Medicaid Program Description and Legislative History" U.S. Social Security Administration, Office of Retirement and Disability Policy, 2011, https://www.socialsecurity.gov/policy/docs/statcomps/supplement/2011/medicaid.html (Accessed 4/27/12).

THE RISING COSTS OF HEALTHCARE

Since the 1970s, in response to the establishment of Medicare and Medicaid and the federal funding that sustains those programs, health expenditures have been rising steadily. Policy considerations addressing the rising cost of healthcare became a priority of the administration of President Jimmy Carter and presented barriers for national reform efforts.[244] Concerns regarding the cost of healthcare continue today as healthcare costs have continued to increase. A visual depiction of the rising trend of national health expenditures is set forth below in Figure 1-2, National Health Expenditures per Capita 1960-2013.

Figure 1-2: National Health Expenditures per Capita, 1960-2013[245]



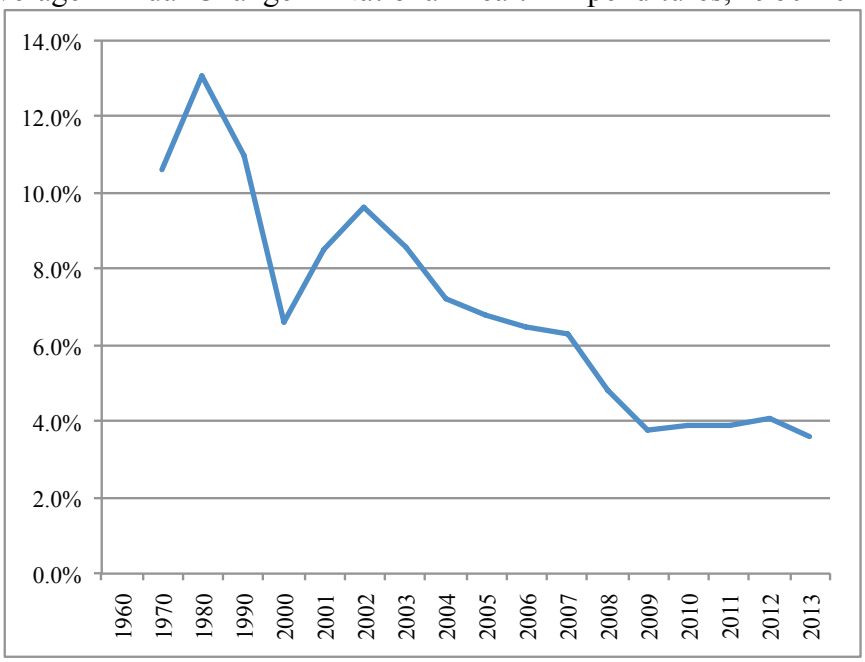
In the decade from 2003 to 2013, national health expenditures have increased more than 64 percent.[246] However, as illustrated below in Figure 1-3: Average Annual Change in National Health Expenditures, 1960-2013, the rate of increase in National Health Expenditures has recently begun to slow.

244 "Timeline: History of Health Reform in the U.S." Kaiser Family Foundation, http://healthreform.kff.org/flash/health-reform-new.html (Accessed 8/20/12).

245 "Table 1 - National Health Expenditures; Aggregate and Per Capita Amounts, Annual Percent Change and Percent Distribution: Selected Calendar Years 1960-2013" from "NHE Tables" located at "NHE Fact Sheet" Centers for Medicare & Medicaid Services, http://www.cms.gov/Research-Statistics-Data-and-Systems/Statistics-Trends-and-Reports/NationalHealthExpendData/NHE-Fact-Sheet.html (Accessed 2/18/15).

246 Ibid.

Figure 1-3: Average Annual Change in National Health Expenditures, 1960-2013[247]



RESPONSES TO RISING COSTS OF HEALTHCARE

Diagnostic Related Groups (DRG), Prospective Payment Systems (PPS), and the Inception of the Resource Based Relative Value System (RBRVS)

Diagnostic Related Groups

In response to the growing costs of medical care, myriad payment reforms were proposed. One of the payment reforms, the Diagnostic Related Group (DRG), was implemented in New Jersey in 1980. This reimbursement reform aimed to realign incentives within hospitals to simultaneously increase efficiency and decrease healthcare expenditures. Despite limited evaluation of the DRG program, many states followed suit, and in 1983 the federal government under President Ronald Reagan adopted the DRG system and integrated it into the Medicare program.[248] Under Medicare Part A, hospitals are reimbursed using DRGs, which classify patients based on the average per discharge cost of caring for their diagnosis.[249] Each DRG is assigned a relative rate based on its average cost, which rate is then multiplied by the input-price level of each market to determine the payment rate for the DRG.[250]

247 Ibid.
248 "Lessons of the New Jersey DRG Payment System" By W.C. Hsiao, et al., Health Affairs, Vol. 5, No. 2 (1986), p. 33.
249 "Hospital Acute Inpatient Services Payment System" MedPAC Payment Basics, October 2008, http://www.medpac.gov/documents/MedPAC_Payment_Basics_08_hospital.pdf (Accessed 9/24/09), p. 1.
250 Ibid.

Prospective Payment Systems

Historically, Medicare and Medicaid reimbursed hospital services using a cost plus method, in which hospitals received reimbursement in excess of all of their costs.[251] In 1982, the federal government introduced a prospective payment system (PPS) as an attempt to remedy rising healthcare costs.[252] Under the PPS, hospitals are reimbursed an average, qualified, and predetermined fee for every recognized DRG (discussed above).[253] The government has also developed a PPS for hospital outpatient services; ambulatory surgery centers (ASCs); skilled nursing facilities (SNFs); rehabilitation facilities; and home healthcare.[254] Applying microeconomic theory, the PPS was proposed at the pinnacle of the Reagan Administration's *revolution* of domestic policy. The U.S. Department of Health and Human Services (HHS) considered PPS to be a self-maintaining system, and it was viewed by some to be "a critical step in the 'deregulation' of American hospitals" to enhance marketplace competition by utilizing incentives versus legislative controls.[255]

> In 1982, the federal government introduced a prospective payment system (PPS) in an effort to remedy the rising healthcare costs.
>
> ***Report to the Congress: Medicare Payment Policy, March 2005.***

Inception of the Resource Based Relative Value System

In 1989, the Resource Based Relative Value System (RBRVS) was presented as a mechanism to control the cost of physician services borne by the Medicare program,[256] although it was not implemented until January 1, 1992, along with the Medicare Fee Schedule.[257] In 1986, in response to the increase in Medicare spending and concerns regarding assertions of inequity in reimbursement rates for procedural services over cognitive clinical services, the Physician Payment Review Commission (PPRC), the precursor to the Medicare Payment Advisory Commission (MedPAC), mandated that the new resource-based physician fee schedule be developed.[258] William C. Hsiao, Ph.D., a professor at the Harvard School of Public Health, was engaged to develop the RBRVS, which was derived from the results of a 1988 study entitled, *A National Study of Resource-Based Relative Value Scales for Physician Service.*[259]

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251 "Medicare Hospital Prospective Payment System: How DRG Rates Are Calculated and Updated" Office of Inspector General, Office of Evaluation and Inspections, Region IX, OEI-09-00-00200, August 2001, p. 1.
252 "Medicare Hospital Prospective Payment System: How DRG Rates Are Calculated and Updated" Office of Inspector General, Office of Evaluation and Inspections, Region IX, OEI-09-00-00200, August 2001, p. 1.
253 Ibid.
254 "Assessing payment adequacy and updating payment in fee-for-service Medicare" in Report to the Congress: Medicare Payment Policy, March 2005, p. 27-32.
255 "Medicare's Prospective Payment System at Age Eight: Mature Success or Midlife Crisis" By Bruce C. Vladeck, University of Puget Sound Law Review, Vol. 14, No. 3 (Spring 1991), p. 453.
256 "Health Care USA: Understanding its Organization and Delivery" By Harry A. Sultz and Kristina M. Young, Sixth Edition, Boston, MA: Jones and Bartlett Publishers, 2009, p. 261.
257 "An Overview of the Development and Refinement of the Resource-Based Relative Value Scale: The Foundation for Reform of U.S. Physician Payment" By William C. Hsiao, et al., Medical Care, Vol. 30, No. 11, Supp. (November 1992), p. NS1-NS2.
258 "Resource-Based Relative Value Units: A Primer for Academic Family Physicians" By Sarah E. Johnson, MD, and Warren P. Newton, MD, MPH, Family Medicine, March 2002, p 172.
259 Ibid., p 172-73.

The study was commissioned and funded by the Health Care Financing Administration (HCFA),[260] currently known as Centers for Medicare & Medicaid Services (CMS), and was supported by the AMA, various specialty groups, and the PPRC. Based on earlier work by Hsiao and others that examined the inconsistencies, inadequacies, and ambiguities in the measurement of the relative value of physician work input and the coding system that was utilized,[261] the 1988 study apportioned physician services into distinct fungible units comprised of work, practice cost, and malpractice cost inputs known as Relative Value Units (RVUs).[262] Phase I of the study examined over 200 practicing physicians performing over 400 services in 18 medical and surgical specialties relying on the Current Procedural Terminology (CPT-4).[263] The process of allocating physician services into distinct, fungible units of defined commodities (i.e., RVUs) embraced the concept that establishing a standard per unit of care across physician services and specialties could augment initiatives to ensure more equitable and reasonable reimbursement rates, while additionally serving as an effective cost containment measure.

The 1989 legislative decision to include the RBRVS was passed on Phase I of the 1988 Hsiao study, which was performed between 1986 and 1988. Following the acceptance of the RBRVS system, but prior to its 1992 implementation through the Omnibus Budget Reconciliation Act of 1990,[264] Hsiao and his peers completed both Phase II (1988-1990) and Phase III (1990-1992) of the study to further refine and expand the scope of the RBRVS system.[265]

The system was intended to replace the previous *Customary Prevailing and Reasonable* (CPR) charge system by aligning payments for medical practice with a prospective payment system, under which reimbursement is based on a predetermined, fixed amount, and on estimates of resource costs incurred in an efficient medical practice.[266] The RBRVS was intended to place greater emphasis on the time a physician spent with a patient when assessing health, diagnosing conditions, and listening to patient complaints, thereby distributing Medicare payments more heavily to primary care physicians and reducing the traditionally higher reimbursement payments to specialists and surgeons.[267]

> In 1989, the resource-based relative value system (RBRVS) was introduced as a mechanism to control the costs of physicians' services borne by the Medicare program.
>
> ***Robert James Cimasi 2009.***

260 HCFA was established in 1977 to manage the Medicare and Medicaid programs. The agency changed its name in 2001. "History" Centers for Medicare & Medicaid Services, https://www.cms.gov/About-CMS/Agency-Information/History/index.html?redirect=/history/ (Accessed 4/7/15).

261 "An Overview of the Development and Refinement of the Resource-Based Relative Value Scale: The Foundation for Reform of U.S. Physician Payment" By William C. Hsiao, et al., Medical Care, Vol. 30, No. 11, Supp., November 1992, p. NS1-NS2; "Toward Developing a Relative Value Scale for Medical and Surgical Services" By William C. Hsiao and William B. Stason, Health Care Financing Review, Fall 1979, p. 23.

262 "A National Study of Resource-Based Relative Value Scales for Physician Services" By William C. Hsiao, et al., Cambridge, MA, 1988, p. 1-25.

263 "An Overview of the Development and Refinement of the Resource-Based Relative Value Scale: The Foundation for Reform of U.S. Physician Payment" By William C. Hsiao, et al., Medical Care, Vol. 30, No. 11, Supp. (November 1992), p. NS1-NS3.

264 "Understanding Health Insurance: A Guide to Billing and Reimbursement" By Michelle A. Green and JoAnn C. Rowell, Ninth Edition, Clifton, NY: Delmar Cengage Learning, 2008, p. 23.

265 "An Overview of the Development and Refinement of the Resource-Based Relative Value Scale: The Foundation for Reform of U.S. Physician Payment" By William C. Hsiao, et al., Medical Care, Vol. 30, No. 11, Supp. (November 1992), p. NS2.

266 "Health Care USA: Understanding Its Organization and Delivery" By Harry A. Sultz and Kristina M. Young, Sixth Edition, Sudbury, MA, Jones and Bartlett Publishers, 2009, p. 261.

267 "RBRVS: How New Physician Fee Schedule Will Work - Resource-Based Relative Value Scale Payment System" By Paul L. Grimaldi, Healthcare Financial Management, Sept 1991.

The Establishment of the Sustainable Growth Rate

The Medicare physician fee schedule is updated by CMS each year based on a formula entailed in the Balanced Budget Act of 1997, which includes application of the Sustainable Growth Rate (SGR).[268] The SGR represents a spending target set for total annual expenditures under Medicare on Part B services and provides a calculation for annual adjustments to the Medicare physician fee schedule based on whether actual spending came in above or below the target.[269] Since its inception, and especially since 2002, intense debate has surrounded the need and benefit of the SGR, which, since 2002, has required annual Congressional intervention to prevent calculated decreases to physician payments. For more information of the SGR and the debates concerning its longevity see Chapter 2, Reimbursement Environment in *An Era of Reform: The Four Pillars*.

The Rise and Fall of Managed Care

In response to ever increasing healthcare costs, employers began relying more heavily on prepaid health insurance models, e.g., Health Maintenance Organizations (HMO), a name coined by Paul Ellwood Jr. in 1970. Even as employers began to utilize HMOs, fewer than four million Americans were enrolled in these health plans in 1971.[270]

Congress passed the Health Maintenance Organization Act of 1973 to fund the development and spread of HMOs, which are prepaid health plans that utilize primary care physicians as gatekeepers to provider networks and capitated provider reimbursement, which incentivizes the reduction of health service utilization and increases in the efficiency of care for HMO members. HMOs and a similar type of prepaid health plan, preferred provider organizations (PPOs), seek to combine the roles of insurance companies, utilization review organizations, and medical services providers in order to offer prepaid medical plans to subscribers that control costs by integrating operational and financial functions.[271]

One of the inevitable goals of the shift to managed care and capitation, from a fee-for-service medical system, was the managed competition between large, consolidated provider.[272] The adoption of managed care at the state and federal levels led to the expeditious consolidation of healthcare entities in both public and private sectors into emerging healthcare organizations.[273]

The adoption of managed care promulgated the aforementioned increase in integration of healthcare organizations.[274] Unfortunately, the managed care movement did not provide the quality and efficiency outcomes that the industry expected.[275] Most organizations only

268 "The Sustainable Growth Rate Formula and Health Reform" By Paul N. Van de Water, Center on Budget and Policy Priorities, April 21, 2010, http://www.cbpp.org/cms/?fa=view&id=3166 (Accessed 2/19/15).
269 "The Sustainable Growth Rate Formula for Setting Medicare's Physician Payment Rates" Congressional Budget Office, Economic and Budget Issue Brief, Sept. 6, 2006, http://www.cbo.gov/ftpdocs/75xx/doc7542/09-07-SGR-brief.pdf (Accessed 10/9/09), p. 2, 4-5.
270 "The Rise of HMOs" By Martin Markovich, Santa Monica, CA: RAND Corporation, 2003, p. 3.
271 "Health Care USA: Understanding its Organization and Delivery" By Harry A. Sultz and Kristina M. Young, Sixth Edition, Boston, MA: Jones and Bartlett Publishers, 2009, p. 240-242.
272 Ibid., p. 242.
273 Ibid., p. 240-242.
274 "Unhealthy Trends: The Future of Physician Services" By Hoangmai H. Pham and Paul B. Ginsburg, Health Affairs, Vol. 26, No. 6 (November/December 2007), p. 1586, 1589-1592.
275 Ibid.

consolidated in order to survive the backlash of managed care. This consolidation to date has, in some aspects, deviated from the original goals of the managed care movement: the fluid delivery of healthcare services along the continuum of care. In light of this misalignment, increased integration has only furthered the fragmentation of healthcare delivery, creating a façade of increased consolidation in a healthcare system that remains, inherently, a "cottage industry."[276] Although managed care was, at one time, believed to be the Pied Piper of cottage healthcare, transformation into postindustrial care is also contingent upon the standardization of care, accounting for performance measures, and employed transparent reporting practices.[277]

The stated goals and original promises of the HMO Act, lower costs and higher quality outcomes for patients (similar to the goals of modern accountable care organizations) due to the fluid delivery of healthcare services along the continuum of care, were not met. Similarly, the projected increases in the number of HMO plans appeared to be woefully optimistic, as the goals of increasing the number of HMO plans from 30 in 1970 to 1,700 by 1976 and covering 90 percent of the population by 1980, were not achieved. Nonetheless, throughout the 1970s and 1980s, the number of HMO plans did increase, and other models of managed care plans flourished, maintaining prominence into 1990s. There were over 600 HMOs in operation by 1996 with almost 65 million enrollees- almost one fourth of the U.S. population at the time.[278]

The capitation form of payment utilized in many managed care plans, which was originally thought to incentivize efficiency and reduce waste in the healthcare delivery system, instead caused physicians and hospitals to underprovide services for fear of sustaining continual financial losses. Patients accused HMO gatekeeper providers and insurers of being of focusing on their own financial benefit, rather than the medical interests of their patients.[279] By 1997, 52 percent of U.S. citizens were in favor of the government stepping in to regulate managed care companies, even if it resulted in increased cost. Further, 54 percent believed the continued use of capitated payment models and gatekeeping functions of managed care plans would harm the quality of medical care.[280]

Despite overall satisfaction with the level of medical care received from HMO providers, the public discontent with managed care plans was heavily publicized, and further encouraged the eventual consumer backlash.[281] Since the 1990s, HMOs have seen continued use in the U.S. healthcare delivery system; however, reports suggest that restrictions on provider preferences have been significantly relaxed.[282]

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276 "Cottage Industry to Postindustrical Care—The Revolution in Health Care Delivery" By Stephen J. Swensen, et al., New England Journal of Medicine, January 20, 2010, p. e12(1); "Unhealthy Trends: The Future of Physician Services" By Hoangmai H. Pham and Paul B. Ginsburg, Health Affairs, Vol. 26, No. 6 (November/December 2007), p. 1586, 1589-1592.

277 "Cottage Industry to Postindustrical Care—The Revolution in Health Care Delivery" By Stephen J. Swensen, et al., New England Journal of Medicine, January 20, 2010, p. e12(3).

278 "A Brief History of Managed Care" Tufts Managed Care Institute, 1998, http://www.thci.org/downloads/briefhist.pdf (Accessed 12/28/11).

279 "The Public, Managed Care, and Consumer Protections" Kaiser Family Foundation, Kaiser Public Opinion Spotlight, January 2006, p. 1; "Understanding the Managed Care Backlash" By Robert J. Blendon, et al., Health Affairs, Vol. 17, No. 4 (July/August 1998), p. 87- 88.

280 "Understanding the Managed Care Backlash" By Robert J. Blendon, et al., Health Affairs, Vol. 17, No. 4 (July/August 1998), p. 83-84.

281 Ibid., p. 90-91.

282 "The Managed Care Backlash: Did Consumers Vote With Their Feet?" By Susan Marquis, et al., Inquiry, Vol. 41 (Winter 2004/2005), p. 387.

The Resulting Erosion of Physician Independence

Although most professions saw an increase in compensation since the 1990s, physician compensation has been fairly stagnant.[283] Physicians have invested in ancillary services providers not only in an effort to counter reductions in professional fee reimbursement revenue, but also to exercise control over their practice environment and ability to provide technologically advanced, high-quality care to their patients.[284] The realignment of the Inpatient PPS (IPPS) with the introduction of severely adjusted DRGs, as well as heightened initiatives aimed at restricting physician ownership of ancillary services and technical component revenue streams have raised some investor concerns.[285]

The overall impact of this and other attacks on physician ownership appears to be aimed at consigning physicians to nothing more than *sharecroppers*. This perceived diminution of the professional standing and investor interest of physicians is further exacerbated by widespread acceptance among even the most ardent proponents of physician independence, such as Arnold Relman, MD, Harvard professor and former editor of the *New England Journal of Medicine*, who, by neglecting to condone physician ownership and advocating for a U.S. healthcare system where the majority of physicians would be employed by not-for-profit group practices, may have redefined his stance on physician "independence."[286]

> *"From the perspective of many, the inevitable outcome of these efforts at placing additional restrictions on physician independence will be to relegate these professionals and their practice of medicine, to the status of, at best, the healthcare equivalent of sharecropping, and, at worst (per Relman), the status of hired help."*[287]

CLINTON ERA HEALTHCARE REFORMS

Healthcare reform was a key policy initiative from the beginning of the Clinton administration's campaign in 1992 and throughout his term. The political landscape during his first term in office seemed to support his efforts: Democrats controlled both the Senate and the House of Representatives; bipartisan concessions were offered; the public supported reform; and many influential industry organizations approved sweeping changes.[288] The bill was primarily

283 "A Guide to Consulting Services for Emerging Healthcare Organizations" By Robert J. Cimasi, New York, NY: John Wiley & Sons, Inc., 1999, p. 5; "Health Care USA: Understanding its Organization and Delivery" By Harry A. Sultz and Kristina M. Young, Sixth Edition, Boston, MA: Jones and Bartlett Publishers, 2009, p. 245-246.

284 "A Guide to Consulting Services for Emerging Healthcare Organizations" By Robert James Cimasi, New York, NY: John Wiley & Sons, Inc., 1999, p. 4; "Enhancing the Bottom Line—Considerations in Developing Ancillary Services" By Darrell L. Schryver and Bruce A Johnson, Directions Newsletter, Vol. 5, No. 2 (2003), http://www.mgma.com/article.aspx?id=1142 (Accessed 2/3/10).

285 "Health Care USA: Understanding its Organization and Delivery" By Harry A. Sultz and Kristina M. Young, Sixth Edition, Boston, MA: Jones and Bartlett Publishers, 2009, p. 240, 257-260; "Specialty Hospitals, Ambulatory Surgery Centers, and General Hospitals: Charting a Wise Policy Course" By David Shactman, Health Affairs, Vol. 24, No. 3 (2005), p. 24.

286 "A Second Opinion: Rescuing America's Health Care: A Plan for Universal Coverage Serving Patients Over Profit" By Arnold S. Relman, New York, NY: PublicAffairs, 2007.

287 "Down on the Farm: The Attack on Physician Ownership" By Robert James Cimasi, SurgiStrategies, May 1, 2008, http://www.surgistrategies.com/articles/physician-ownership-law-asc-cimasi.html# (Accessed 10/08/09), p. 4.

288 "What Happened to Health Care Reform?" By Paul Starr, The American Prospect, No. 20 (Winter 1995), p. 20-31.; "Learning from Failure in Health Care Reform" By Jonathan Oberlander, Ph.D., The New England Journal of Medicine, Vol. 357, No. 17 (October 25, 2007), p. 1677-1679.

championed by First Lady, Hilary Rodham Clinton,[289] who served as Chair of the Task Force on National Health Care Reform, established by President Clinton on January 25, 1993, at the beginning of his term.[290] The healthcare reform proposal, H.R. 3600, The Health Security Act, which was submitted to Congress on November 20, 1993,[291] attempted to institute universal coverage; regulate the private insurance market; change healthcare financing through the implementation of an employer mandate; control costs to levels enforced by a national health board; and transform the healthcare delivery system through managed care.[292] The plan combined the liberal *ends* of universal coverage with the conservative *means* of managed competition.[293]

Several factors contributed to the sharp change in sentiment toward healthcare between 1993 and 1994 when the Clinton healthcare reform bill was being debated. President Clinton could not muster the requisite political capital to finish his push for reform, expending much of his political clout on other issues, such as the federal budget and the North American Free Trade Agreement (NAFTA), as well as the political fallout from the Whitewater scandal.[294] In the face of the approaching midterm elections, Republicans stopped making concessions and instead touted the bill's defeat as a means to humiliate President Clinton.[295] Further, the economy had started to improve and, as a result, constituents were less concerned with reforming healthcare.[296] President Clinton reduced the scope of his envisioned reform by focusing on universal coverage and threatening to veto any bill that did not include it.[297] In the end, no compromise was found, and the Clinton plan died in Congress.[298]

MEDICARE PART C AND THE CHILDREN'S HEALTH INSURANCE PROGRAM (CHIP)

Medicare Part C, or *Medicare Advantage*, and the State Children's Health Insurance Program (SCHIP) were established as part of the Balanced Budget Act of 1997. In addition, as set forth below, the Act added civil monetary penalty provisions to the Anti-Kickback Statute in an amount of $50,000, in addition to three times the amount of illegal remuneration, or *treble damages*.[299]

289 Hillary Clinton was a member of the Jackson Hole Group, a group of healthcare experts consisting of approximately 100 academics, insurance executives, hospital and pharmaceutical executives, physicians, and associated business and policy makers. Meeting at the home of Dr. Paul M. Ellwood (a main proponent of managed competition), in Jackson Hole WY, the group was one of the driving forces behind the formation of the Health Security Act based on their publication, "The 21st Century American Health System – Managed Competition: A Proposal for Public and Private Health Care Reform." Alan Enthoven (founder of the concept of managed competition) participated in the group stating, "*What was valuable is that we brought together people from many perspectives. We learned from each other*." "Hillary Clinton's Potent Brain Trust on Health Reform" By Robin Toner, The New York Times, February 28, 1993.

290 "President's Task Force on National Health Care Reform" Federal Register Daily Journal, https://www.federalregister.gov/agencies/president-s-task-force-on-national-health-care-reform (Accessed 8/23/12).

291 "The Health Security Act" H.R. 3600 (November 20, 1993).

292 "Learning from Failure in Health Care Reform" By Jonathan Oberlander, PhD, The New England Journal of Medicine, Vol. 357, No. 17 (October 25, 2007), p. 1677-1679.

293 "What Happened to Health Care Reform?" By Paul Starr, The American Prospect, No. 20 (Winter 1995), p. 20-31; "The Rationale Behind the Clinton Health Care Reform Plan" By W. A. Zelman, Health Affairs, Vol. 13, No. 1 (Spring 1994), p. 9-29.

294 "What Happened to Health Care Reform?" By Paul Starr, The American Prospect, No. 20 (Winter 1995), p. 20-31.

295 Ibid.

296 Ibid.

297 Ibid.

298 Ibid.

299 "The Balanced Budget Act of 1997" Pub. L. No. 105-33, § 4304, 111 Stat. 251, 383 (August 5, 1997).

Medicare Part C offers a managed care alternative to Medicare Parts A and B, which allowed private insurance coverage to offer plans that include hospital coverage (Part A), medical coverage (Part B), and other services without the need to purchase a Medigap plan (a private plan that aids the elderly in meeting the expenses that Medicare Parts A and B leave uncovered).[300]

The State Children's Health Insurance Program (SCHIP) (currently known as the Children's Health Insurance Program (CHIP)) is a federal partnership with the states that provides health insurance to children and pregnant women in families whose income is above the threshold for regular Medicaid.[301] The Patient Protection and Affordable Care Act (ACA) extended the authorization of federal CHIP funding through September 30, 2015.[302]

MEDICARE PART D

In response to the increase in utilization, demand, and price of prescription drugs, Congress enacted the Medicare Prescription Drug, Improvement, and Modernization Act (MMA) of 2003 during the George W. Bush Administration, which resulted in some of the most significant changes to the Medicare Program in the 38 years since its enactment, including *Medicare Part D*, an entitlement benefit for prescription drugs, which had seen drastically increased utilization.[303] As part of the MMA, Medicare Advantage plans were altered to allow insurers the ability to offer Medicare Part D coverage, and to restrict patient access and prescription drug choice.[304] The MMA also replaced and expanded medical savings accounts, by establishing the regulatory scheme for *health savings accounts* (HSA).[305]

FEDERAL FRAUD AND ABUSE STATUTES

After the implementation of Medicare and Medicaid, it quickly became apparent that, with the massive amount of federal and state funding at stake, regulation to protect these important public coffers was required. These statutes and regulations, first implemented in the 1970s, are constantly changing, resulting in the rapidly evolving healthcare regulatory environment.

300 "Part C – Medicare+Choice Program: Eligibility, Election, and Enrollment" Social Security Act § 1851 (42 U.S.C. § 1395w-21); "Medigap (Medicare Supplement Health Insurance)" Centers for Medicare & Medicaid Services, March 26, 2012, http://www.cms.gov/Medicare/Health-Plans/Medigap/index.html?redirect=/Medigap/ (Accessed 5/14/12).

301 "Medicaid & CHIP Coverage" Centers for Medicare and Medicaid Services, https://www.healthcare.gov/medicaid-chip/ (Accessed 2/19/15).

302 "Children's Health Insurance Program Overview" National Conference of State Legislatures, August 1, 2011, http://www.ncsl.org/research/health/childrens-health-insurance-program-overview.aspx (Accessed 2/19/15); "Financing" Centers for Medicare and Medicaid Services, http://medicaid.gov/chip/financing/financing.html (Accessed 2/19/15).

303 "Fact Sheet: Medicare Prescription Drug, Improvement, and Modernization Act of 2003" The White House Press Release, December 8, 2003, http://georgewbush-whitehouse.archives.gov/news/releases/2003/12/20031208-3.html (Accessed 2/19/15).

304 "Medicare Prescription Drug, Improvement, and Modernization Act of 2003" Pub. L. No. 108-173, § 101, 117 Stat. 2017-2081 (December 8, 2003).

305 "Medicare Prescription Drug, Improvement, and Modernization Act of 2003" Pub. L. No. 108-173, § 1201, 117 Stat. 2017, 2066, 2469-2478 (December 8, 2003).

The Anti-Kickback Statute

The Medicare Anti-kickback Statute (AKS) was enacted in 1972 and subsequently amended to provide felony criminal penalties for knowingly and willfully offering, paying, soliciting, or receiving remuneration in order to induce business reimbursed under the Medicare or state healthcare programs.[306] In 1987, the Office of Inspector General (OIG) was given authority to issue civil penalties, including exclusion from the Medicare Program.[307] These civil penalties were believed to be a more effective way of enforcing the statute, as they did not require the government to prove violation of the statute *beyond a reasonable doubt*, but merely by the lesser standard of *preponderance of the evidence*.[308]

Given the relatively broad scope of the AKS, the statute also includes several safe harbors (exceptions to the statute) to protect legitimate business arrangements.[309] It was the intent of Congress that the rules evolve and be updated to reflect changes within the healthcare industry and in technologies affecting the industry.[310] As intended, the safe harbors have continuously developed and changed since their enactment, the most recent of which include the addition of waivers for:

(1) Cost sharing for financially needy Medicare Part D beneficiaries;
(2) Cost sharing for emergency ambulance services furnished by state or municipality owned ambulance services; and
(3) Protection for free or discounted local transportation services, among others.[311]

The Stark Law

More commonly known as the *Stark Law*, after the legislation's chief supporter, Congressman Fortney "Pete" Stark (D-CA), the Ethics in Patient Referral Act of 1989 originally prohibited physicians from making referrals to clinical laboratories if the physician, or an immediate family member of the physician, had an ownership or investment interest in the lab.[312] Further, the lab was prohibited from billing for those services.[313] Congressman Stark supported the legislation

306 "Anti-Kickback Statute" By Terri Sabella, American Health Lawyers Association, Health Law Resources, https://www.healthlawyers.org/hlresources/Health%20Law%20Wiki/Anti-Kickback%20Statute.aspx (Accessed 2/19/15).
307 "Anti-Kickback Statute" By Terri Sabella, American Health Lawyers Association, Health Law Resources, https://www.healthlawyers.org/hlresources/Health%20Law%20Wiki/Anti-Kickback%20Statute.aspx (Accessed 2/19/15); "Exclusion of entities owned or controlled by a sanctioned person" 42 C.F.R. § 1001.1001 (October 1, 2011).
308 "Institute on Medicare and Medicaid Payment Issues: Fraud and Abuse Primer" By John T. Brennan, American Health Lawyers Association, March 16-18, 2005, http://www.crowell.com/documents/DOCASSOCFKTYPE_PRESENTATIONS_721.pdf (Accessed 2/19/15), p. 12.
309 "Exceptions" 42 C.F.R. § 1001.952 (March 18, 2002).
310 "Medicare and State Health Care Programs: Fraud and Abuse; Clarification of the Initial OIG Safe Harbor Provisions and Establishment of Additional Safe Harbor Provisions Under the Anti-Kickback Statute; Final Rule" Federal Register Vol. 64, No. 223 (November 19, 1999), p. 63518.
311 "Exceptions" 42 C.F.R. § 1001.952 (March 18, 2002); "Medicare and State Health Care Programs: Fraud and Abuse; Revisions to Safe Harbors under the Anti-Kickback Statute, and Civil Monetary Penalty Rules Regarding Beneficiary Inducements and Gainsharing" Federal Register Vol. 79, No. 192 (October 3, 2014), p. 59718.
312 "Medicare Program; Physician Financial Relationships With, and Referrals to, Health Care Entities That Furnish Clinical Laboratory Services and Financial Relationship Reporting Requirements: Final Rule with Comment Period" Federal Register Vol. 60, No. 156 (August 14, 1995), p.41915.
313 Ibid.

based on studies indicating that despite the broad scope of the Anti-Kickback Statute, self-referrals were prevalent in the healthcare industry.[314]

This act marked the beginning of the stream of numerous restrictive amendments to the Stark Law, which have significantly impacted the ways in which physicians and healthcare enterprises interact. Currently, the Stark Law prohibits a physician from making a referral to an entity for designated health services (a list of 12 services, including inpatient and outpatient hospital services), if that physician has a financial relationship with the entity.[315]

Similar to the Anti-Kickback Statute, there are a variety of exceptions to the Stark Law that permit narrowly defined financial agreements between physicians and designated health service entities.[316]

The False Claims Act

The False Claims Act (FCA) is a longstanding statute that was established by President Abraham Lincoln to address fraudulent bills submitted by defense contractors to the United States Army.[317] The statute imposes civil monetary penalties upon violators in an amount between $5,000 to $10,000 per claim, as well as three times the amount of damages that the Government sustains,[318] if a person performs any of the following actions:

(1) Knowingly presents, or causes to be presented, a false or fraudulent claim for payment or approval;
(2) Knowingly makes, uses, or causes to be made or used, a false record or statement material to a false or fraudulent claim;
(3) Conspires to commit a violation of the FCA; or
(4) Knowingly makes, uses, or causes to be made or used, a false record or statement material to an obligation to pay or transmit money or property to the Government, or knowingly conceals or knowingly and improperly avoids or decreases an obligation to pay or transmit money or property to the Government.[319]

The FCA is a potent fraud and abuse enforcement tool, as it allows private individuals, also known as *qui tam relators* or *whistleblowers*, to bring suits on behalf of the Government.[320]

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314 "Health Care Fraud and Abuse: Practical Perspectives" Edited By Linda A. Baumann, Washington, DC: American Bar Association, 2002, p. 52.

315 "Physician Self-Referral" Centers for Medicare and Medicaid Services, January 5, 2015, https://www.cms.gov/Medicare/Fraud-and-Abuse/PhysicianSelfReferral/index.html?redirect=/physicianselfreferral/ (Accessed 2/19/15); "Limitation on Certain Physician Referrals" 42 U.S.C. § 1395nn(a)(1) (January 7, 2011).

316 "Limitation on Certain Physician Referrals" 42 U.S.C. § 1395nn(b)-(e) (January 7, 2011); "General exceptions to the referral prohibition related to both ownership/investment and compensation" 42 C.F.R. § 411.355(a)-(i) (October 1, 2011); "Exceptions to the referral prohibition related to ownership or investment interests" 42 C.F.R. § 411.356(a)-(c) (October 1, 2010); "Exceptions to the referral prohibition related to compensation arrangements" 42 C.F.R. § 411.357(a)-(p) (October 1, 2011).

317 "False Claims Act" The American Health Lawyers Association, Health Law Resources, https://www.healthlawyers.org/hlresources/Health%20Law%20Wiki/False%20Claims%20Act.aspx (Accessed 2/19/15).

318 "False Claims" 31 U.S.C. § 3729(a) (January 3, 2012).

319 Ibid.

320 "False Claims Act" The American Health Lawyers Association, Health Law Resources, https://www.healthlawyers.org/hlresources/Health%20Law%20Wiki/False%20Claims%20Act.aspx (Accessed 2/19/15); "Qui Tam: The False Claims Act and Related Federal Statutes" By Charles Doyle, Congressional Research Service, August 6, 2009, https://www.fas.org/sgp/crs/misc/R40785.pdf (Accessed 2/19/15), Summary, p. 1.

Further still, the FCA allows these private individuals to share in the Government's recovery, as recompense for their assistance.[321] In the context of healthcare, violations the Stark Law and AKS serve as predicate actions that may be enforced through the FCA.[322]

THE PATIENT PROTECTION AND AFFORDABLE CARE ACT (ACA)

Perhaps the most significant transformation of the delivery of healthcare in the U.S., the Patient Protection and Affordable Care Act (ACA) was signed into law by President Barack Obama on March 23, 2010, following a period of divisive political debate which has continued nearly five years after the ACA's enactment. The regulation contains many provisions affecting the triple aim of healthcare reform (access, quality, and cost of healthcare), including ACA §3022, which establishes the Medicare Shared Savings Program (MSSP), regulations that govern Federal Accountable Care Organizations (ACOs).[323] Its provisions include: the implementation of *risk adjustment*, *reinsurance*, and *risk corridors*;[324] *increased transparency* through *publication of physician payments from industry*;[325] *expanded access* to *affordable insurance*;[326] and expanded access to care (especially to primary care providers).[327]

Challenges to the ACA

Challenges to the Individual Mandate and Medicaid

On June 28, 2012, the Supreme Court of the United States (SCOTUS) handed down its highly anticipated decision upholding most of the 2010 healthcare reform. A national controversy was ignited upon the passage of the ACA,[328] and the *individual mandate* was challenged in court by certain States' Attorneys General, who challenged Congress's ability to mandate the purchase of health insurance, invoking both the Supremacy and Commerce Clauses.[329] Similarly, the National Federation of Independent Business filed a suit challenging the constitutionality of the ACA's Medicaid expansion provisions, which would require states to expand their Medicaid coverage to certain low-income individuals, or face revocation of *all* Federal Medicaid funding.[330]

321 "False Claims Act" The American Health Lawyers Association, Health Law Resources, https://www.healthlawyers.org/hlresources/Health%20Law%20Wiki/False%20Claims%20Act.aspx (Accessed 2/19/15); "Qui Tam: The False Claims Act and Related Federal Statutes" By Charles Doyle, Congressional Research Service, August 6, 2009, https://www.fas.org/sgp/crs/misc/R40785.pdf (Accessed 2/19/15), p 1.

322 "A Public Policy Discussion: Taking the Measure of the Stark Law" American Health Lawyers Association, https://www.healthlawyers.org/hlresources/PI/ConvenerSessions/Documents/Stark%20White%20Paper.pdf (Accessed 2/19/15), p. 8.

323 "Patient Protection and Affordable Care Act," Pub. L. No 111-148, § 3022, 124 Stat. 119, 395 (2010).

324 "Explaining Health Care Reform: Risk Adjustment, Reinsurance, and Risk Corridors" The Henry J. Kaiser Family Foundation, January 2014, https://kaiserfamilyfoundation.files.wordpress.com/2014/01/8544-explaining-health-care-reform-risk-adjustment-reinsurance-and-risk-corridors1.pdf (Accessed 2/19/15), p. 1.

325 "Open Payments (Physician Payments Sunshine Act)" Centers for Medicare and Medicaid Services, http://www.cms.gov/Regulations-and-Guidance/Legislation/National-Physician-Payment-Transparency-Program/Downloads/Physician-fact-sheet.pdf (Accessed 2/19/15), p. 1.

326 "Summary of Coverage Provisions in the Affordable Care Act" The Henry J. Kaiser Family Foundation, July 17, 2012, https://kaiserfamilyfoundation.files.wordpress.com/2013/01/8023-r.pdf (Accessed 2/19/15), p. 1.

327 "How the Affordable Care Act will Strengthen the Nation's Primary Care Foundation" By Karen Davis, et al., Journal of General Internal Medicine, Vol. 26, No. 10 (April 27, 2011), p. 1.

328 "National Federation of Independent Business v. Sebelius" 132 S. Ct. 2566, 2572 (SCOTUS 2012).

329 "Showdown gets a head start" By Rich Daly and Jessica Zigmond, Modern Healthcare, March 26, 2012, http://www.modernhealthcare.com/article/20120324/MAGAZINE/303249947 (Accessed 8/17/12).

330 "National Federation of Independent Business v. Sebelius" 132 S. Ct. 2566, 2580 (SCOTUS 2012).

Despite agreeing with the argument that the *individual mandate* violated the Constitution's Commerce clause, SCOTUS chose to uphold the provision, and the ACA, as an exercise of the *federal taxing power*. SCOTUS also upheld the provision mandating the expansion of the Medicaid program, although the Court did limit Congress's attempt to *pressure* states into participating.[331] SCOTUS found that Congress can offer new funding to entice Medicaid expansion by the States, but cannot withdraw existing funds.

Touted as the one of the most significant SCOTUS decisions of this century, the Court's 5 to 4 ruling to uphold the ACA has caused repercussions throughout the U.S. healthcare delivery system and the businesses and professionals that operate therein. [332]

Challenging the ACA's Tax Subsidies

Recently, the permissibility of making subsidies available to low income individuals and families in the form of tax credits, which assist millions in affording health insurance via the state and federally run health insurance exchanges established by the ACA,[333] has come under siege.[334] The petitioners alleged that, on its face, the ACA only allowed the U.S. Treasury to distribute subsidies in the form of tax credits for health insurance that is purchased through a state established exchange, but not for health insurance that is purchased through the HHS established exchange.[335] The respondents, in turn, argued that this reading of the statute is inappropriate, declaring such an interpretation to be "…contrary to the [ACA]'s text and structure and would render the Act unrecognizable to the Congress that passed it."[336] Ultimately, the Supreme Court upheld the Government's interpretation of the statute, noting that the petitioner's interpretation would result in serious damage to the health insurance markets that the ACA was designed to reform.[337]

If the Supreme Court found in favor of the petitioners and limited distribution of tax subsidies to only those individuals who purchase insurance through state established exchanges, an estimated 8.2 million additional people would have become uninsured.[338] Further still, few of the newly uninsured would be required to obtain coverage or pay a penalty as required by the individual mandate, because the cost of health insurance would exceed 8% of income.[339] This would likely have resulted in an older and less healthy mix of individuals enrolling in nongroup insurance, thereby increasing average premiums in the nongroup insurance market by an estimated 35%.[340]

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331 "National Federation of Independent Business v. Sebelius" 132 S. Ct. 2566, 2604 (SCOTUS 2012).
332 "National Federation of Independent Business v. Sebelius" 132 S. Ct. 2566, 2566 (SCOTUS 2012).
333 "Affordable Care Act Tax Provisions" Internal Revenue Service, February 18, 2015, http://www.irs.gov/Affordable-Care-Act/Affordable-Care-Act-Tax-Provisions (Accessed 2/19/15).
334 "Halbig, et al. v. Burwell" Appeal from the United States District Court for the District of Columbia, Opinion, No. 14-5018, July 22, 2014, p. 1; "King, et al. v. Burwell" Appeal from the United States District Court for the Eastern District of Virginia, at Richmond, No. 14-1158, July 22, 2014, p. 5; "King, et al. v. Burwell" Brief for the Respondents, No. 14-114, January 21, 2015, p. I.
335 "King, et al. v. Burwell" Brief for the Petitioners, No. 14-114, December 22, 2014, p. 3, 5-6.
336 "David King et al. v. Sylvia Mathews Burwell et al." Case No. 14-114 (SCOTUS 2015), Brief for the Respondents in Opposition, p. 12.
337 "King et al. v. Burwell, Secretary of Health and Human Services, et al" No. 14-114 (U.S. June 25, 2015), Slip Opinion, p. 21.
338 "The Implications of a Supreme Court Finding for the Plaintiff in King vs. Burwell: 8.2 Million More Uninsured and 35% Higher Premiums" Robert Wood Johnson Foundation, January 2015, http://www.urban.org/UploadedPDF/2000062-The-Implications-King-vs-Burwell.pdf (Accessed 2/19/15), p. 1.
339 Ibid.
340 Ibid.

THE SHIFT FROM INPATIENT TO OUTPATIENT TREATMENT

The idea that medical care is delivered on an inpatient basis is continually being eroded as reforms associated with the ACA reverberate throughout the healthcare industry and new technologies continue to evolve, allowing patients to be treated for increasingly complicated diagnoses on an outpatient basis.[341] Inpatient admissions have only increased from over 31 million, in 1992, to approximately 34 million admissions, in 2012,[342] while, over the same period, outpatient visits increased from 347 million to 674 million.[343] Conversely, the number of inpatient surgeries has decreased, from just over 10 million, in 1992, to 9.5 million, in 2012,[344] while the number of outpatient surgeries has increased from 12 million to over 17 million over the same period.[345]

Compounding the mass migration to delivery of healthcare on an outpatient basis, the United States Census predicted that between 2015 and 2060, the U.S. population would increase from 320 million to over 416 million.[346] Further still, the number of people aged sixty-five and older, the segment of the population that utilizes a greater proportion of medical services relative to the rest of the general population,[347] is expected to more than double, increasing from 41 to 86 million between 2010 and 2050.[348] The continuing increases in healthcare cost containment pressures, coupled with improvements in technology and exploding growth in the over age sixty-five population, should preserve growth in outpatient demand.

> U.S. outpatient visits have increased from 347 million to 674 million between 1992 and 2012.
>
> ***American Hospital Association, 2014.***

THE HEALTHCARE MANPOWER SHORTAGE: A BARRIER TO MANAGED CARE

In 1980, the Graduate Medical Education National Advisory Committee projected a surplus of 70,000 physicians in the year 2000. As a result of this estimate, a cap on medical school

341 "The Great Migration" By Rebecca Vesely, Hospitals and Health Networks, March 11, 2014, http://www.hhnmag.com/display/HHN-news-article.dhtml?dcrPath=/templatedata/HF_Common/NewsArticle/data/HHN/Magazine/2014/Mar/cover-story-great-migration (Accessed 2/19/15); "The New Normal? Shift to put patient care, payer pressure hit hospitals" By Beth Kutscher and Melanie Evans, Modern Healthcare, August 10, 2013, http://www.modernhealthcare.com/article/20130810/MAGAZINE/308109974 (Accessed 2/19/15).

342 "Trendwatch Chartbook 2014: Trends Affecting Hospitals and Health Systems" American Hospital Association, 2014, http://www.aha.org/research/reports/tw/chartbook/2014/14chartbook.pdf (Accessed 1/15/15), A-26.

343 "Trendwatch Chartbook 2014: Trends Affecting Hospitals and Health Systems" American Hospital Association, 2014, http://www.aha.org/research/reports/tw/chartbook/2014/14chartbook.pdf (Accessed 1/15/15), A-29.

344 Ibid., A-26.

345 Ibid., A-29.

346 "U.S. Population Projections: 2015 to 2060" United States Census Bureau, December 10, 2014, http://www.census.gov/population/projections/data/national/2014/summarytables.html (Accessed 1/15/15).

347 "US Health Spending Trends by Age and Gender: Selected Years 2002-10" By David Lassman et al., Health Affairs, Vol. 33, No. 5 (May 2014), p. 830.

348 "10 Projections for the Global Population in 2050" By Rakesh Kochhar, Pew Research Center, February 3, 2014, http://www.pewresearch.org/fact-tank/2014/02/03/10-projections-for-the-global-population-in-2050/ (Accessed 1/15/15).

enrollment was put in place to control supply of physicians to the market.[349] Due to "tightly controlled" managed care in the 1990s, the projections of a physician surplus in the next decade were reaffirmed, and the number of graduates per year remained unchanged for nearly twenty-five years.[350] However, in 2006, foreseeing a physician shortage, the Association of American Medical Colleges (AAMC) recommended a 30 percent increase in U.S. medical school enrollment by 2015 in hopes of alleviating the shortage.[351]

The supply of physicians in the U.S. has not kept pace with the demand for healthcare services. In fact, the gap between supply and demand may increase, as the sources of physician supply remain insufficient and the drivers of demand (e.g., the aging population and the increase in the number of insured under the ACA's individual mandate) intensify.[352] However, new models of care delivery, as well as advances in medical technology, may reduce the risk of potential future shortages. Given the demographic shift towards an older population, primary care is an area of particular concern.

Various organizations have constructed forecasts regarding the potential shortage of physicians over the next several years. For example, in June 2010, the Association of American Medical Colleges (AAMC) projected that by 2025, the U.S. would have a shortage of 130,000 physicians, over half of whom would be primary care physicians.[353] More recently, in November 2013, the Health Resources and Services Administration (HRSA) projected that by 2020, the U.S. would need an additional 20,000 primary care physicians in order to meet demand.[354] The same HRSA projection also forecasted an increase in the supply of nurse practitioners (NPs) and physician assistants (PAs), which reduced the projected shortage to 6,400 full-time equivalent (FTE) physicians.[355] However, it should be noted that these findings are restricted to primary care. Increased assistance from NPs and PAs may do little to help a shortage in certain areas of care that require the advanced training of a specialized physician.

> The Association of American Medical Colleges (AAMC) projected a physician shortage of 130,000 physicians by the year 2025.
>
> ***Association of American Medical Colleges, 2010.***

As suggested by the inclusion of NPs and PAs in the HRSA forecast, projections of a physician shortage may be overstated. Research by the Research and Development (RAND) Corporation

349 "The Complexities of Physician Supply and Demand: Projections Through 2025" By Michael J. Dill and Edward S. Salsberg, Association of American Medical Colleges, November 2008, p. 12.
350 "Looming Shortage of Physicians Raises Concerns About Access to Care" By Mike Mitka, Journal of the American Medical Association, Vol. 297, No. 10 (March 14, 2007), p. 1045-1046.
351 "The Complexities of Physician Supply and Demand: Projections Through 2025" By Michael J. Dill and Edward S. Salsberg, Association of American Medical Colleges, November 2008, p. 12.
352 "The Impact of Health Care Reform on the Future Supply and Demand for Physicians: Updated Projections Through 2025" Association of American Medical Colleges, June 2010, https://www.aamc.org/download/158076/data/updated_projections_through_2025.pdf (Accessed 5/22/14).
353 Ibid.
354 "Projecting the Supply and Demand for Primary Care Practitioners Through 2020" Health Resources and Services Administration, November 2013, http://bhpr.hrsa.gov/healthworkforce/supplydemand/usworkforce/primarycare/projectingprimarycare.pdf (Accessed 5/21/14), p. 1-3.
355 Ibid.

found that the potential shortage of primary care physicians may be lessened not only by the inclusion of NPs and PAs, but also by modifying how primary care is delivered.[356] Specifically, the RAND research found that if (1) the use of Patient Centered Medical Homes (PCMHs) grew from 15% to 45%; (2) the use of Nurse-managed Health Centers (NMHCs) grew from 0.5% to 5%; and (3) medical homes could use improvements in technology and techniques to handle 20% more patients, then the projected shortage of primary care physicians could be virtually eliminated by 2025.[357] In the event that a physician shortage does occur, such a shortage may interrupt the efficient delivery of healthcare, which could cause deterioration in the cost and quality of healthcare services.[358]

In addition to the shortage of physicians across all specialties, there is a growing shortage of physicians seeking to practice in primary care medicine as compared to specialty practitioners.[359]

Possibly the largest factor contributing to the shortage is the disparity in pay, as specialists often earn twice the pay of primary care physicians and work more predictable hours.[360] Given that medical students graduate with a significant amount of debt (the class of 2014 had an average debt load of $176,348, which was an increase of 4% compared to the following year[361]), many young practitioners are drawn to the more lucrative specialty practices.[362]

> "Primary care physicians (PCPs) believe they treat the conditions that patients have, while specialists and surgeons believe their patients have the conditions they treat."

> **Old Medical Adage**
>
> "Specialists and surgeons relegate the complaints of primary care physicians as 'the revenge of the C student.'"

356 "Research Highlight: New Approaches for Delivering Primary Care could Reduce Predicted Physician Shortage" RAND Corporation, 2013, http://www.rand.org/content/dam/rand/pubs/research_briefs/RB9700/RB9752/RAND_RB9752.pdf (Accessed 12/3/14); "Nurse Managed Health Centers and Patient-Centered Medical Homes Could Mitigate Expected Primary Care Physician Shortage" By David I. Auerbach, et al., Health Affairs, Vol. 32, No. 11 (November 2013), p. 1933-1941.

357 Ibid.

358 "Physician Supply and the Affordable Care Act" By Elayne J. Heisler, Congressional Research Service, January 15, 2013, http://op.bna.com/hl.nsf/id/myon-93zpre/$File/crsdoctor.pdf (Accessed 5/22/14), p. 1.

359 "Can't find a Doctor? You're Not Alone" By Nancy Shute, U.S. News and World Report, March 19, 2008, http://health.usnews.com/articles/health/living-well-usn/2008/03/19/cant-find-a-doctor-youre-not-alone.html (Accessed 10/05/09).; "Match Day: High-Paid Specialties Still IN, Primary Care Still Out" By Jacob Goldstein, Wall Street Journal Blogs, (March 19, 2009), http://blogs.wsj.com/health/2009/03/19/match-day-high-paid-specialties-still-in-primary-care-still-out/ (Accessed 3/27/09); "Will Generalist Physician Supply Meet Demands of an Increasing Aging Population" By Jack M. Colwill, James M. Cultice, and Robin L. Kruse, Health Affairs, Web Exclusive, Vol. 27, No. 3 (April 29, 2008), p. w232-w241.

360 "Can't find a Doctor? You're Not Alone" By Nancy Shute, U.S. News and World Report, March 19, 2008, http://health.usnews.com/articles/health/living-well-usn/2008/03/19/cant-find-a-doctor-youre-not-alone.html (Accessed 10/05/09).; "Match Day: High-Paid Specialties Still IN, Primary Care Still Out" By Jacob Goldstein, Wall Street Journal Blogs, March 19, 2009, http://blogs.wsj.com/health/2009/03/19/match-day-high-paid-specialties-still-in-primary-care-still-out/ (Accessed 03/27/09).

361 "Medical Student Education: Debt, Costs, and Loan Repayment Fact Card" Association of American Medical Colleges, October 2014, https://www.aamc.org/download/152968/data/debtfactcard.pdf (Accessed 1/30/15).

362 "Can't find a Doctor? You're Not Alone" By Nancy Shute, U.S. News and World Report, March 19, 2008, http://health.usnews.com/articles/health/living-well-usn/2008/03/19/cant-find-a-doctor-youre-not-alone.html (Accessed 10/05/09).; "Match Day: High-Paid Specialties Still IN, Primary Care Still Out" By Jacob Goldstein, Wall Street Journal Blogs (March 19, 2009), http://blogs.wsj.com/health/2009/03/19/match-day-high-paid-specialties-still-in-primary-care-still-out/ (Accessed 03/27/09).

Table 1-8 outlines several of the most important twentieth century figures and events as they relate to the healthcare profession.

Table 1-8: Influential Figures, Key Places, and Important Events During the Twentieth Century

Influential Figures*,**,†,††			
Name	**Birth/Death**	**Location**	**Claim to Fame**
Franklin D. Roosevelt	1882–1945	Washington, D.C., U.S.	U.S. President from 1932–45, who attempted to implement a national health insurance program in 1935 and again in 1939
Harry S. Truman	1884–1972	Washington, D.C., U.S.	U.S. President from 1945–53, who attempted to implement a national health insurance program
John F. Kennedy	1917–63	Washington, D.C., U.S.	U.S. President from 1961–63, whose term was plagued by a recession, unemployment, and a stagnant economy
Lyndon B. Johnson	1908–73	Washington, D.C., U.S.	U.S. President from 1963–69, who, with assistance from a democratic sweep, passed Medicare parts A and B, and Medicaid
Paul Starr	1949–present	Princeton, N.J., U.S.	Renowned sociologist who won the Pulitzer Prize for his book, *The Social Transformation of American Medicine*

Events‡	
Name	**Definition**
Bureau of Health Professions	Part of HHS, deals with grants, studies, and designations of the health workforce

* *"Harry S. Truman Versus the Medical Lobby" By Monte M. Poen, University of Missouri Press, 1979.*

** *"A Brief History: Universal Health Care Efforts in the U.S." By Karen S. Palmer, MPH, MS, Physicians for a National Health Program, Spring 2009, www.pnhp.org/facts/a_brief_history_universal_health_care_efforts_in_the_us.php?page=all (Accessed 2/17/10)*

† *"The Social Transformation of American medicine," By Paul Star, New York, NY: Basic Books, Inc., 1982.*

†† *"Paul Starr: Biographical Sketch", Princeton University, October 19, 2008, www.princeton.edu/~starr/starrbio.html (Accessed 2/24/10)*

‡ *"Projected supply, demand, and shortages of registered nurses: 2000–2020" United States Department of Health and Human Services, Health Resources and Services Administration, Bureau of Health Professions, National Center for Health Workforce Analysis, July 2002, www.ahcancal.org/research_data/staffing/Documents/Registered_Nurse_Supply_Demand.pdf (Accessed 4/10/09).*

THE HEALTHCARE PROFESSIONAL'S DUTY TO THE STATE

The practice of medicine began as hypothetical thought and transformed over time into a scientific industry in growing demand. Ultimately, a company's success is a function of market control and profit. However, market competition within the healthcare industry is ultimately driven by the ethical duties unique to the medical profession. In addition to the duty to *primum non nocere*—first (or above all) do no harm—healthcare professionals are also expected to exhibit "[q]ualities such as wisdom, compassion, human concern, and service."[363] However, business objectives built around these ethical values may conflict with the entrepreneurial objectives that take priority in most industries.[364] Further, due to the community-based nature of many healthcare services, industry trends are driven largely by public opinion on matters related to health status.[365] As such, the healthcare professional's ethical duties are rooted deeply in

363 "'Primum Non Nocere' and the Principle of Non-Maleficence" By Raanan Gillon, British Journal of Medicine, Vol. 21 (July 13, 1985) p.130; "Medical Ethics: Common Ground for Understanding" By K.D. O'Rourke and D. Brodeur, St. Louis, MO: The Catholic Health Association of the United States, 1986, p. 36.

364 "Medical Ethics: Common Ground for Understanding" By K.D. O'Rourke and D. Brodeur, St. Louis, MO: The Catholic Health Association of the United States, 1986, p. 36-39.

365 "No Margin, No Mission: Health-Care Organizations and the Quest for Ethical Excellence" By S.D. Pearson, J.E. Sabin and E.J. Emanuel, New York, NY: Oxford University Press, 2003, p. vii- viii.

community benefit.[366] Healthcare delivery is subject to a unique *sixth force* of the competitive equation: the requirement that community benefit maintain weighted significance in the decisions that impact the provision of care.[367]

According to the AMA's 1908 publication, *The Doctor's Duty to the State*:

> "*The doctor's highest duty is to be honest and to fight for honesty in his profession and the state...He, as others, sees in history the same process exhibited in the remote effects of corporate and governmental vice...To whom then shall the state look for preservation of its health, to whom shall the state call for help in time of trouble, in whom shall the state place its hope for deliverance...The honest citizen; and the honest doctor is his best representative.*"[368]

Unfortunately, the public's perception of healthcare providers has gradually eroded during the past decade, with patients becoming increasingly distrustful of hospitals, doctors, and drug companies and with a growing perception that there has been a lapse in attention to the healthcare professional's highest ethical duty.[369] The ACA has implemented a tool to combat the growing distrust of healthcare professionals among patients, the *Open Payments* database.[370] The *Open Payments* database is a federally run program that collects the information about financial relationships between doctors and hospitals and other third parties to make these transactions public information.[371] This availability will add a level of transparency between the patient and physician in attempts to rebuild trust.[372]

In the face of rapidly accelerating changes in the healthcare industry, it is an ever-present challenge for healthcare professionals to maintain their professional obligations as well as their financial solvency. Notwithstanding this duality of objective, medical ethics remain a market driver that distinguishes healthcare from all other industries.

366 "Medical Ethics: Common Ground for Understanding" By K.D. O'Rourke and D. Brodeur, St. Louis, MO: The Catholic Health Association of the United States, 1986, p. 41-42.
367 Ibid., p. 36-39.
368 "The Doctor's duty to the State: Essays on the Public Relations of Physicians" By J. B. Roberts, Chicago, IL: American Medical Association, 1908, p. 9, 31.
369 "Futurescan: A Forecast of Healthcare Trends, 2003-2007" By R. Coile, Chicago, IL: Health Administration Press, 2003, p. 33.
370 "Open Payments (Physician Payments Sunshine Act)" Centers for Medicare and Medicaid Services, http://www.cms.gov/Regulations-and-Guidance/Legislation/National-Physician-Payment-Transparency-Program/Downloads/Physician-fact-sheet.pdf (Accessed 2/19/15), p. 1.
371 "Open Payments" Centers for Medicare and Medicaid Services, http://www.cms.gov/openpayments/ (Accessed 1/30/15).
372 "Open Payments (Physician Payments Sunshine Act)" Centers for Medicare and Medicaid Services, http://www.cms.gov/Regulations-and-Guidance/Legislation/National-Physician-Payment-Transparency-Program/Downloads/Physician-fact-sheet.pdf (Accessed 2/19/15), p. 1.

THE HISTORY YOU DON'T KNOW

The only thing new in the world is the history you don't know.

Harry S. Truman (1974), in Plain Speaking: An Oral Biography of Harry S. Truman

Discussed in subsequent chapters of this *Guide*, and as mentioned in the introduction, the healthcare industry's four pillars, the reimbursement, regulatory, competitive, and technology environments, are founded in the historical development of medicine and science. These historical foundations have played a significant role in influencing the development of several other aspects of the healthcare delivery system, for example, the organizational structure and emerging models of healthcare, and they also have had an impact on the practice of the healthcare consulting, both of which are discussed in more herein.

Key Sources

Key Source	Description	Citation	Website
The Social Transformation of American Medicine	Paul Starr's work discussing the evolution of American Medicine.	"The Social Transformation of American Medicine: The Rise of a Sovereign Profession and the Making of a Vast Industry" By Paul Starr, New York, NY: Basic Books Inc., 1982.	n/a
Oath of Hippocrates	An oath taken by physicians that was originally written by Hippocrates but has been revised multiple times to date.	**Original**: "The Hippocratic Oath: Text, Translation, and Interpretation" By Ludwig Edelstein, Baltimore, MD: Johns Hopkins Press, 1943.	**Original:** http://guides.library.jhu.edu/content.php?pid=23699&sid=190555
		Modern: "The Hippocratic Oath and the Ethics of Medicine" By Steven H. Miles, Oxford University Press, 2004.	**Modern:** http://guides.library.jhu.edu/content.php?pid=23699&sid=190964
Centers for Medicare and Medicaid	"The US federal agency which administers Medicare, Medicaid, and the Children's Health Insurance Program."	"Guidelines for Ensuring the Quality of Information Disseminated to the Public: E. Centers for Medicare & Medicaid Services" Centers for Medicare and Medicaid, http://aspe.hhs.gov/infoquality/Guidelines/CMS-9-20.shtml (Accessed 4/2/15).	www.cms.hhs.gov
The Doctor's Duty to the State	Roberts' work discussing the healthcare professional's state and federal responsibility to community benefit.	"The Doctor's Duty to the State: essays on the Public Relations of Physicians" By John Bigham Roberts, Chicago, IL: American Medical Association, 1908.	n/a

Associations

Type of Association	Professional Association	Description	Citation	Contact Information
National	American Medical Association	The American Medical Association *"promote[s] the art and science of medicine and the betterment of public health*" through several *guiding principles*.	"AMA Mission & Guiding Principles," American Medical Association, www.ama-assn.org/ama/pub/about-ama/our-mission.shtml (Accessed 4/2/15).	American Medical Association AMA Plaza 330 North Wabash Avenue Suite 39300 Chicago, IL 60611-5885 Phone: 800-621-5885 Fax: n/a E-mail: n/a www.ama-assn.org
National	Association of American Medical Colleges (AAMC)	The AAMC represents all 141 accredited U.S. and 17 accredited Canadian medical schools; approximately 400 major teaching hospitals and health systems, including 51 Department of Veterans Affairs medical centers; and 90 academic and scientific societies. Through these institutions and organizations, the AAMC represents 148,000 faculty members, 83,000 medical students, and 115,000 resident physicians.	"About the AAMC," the Association of American Medical Colleges, https://www.aamc.org/about/ (Accessed 4/2/15).	Association of American Medical Colleges 2450 N Street, NW Washington, DC 20037-1126 Phone: 202-828-0400 E-mail: n/a Fax: 202-828-1125 www.aamc.org

Chapter 2

Reimbursement Environment

KEY TERMS

BlueCross BlueShield
Bundling
Capitation
Charge Capture
Children's Health Insurance Program
Civilian Health and Medical Program of the Department of Veteran Affairs
Civilian Health and Medical Program of the Uniformed Services
Disproportionate Share Hospital (DSH) Payments
Fee Schedule
Fee-for-Service
Health Maintenance Organization (HMO)
Health Savings Accounts
Independent Practice Association
International Classification of Diseases, Ninth Revision (ICD-9)
International Classification of Diseases, Tenth Revision (ICD-10)
Lockboxes
Managed Care
Medicaid
Medicare
Nonparticipating Provider
Participating Provider
Point-of-Service Plans (POS)
Preferred Provider Organization (PPO)
Revenue Cycle
Self-Insurance
TRICARE

Key Concept	Definition	Citation	Mentioned on Page #
Reimbursement	Payment for provider services made by patients and third-party payors. Unlike most businesses, healthcare providers may have hundreds of different contracts with payors, each with varying terms and rates for the same services.	"Reimbursements" in "Medical Practice Management System" By Linda Nadeau, Clifton Park, NY: Thomson Delmar Learning, 2007, p. 198; "Financial Environment of Health Care Organizations" in "Essentials of Health Care Finance" By William O. Cleverley and Andrew E. Cameron, Sixth Edition, Sudbury, MA: Jones and Bartlett Publishers, Inc., 2007, p. 36–37.	84
Pay-for-Performance (P4P)	A remuneration system in which part of the payment is dependent on performance as measured against a defined set of criteria. Although a P4P system can be structured in several ways, the common elements to all systems are (1) a set of targets or objectives that define what will be evaluated; (2) measures and performance standards for establishing the target criteria; and (3) rewards—typically financial incentives—that are at risk, including the amount and the method for allocating the payments among those who meet or exceed the reward threshold.	"Pay-for-Performance in Health Care" By Jim Hahn, CRS Report for Congress, December 12, 2006, http://www.allhealth.org/briefingmaterials/crsreportingforcongress-pay-for-performanceinhealthcare-501.pdf (Accessed 2/23/15), p. i.	169
Medical Home	A patient-centered model of healthcare delivery and payment reform that focuses on improving the quality of care and reducing costs through its emphasis on the role of primary care.	"Medical Home Models: Improving Care and Reducing Costs in Healthcare" By Laura M. Greene, Healthcare Intelligence Network, May 2009, www.hin.com/cgi-local/link/ news/pl.cgi?pcmh09 (Accessed 5/24/10).	183
Resource Based Relative Value System (RBRVS)	The scale on which Medicare bases its standardized physician payment schedule. The RBRVS determines payments based on the value of the resources necessary to provide a particular service.	"Overview of the RBRVS" American Medical Association, http://www.ama-assn.org/ama/pub/physician-resources/solutions-managing-your-practice/coding-billing-insurance/medicare/the-resource-based-relative-value-scale/overview-of-rbrvs.shtml (Accessed 10/5/09).	106
Relative Value Unit (RVU)	The RBRVS assigns each procedure a relative value unit, or RVU. Three types of RVUs exist: one for physician work (wRVU), one for practice expense (PE), and one for malpractice costs. The three components of the RVU can be broken down as follows: 1. Work. The estimated value of the time, effort, expertise, and intensity of the service, approximately 55 percent of the RVU value. 2. Professional Liability Insurance (PLI). The estimated value of malpractice cost for the service—approximately 3 percent of RVU value. 3. Practice expense. The estimated value of overhead and other expenses necessary to run the practice, approximately 42 percent of the RVU value.	"Gauging Emergency Physician Productivity: Are RVUs the Answer" By John Proctor, American College of Emergency Physicians, www.acep.org/practres.aspx?id=30306 (Accessed 4/1/09).	108

Key Concept	Definition	Citation	Mentioned on Page #
Healthcare Common Procedure Coding System (HCPCS)	A coding system that provides the payor information in regard to the procedures performed in the treatment of patients. The system does not relay diagnosis information. HCPCS codes are used by hospitals to report information on procedures performed for outpatient services and by physicians to report information in connection with the performance of procedures in both the inpatient and outpatient settings. Two HCPCS levels exist: Level I codes are referred to as Current Procedural Terminology (CPT) codes, and Level II codes are temporary codes used to represent services, supplies, and procedures for which CPT codes do not yet exist.	"Billing and Coding for Health Services" in "Essentials of Health Care Finance" By William O. Cleverley and Andrew E. Cameron, Sixth Edition, Sudbury, MA: Jones and Bartlett Publishers, Inc., 2007, p. 18.	91
Current Procedural Terminology (CPT)	A system developed by the American Medical Association that is used by providers to report information to patients and insurers about services and procedures provided to patients.	"Understanding Health Insurance: A Guide to Billing and Reimbursement" By Michelle A. Green and JoAnn C. Rowell, Twelfth Edition, Stamford, CT: Cengage Learning, 2013, p. 218-219.: A Guide to Billing and Reimbursement" By Michelle A. Green and JoAnn C. Rowell, Twelfth Edition, Stamford, CT: Cengage Learning, 2013, p. 218.	91
Diagnosis-Related Group (DRG)	A way to categorize patients in hospitals based on the relative intensity of services related to that diagnosis. Patients typically are classified based on their admitting diagnosis, which is grouped with other diagnoses into a DRG so that the hospital can identify groups of patients that require roughly the same amount of resources.	"Diagnosis-related group (DRG)," By Charlyn Stanberry, American Health Lawyers Association, 8/10/2012, p. 1, http://www.healthlawyers.org/hlresources/Health%20Law%20Wiki/Diagnosis-related% 20group%20(DRG).aspx (Accessed 6/3/14).	115
Workers' Compensation	Laws that provide healthcare coverage and monetary payments to employees injured at work or suffering from an occupational disease and monetary benefits for the dependents of employees killed on the job. In addition, the laws limit the financial liability of employers, and they nearly eliminate the financial liability of co-workers for most accidents.	"Understanding Health Insurance: A Guide to Billing and Reimbursement" By Michelle A. Green and JoAnn C. Rowell, Twelfth Edition, Stamford, CT: Cengage Learning, 2013, p. 600.	151
Indian Health Services (IHS)	An agency located within the United States Department of Health and Human Services. It provides healthcare services to approximately 1.9 million American Indians and Alaska Natives directly through tribal healthcare programs and indirectly through purchases from private providers.	"Indian Health Service Introduction" By Indian Health Services, I.gov, June 2009, http://www.ihs.gov/PublicInfo/PublicAffairs/Welcome_Info/IHSintro.asp (Accessed 8/10/09).	153

(continued)

Key Concept	Definition	Citation	Mentioned on Page #
Commercial Insurers	Plans that are offered by life insurance companies, casualty insurance companies, and companies that were formed for the sole purpose of offering health insurance.	"The Financial Environment" in "Healthcare Finance: An Introduction to Accounting and Financial Management" By Louis C. Gapenski, Third Edition, Chicago, IL: Health Administration Press, 2004, p. 35.	154
Fee Allowance Schedule	A managed care reimbursement scheme by which the fees for procedures are explicitly laid out and the physician agrees to accept those fees as full payment, unless the discounted charges are less than the fee schedule in which case the plan pays the lesser of the two.	"The Managed Health Care Handbook, Third Edition" By Peter R. Kongstvedt, Ernst & Young, 1996, p. 140–41.	170
Relative Value Scale (RVS)	The reimbursement scheme by which each procedure is assigned a relative value which is multiplied by a negotiated factor (the multiplier), usually a discount, to arrive at a payment.	"The Managed Health Care Handbook, Third Edition" By Peter R. Kongstvedt, Ernst & Young, 1996, p. 140–41.	84
Performance Based Fee-For-Service	A managed care reimbursement scheme using a scale that adjusts fees based on individual medical specialties. In this approach, each specialty has a per-member-per-month budget (for example, $2 per member per month for OB/GYN), and actual costs are measured against that budget. If costs exceed the budget, then fees are lowered but only for that specialty and vice versa if costs are better than budget. This system requires a highly sophisticated tracking system and a large enough patient base to make the analysis statistically significant, which makes it well suited for independent practice associations.	"The Managed Health Care Handbook, Third Edition" By Peter R. Kongstvedt, Ernst & Young, 1996, p. 181.	170
Retainer	A managed care reimbursement scheme that involves a set monthly payment amount for each physician, reconciled at periodic intervals based on actual utilization, either as a pre-negotiated discount on charges or on some other objective measure. This ensures the availability of physicians to members and provides for the steady income desired by physicians, while still allowing payment on the basis of actual utilization.	"The Managed Health Care Handbook, Third Edition" By Peter R. Kongstvedt, Ernst & Young, 1996, p. 186.	170
Hourly & Salary Reimbursement	A way to pay physicians at an hourly rate or a salary for performing services. This type of arrangement is common in emergency departments or other settings in which a physician needs to be available for a defined period of time. This arrangement also works when buying on-call coverage to back up an in-house physician.	"The Managed Health Care Handbook, Third Edition" By Peter R. Kongstvedt, Ernst & Young, 1996, p. 186.	170

Key Concept	Definition	Citation	Mentioned on Page #
Single Fee Reimbursement	A scheme under which fees are paid for a procedure no matter how much time and effort is required. Two applications of this method exist: 1. Case rates or flat rates. The same rate is paid for a procedure no matter what choice of treatment used; for example, a physician is reimbursed the same amount for delivering a baby regardless of whether it was a vaginal birth or delivery by way of a cesarean section surgery. 2. Global fees. A flat rate encompassing more than a single type of service. For example, a global fee for surgery may include all preoperative and postoperative care as well as one or two follow-up office visits. A global fee for obstetrics may include all prenatal and postnatal care.	"The Managed Health Care Handbook, Third Edition," by Peter R. Kongstvedt, Ernst & Young, 1996, p. 186–87.	170
Bundled Case Rates or Package Pricing	A form of reimbursement that combines institutional and professional charges into a single payment; for example, a plan may negotiate a bundled case rate of $20,000 for cardiac bypass surgery, which covers all staff for preoperative and postoperative care. Usually outlier provisions exist for cases that become catastrophic.	"The Managed Health Care Handbook, Third Edition," by Peter R. Kongstvedt, Ernst & Young, 1996, p. 187.	170
Periodic Interim Payments (PIPs) and Cash Advances	A managed care reimbursement plan that advances the provider a set amount of cash equivalent to a defined time period's expected reimbursable charges. As claims come in from a physician, the claims are subtracted from the PIP, which is routinely replenished. In this way, the physician has a positive cash flow, as well as the use of the plan's money, interest free. This method may be employed in a plan with a heavy POS enrollment.	"The Managed Health Care Handbook, Third Edition" By Peter R. Kongstvedt, Ernst & Young, 1996, p. 187.	170

OVERVIEW

Healthcare reimbursement is the payment received by providers for the services they render to patients.[1] Most providers will be reimbursed for their services by patients and by third-party payors, including, but not limited to, employers, insurance companies, and government agencies.[2] Unlike most businesses, which bill their customers based on a fixed-price per unit set by the business and multiplied by the quantity sold, healthcare providers may have hundreds of different contracts with payors, each with varying terms and rates for the same services.[3] These payments may take a variety of forms, including payment at a fee set by the provider, a discounted fee negotiated by the parties, a fee schedule set by the payor, a relative value scale that takes into consideration various costs incurred by the provider rendering the service in a particular geographic locale, *capitation* based on the number of individuals enrolled in a plan, bundled payments which pay providers on a per-diem or per-case rate multiplied by the length of stay, or a *prospective payment system* (PPS), which reimburses providers a set amount in accordance with a patient's diagnosis or treatment.[4]

In 2013, U.S. healthcare expenditures totaled $2.9 trillion, or 17.4 percent of the gross domestic product (GDP).[5] U.S. healthcare costs have exceeded general inflation for twenty years.[6] To combat these rising costs, private payors, state governments, and the federal government have implemented PPSs, fee schedules, selective contracting agreements, and managed care principles, but, until recently, this continued growth has yet to slow.[7] In addition, healthcare reform has taken center stage in federal and state politics, with reform efforts aimed at reducing the cost of care and improving healthcare by tying provider reimbursement to patient outcomes and the quality of care, allowing providers to receive a share of the savings attributable to their cost-cutting efforts, increasing the coordination of care, increasing the reliance on capitated payments and bundling provider payments.

HEALTHCARE REVENUE CYCLE

The *revenue cycle* describes the process by which a provider practice schedules patients, diagnoses conditions, documents and codes the diagnoses, bills payors, complete claims resolutions, and collects billable charges from the payor and the patient to recover revenue for the services provided.[8] See Figure 2-1 for a pictorial description of the revenue cycle in healthcare.

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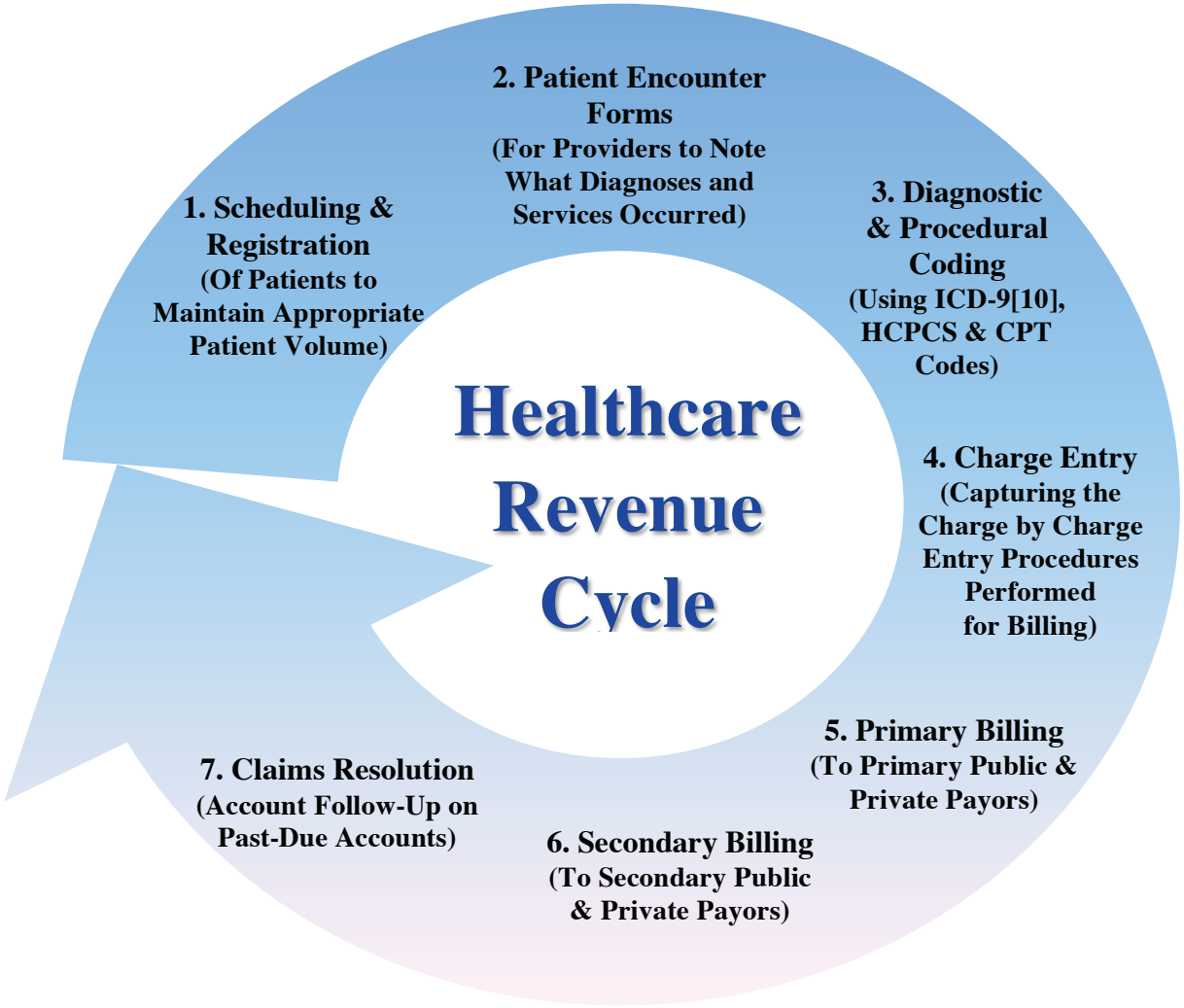
1 "Healthcare Valuation: The Financial Appraisal of Enterprises, Assets, and Services in an Era of Reform" By Robert James Cimasi, Volume I, New York, NY: John Wiley & Sons, 2014, p. 85.
2 "Medical Practice Management System" By Linda Nadeau, Clifton Park, NY: Thomson Delmar Learning, 2007, p. 198.
3 "Essentials of Heath Care Finance" By William O. Cleverley and Andrew E. Cameron, 6th Edition, Sudbury, MA: Jones and Bartlett Publishers, Inc., 2007, p. 36-37.
4 "Essentials of Heath Care Finance" By William O. Cleverley and Andrew E. Cameron, 6th Edition, Sudbury, MA: Jones and Bartlett Publishers, Inc., 2007, p. 36-45.
5 "NHE Fact Sheet" Centers For Medicare & Medicaid Services, December 3, 2014, http://www.cms.gov/ Research-Statistics-Data-and-Systems/Statistics-Trends-and-Reports/NationalHealthExpendData/NHE-Fact-Sheet.html (Accessed 1/29/15).
6 "IT Investments for Naught Unless They Cut Healthcare Costs, Says Greenspan" By Neil Versel, Healthcare IT News, April 9, 2009, http://www.healthcareitnews.com/news/it-investments-naught-unless-they-cut-healthcare-costs-says-greenspan (Accessed 8/25/09).
7 "Introduction to Health Services" By Stephen J. Williams and Paul R. Torrens, Seventh Edition, Clifton Park, NY: Thomson Delmar Learning, 2008, p. 106.
8 "Financial Management of the Medical Practice" By Max Reiboldt, Second Edition, The Coker Group, American Medical Association, 2002, p. 12-14.

ELEMENTS OF THE REVENUE CYCLE

Figure 2-1: The Healthcare Revenue Cycle



Step 1: Scheduling and Registration

The revenue cycle typically begins when a patient schedules his or her appointment.[9] The importance of a practice's scheduling system should not be underestimated, as patient-physician relationships and a healthy revenue cycle depend on it.[10] Although a system that overbooks appointments may lead to a stressful office environment that could negatively affect revenue, a steady flow of patients is what brings in revenue to the practice.[11] Therefore, to maximize

9 "Financial Management of the Medical Practice" By Max Reiboldt, Second Edition, The Coker Group, American Medical Association, 2002, p. 11.
10 "Medical Practice Management System" By Linda Nadeau, Clifton Park, NY: Thomson Delmar Learning, 2007, p. 96.
11 Ibid.

revenue, when developing a scheduling system, private practices should give sufficient thought to the type of patients to be seen, their medical conditions, provider tasks that need to be completed throughout the day (for example, chart review and dictation), the provider's scheduling preferences, and the likelihood of walk-ins and no-shows.[12]

A key element of the revenue cycle is an effective registration system that accurately collects patient information. This is especially important when dealing with claims that are paid by third-party payors, because erroneous or omitted information may delay reimbursement.[13] To ensure revenue maximization, a patient's demographic information should be verified every time the patient sees a provider.[14] In addition, staff should check the patient's eligibility status and satisfy any pre-authorization requirements before the patient receives services in order to avoid the denial of a claim.[15]

Volume Management

Volume management is critical to a successful practice because the main objective of an appointment scheduling system is to have a continuous succession of patients each day.[16] Too often, healthcare practices use off-the-shelf software or appointment books, and they proceed to schedule patients in the predetermined time slots without considering whether this schedule realistically accommodates the needs of the practice.[17] To better manage patient volume, an appointment scheduling system should be set according to the amount of time each provider prefers to spend per patient type and appointment type, the maximum number of patients to schedule per day, and the amount of time required per appointment type for every provider in the practice.[18] An appointment system based on these criteria will ensure a workable schedule that maximizes patient satisfaction and physician efficiency.[19]

Step 2: Patient Encounter Forms

Before services are coded for the billing process, providers must note the principal and related diagnoses and must document, with specificity, the nature and scope of services rendered during a patient encounter.[20] Providers document patient history and responses, diagnoses, procedures performed, and follow-up information on either a paper or an electronic form, known as a patient encounter form, superbill, or charge ticket. This information may be incorporated into a patient's electronic medical record (EMR).[21]

12 "Financial Management of the Medical Practice" By Max Reiboldt, Second Edition, The Coker Group, American Medical Association, 2002, p. 12.
13 Ibid.
14 Ibid.
15 "Medical Practice Management System" By Linda Nadeau, Clifton Park, NY: Thomson Delmar Learning, 2007, p. 96.
16 Ibid.
17 Ibid.
18 Ibid p. 96-98.
19 Ibid, p. 96.
20 "From Patient to Payment: Insurance Procedures for the Medical Officer, 3rd ed." By Linda Nadeau, Clifton Park, NY: Thomson Delmar Learning, 2007, p. 96.
21 Ibid, p. 31.

Step 3: Diagnostic and Procedural Coding

Accurate coding and documentation are necessary to ensure proper payment, as treatment information in a patient's medical record is used to trigger payment in the billing process.[22] The proper education of the provider and staff, and the regular review of coding procedures, can help ensure accuracy and the legitimate maximization of practice revenue.[23]

> Providers typically bill for a professional component (PC), technical component (TC), or the global diagnostic code (PC + TC) when billing for diagnostic services.
>
> ***Federal Register, 2009.***

In the case of diagnostic services, providers typically bill for both a professional fee component and a *technical component*[24] or they may report a global diagnostic code, which is a combination of both the professional fee and *technical components*.[25] If reporting is done with a global diagnostic code, reimbursement is equal to the sum of the professional fee and *technical components* that could have been billed separately for the services.[26]

The Health Insurance Portability and Accountability Act of 1996 (HIPAA) requires providers to classify (1) diagnoses and (2) clinical procedures by using several coding systems (see chapter 3, *Health Insurance Portability and Accountability Act of 1996 (HIPAA)*).[27]

> The most commonly implemented coding systems include: ICD-9, HCPCS, ICD-10, CPT-4, CDT, and the NDC.
>
> ***Centers for Medicare and Medicaid, 2014.***

The most commonly implemented coding systems include the *International Classification of Diseases, Ninth Revision (ICD-9)*, the Healthcare Common Procedure Coding System (HCPCS), for classifying ancillary services and procedures, the imminent ICD-10 (as of October 1, 2015), the Current Procedural Terminology (CPT-4) for physician procedures in both inpatient and outpatient settings, the Current Dental Terminology for dental procedures (CDT), and the National Drug Code (NDC) system.[28] For diagnosis reporting, all healthcare providers, including both physician professional practices and other facilities (for example, hospitals), use the *ICD-9, Clinical Modification* (*ICD-9-CM*). The *ICD-9 Procedure Coding System* (*ICD-9-PCS*) is used for procedure reporting for hospital inpatients. Despite the fact that ICD-9 is used universally for classifying diagnoses, procedural reporting is not as simple. Procedural coding depends on

22 "Essentials of Health Care Finance" By William O. Cleverley and Andrew E. Cameron, Sixth Edition, Sudbury, MA: Jones and Bartlett Publishers, Inc., 2007, p. 17.
23 "Financial Management of the Medical Practice" By Max Reiboldt, Second Edition, The Coker Group, American Medical Association, 2002, p. 12.
24 See the Professional Component versus Ancillary Services and Technical Component section.
25 "Medicare Program; Payment Policies Under the Physician Fee Schedule and Other Revisions to Part B for CY 2010; Proposed Rule" Federal Register Vol. 74, No. 132, (July 13, 2009), p. 33526.
26 Ibid.
27 "Transaction & Code Sets Standards: Overview" Centers For Medicare & Medicaid Services, September 26, 2014, https://www.cms.gov/Regulations-and-Guidance/HIPAA-Administrative -Simplification/TransactionCodeSetsStands/index.html?redirect=/TransactionCodeSetsStands/02_TransactionsandCodeSetsRegulations.asp (Accessed 1/30/15).
28 Ibid.

(1) whether the designated provider is a physician or a facility and (2) in the circumstance of a facility provider, whether the procedure was performed within an inpatient or outpatient system. Procedures and services submitted on a claim must be linked, by way of appropriate *CPT*, *HCPCS* Level II, or ICD-9 codes, to the ICD-9-CM code that corresponds to the diagnostic reasoning behind the claim.[29] Table 2-1 illustrates the coding systems used for services provided by each provider type within each setting.[30]

Table 2-1: HIPAA-Designated Coding[31]

Provider Type	Inpatient		Outpatient	
	Diagnosis	Procedure	Diagnosis	Procedure
Physician	ICD-9-CM	CPT	ICD-9-CM	CPT
Facility	ICD-9-CM	ICD-9-CM	ICD-9-CM	HCPCS (CPT and HCPCS Level II)

International Classification of Diseases 9th Revision—Clinical Modification

The ICD-9 system has codes that supply a payor with information regarding both the patient diagnosis and the procedures performed in treating the diagnosis.[32] HIPAA requires all healthcare providers to use the ICD-9 codes when reporting diagnosis information to payors.[33] In addition, HIPAA requires that hospitals use the ICD-9 procedural codes when reporting information to payors detailing the treatment of hospital inpatients.[34]

Shift from ICD-9 to ICD-10 Coding

In early 2009, the United States Department of Health and Human Services (HHS) announced a final rule that called for the replacement of the current ICD-9 code set used to report healthcare diagnoses and procedures with the *International Classification of Diseases, Tenth Revision (ICD-10)* set by October 1, 2013.[35] This date was delayed twice, most recently as a part of the Protecting Access to Medicare Act of 2014, which set the compliance date for October 1, 2015.[36] The delays of implementation have been the result of concerns among many in the industry that adopting ICD-10 will require substantial capital spending and require complete I implementation. However, the adoption of the new system will offer several benefits to help enhance the quality and efficiency of care. These include the facilitation of quality data reporting, support for pay for performance payment methodologies, improved billing accuracy, and the ability for international comparison of the incidence and spread of disease.[37]

29 "Essentials of Health Care Finance" By William O. Cleverley and Andrew E. Cameron, Sixth Edition, Sudbury, MA: Jones and Bartlett Publishers, Inc., 2007, p. 17.
30 Ibid.
31 Ibid.
32 Ibid.
33 Ibid.
34 Ibid.
35 "Health Insurance Reform: Modifications to the Health Insurance Portability and Accountability Act (HIPAA); Final Rule" Federal Register Vol. 74, No. 3328 (January 16, 2009), p. 3328; "Switching to ICD-10: The Impact on Physicians" By Lindsay Law and Mary Ann Porucznik, American Academy of Orthopaedic Surgeons/American Association of Orthopaedic Surgeons, AAOS.org, February 2009, http://www.aaos.org/news/aaosnow/feb09/reimbursement1.asp (Accessed 8/9/09).
36 "Protecting Access to Medicare Act of 2014" Pub. L. No. 113-93, § 212, 128 Stat. 1040, 1047 (April 1, 2014).
37 "HHS Issues Final ICD-10 Code Sets and Updated Electronic Transaction Standards Rules" Centers For Medicare & Medicaid Services, News Release, January 15, 2009, http://www.hhs.gov/news/press/2009pres/01/20090115f.html (Accessed 10/07/09).

Even with the calls for further delays, many in the industry are preparing for the October 1, 2015 date to take effect. In 2014, an HIMSS survey of healthcare IT professionals found that while only 69% of respondents felt the conversion to ICD-10 was a top IT priority, 92% of the respondents indicated their conversion would be complete by October 2014.[38] Additionally, as of 2013, 64% of hospital respondents began the process of re-training their coding staff and 68% began updating their document improvement education for the conversion to ICD-10.[39]

Differences between ICD-9 and ICD-10

Note the several major differences between the current ICD-9 code set and the new ICD-10 code set:

(1) **Size.** The ICD-9 code set contains 13,000 codes and parts of the code set are running out of space, whereas the ICD-10 code set contains more than 68,000 codes and has ample room for the addition of new diagnoses and procedures.[40]
(2) **Specificity.** The new ICD-10 code set provides for greater specificity when diagnosing conditions to allow for a greater amount of detailed and specific information to be documented in an episode of care. For example, under the new system, 1,170 codes describe angioplasty, whereas the ICD-9 code set has only one. This allows the episode of care to document the precise location of the blockage and what instruments were used to expand the vessel.[41]
(3) **Basic information.** It is anticipated that the ICD-10 system will improve the quality of care provided through the communication of basic information the ICD-9 code does not provide, such as informing providers about which side of a patient's body the condition occurred.[42]

Financial Impact of the Shift

The switch to the ICD-10 code set will not be without costs. According to a 2008 study, physicians will incur significant expenditures associated with the change in six key areas:

(1) employee education and training;
(2) business processes;
(3) billing documents;
(4) information technology systems;
(5) documentation; and
(6) disruptions in cash flow.[43]

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38 "25th Annual HIMSS Leadership Survey," HIMSS, February 24, 2014, http://himss.files.cms-plus.com/FileDownloads/2014-HIMSS-Leadership-Survey.pdf (Accessed 4/11/14).

39 "One Year from ICD-10 Transition, Small- and Mid-Sized Hospitals Increased Staff Training Programs but Lag in Payer Participations, Financial Modeling and Denial Strategies" HRAA, October 1, 2013, http://healthrevenue.com/news/one-year-icd-10-transition-small-and-mid-sized-hospitals-increased-staff-training-programs-lag (Accessed 4/11/14).

40 "ICD-10 Changes from ICD-9" Centers For Medicare & Medicaid Services, 2014, http://www.medicaid.gov/medicaid-chip-program-information/by-topics/data-and-systems/icd-coding/icd-10-changes-from-icd-9.html (Accessed 1/30/15).

41 "Health Plans Estimated Costs of Implementing ICD-10 Diagnosis Coding" By Hannah Yoo and Kelly Buck, America's Health Insurance Plans' Center for Policy & Research, September 2010, https://www.ahip.org/SurveyICD-10CostsSept2010/ (Accessed 1/30/15), p. 2.

42 "HHS Issues Final ICD-10 Code Sets and Updated Electronic Transaction Standards Rules" Centers For Medicare & Medicaid Services, News Release, January 15, 2009, http://www.hhs.gov/news/press/2009pres/01/20090115f.html (Accessed 10/07/09).

43 "The Impact of Implementing ICD-10 on Physician Practices and Clinical Laboratories: A Report to the ICD-10 Coalition" By Nachimson Advisors, LLC, Nachimsonadvisors.com, October 8, 2008, http://nachimsonadvisors.com/Documents/ICD-10%20Impacts%20on%20Providers.pdf (Accessed 10/07/09).

Although the extent of these expenditures will vary by practice, the study estimates that they will range from slightly more than $83,000 for a "small" practice, consisting of three physicians and two administrative employees, to slightly more than $2.7 million for a "large" practice, consisting of one hundred providers, ten full time coders, and fifty-four medical records employees.[44] This study was recreated in 2014, and the researchers found the updated expenses to range between approximately $56,639 for a small practice to $8,018,364 for a large practice.[45] The variation of costs is categorized and detailed in Table 2-2 below.

Table 2-2: ICD-10 Increased Cost Estimates from the American Medical Association 2014 Study[46]

Type of Cost	Typical Small Practice	Typical Medium Practice	Typical Large Practice
Training	$2,700–$3,000	$4,800–$7,900	$75,100
Assessment	$4,300–$7,000	$6,535–$9,600	$19,320
Vendor/Software Upgrades	$0–$60,000	$0–$200,000	$0–$2,000,000
Process Remediation	$3,312–$6,701	$6,211–$12,990	$14,874–$31,821
Testing	$15,248–$28,805	$47,906–$93,098	$428,740–$880,660
Productivity Loss	$8,500–$20,250	$72,649–$166,649	$726,487–$1,666,487
Payment Disruption	$22,579–$100,349	$75,263–$334,498	$752,630–$3,344,976
Total Costs	$56,639–$226,105	$213,364–$824,735	$2,017,151–$8,018,364

In 2008, expenditures for the shift from ICD-9 to ICD-10 were estimated to cost anywhere from $83,000 to $2.7 million, depending on the size of the practice. As of 2014, these costs are predicted to range between approximately $56,639 for a small practice with minimum expenses to $8,018,364 for a large practice with maximum expenses.

Nachimson Advisors, LLC, 2008; American Medical Association, 2014.

Procedural Coding

Procedure codes are used to identify and classify medical services including surgical procedures and diagnostic tests, evaluation and management codes for patient visits and examinations, and to evaluate medical necessity of report charges.[47] Specifically, this type of coding depends on whether the designated provider is a physician or a facility; and in the circumstances of the facility provider, whether the services were performed as an inpatient or an outpatient procedure.[48] Any service that is submitted on a claim for payment must be linked through its appropriate procedure code, corresponding to the diagnostic reasoning behind the claim.[49]

44 Ibid.
45 "ICD-10 Cost Estimates Increased for Most Physicians" American Medical Association, Feb. 12, 2014, http://www.amaassn.org/ama/pub/news/news/2014/2014-02-12-icd10-cost-estimates-increased-for-most-physicians.page# (Accessed 1/30/15).
46 Ibid.
47 "From Patient to Payment: Insurance Procedures for the Medical Office" By Cynthia Newby, Third Edition, Columbus, OH: Glencoe/McGraw-Hill, 2002, p. 48.
48 "Healthcare Valuation: The Four Pillars of Healthcare" By Robert James Cimasi, MHA, ASA, FRICS, MCBA, AVA, CM&AA, Vol. I, Hoboken, NJ: John Wiley & Sons, Inc., 2014, p. 94.
49 "Essentials of Heath Care Finance" By William O. Cleverley and Andrew E. Cameron, Sixth Edition, Sudbury, MA: Jones and Bartlett Publishers, Inc., 2007, p. 17.

Healthcare Common Procedure Coding System (HCPCS)

The *Healthcare Common Procedure Coding System* (*HCPCS*) provides the payor information regarding the procedures performed in the treatment of patients.[50] The system does not relay diagnosis information.[51] Hospitals use *HCPCS* codes to report information on procedures performed for outpatient services, while physicians use them to report information in connection with the performance of procedures in both the inpatient and outpatient settings.[52] There are two *HCPCS* levels: Level I codes are referred to as Current Procedural Terminology (*CPT*) codes, and Level II codes are temporary codes used to represent services, supplies, and procedures for those *CPT* codes that do not yet exist.[53]

Current Procedural Terminology (CPT)

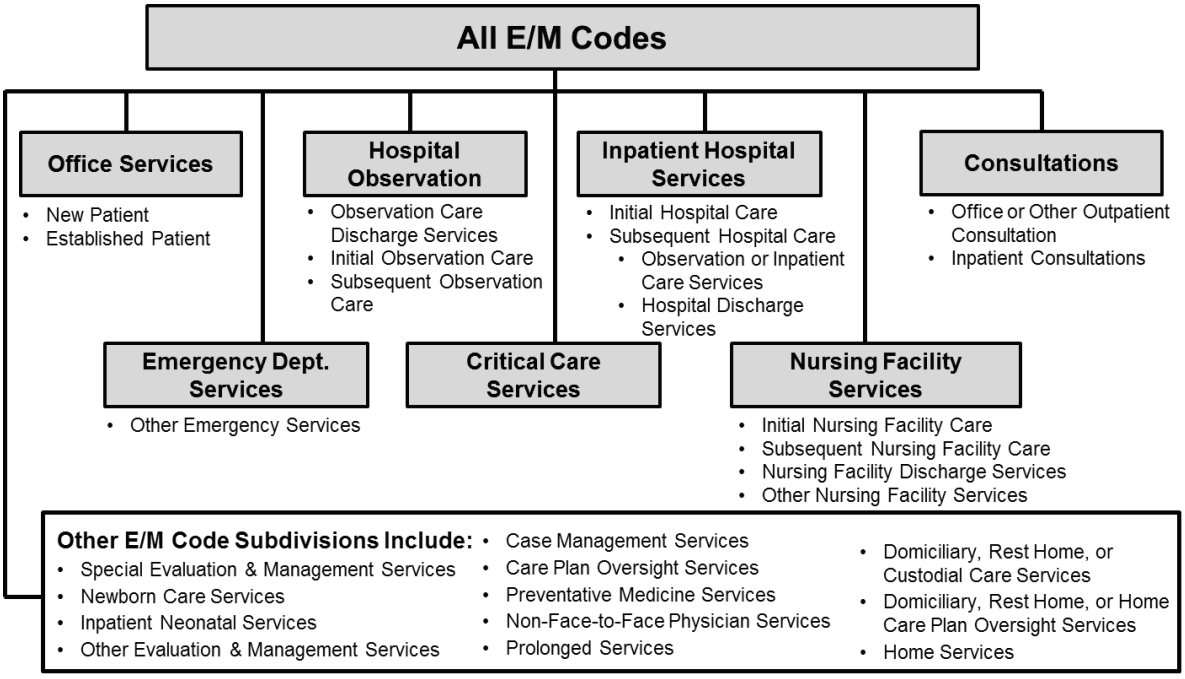
Current Procedural Terminology (*CPT*) is a system developed by the American Medical Association (AMA) that providers use to report information to patients and to insurers about services and procedures provided to patients.[54] In response to the *Medicare Prescription Drug, Improvement, and Modernization Act of 2003* (MMA), the Centers for Medicare and Medicaid Services (CMS) adopted regulations that require "new, revised, and deleted CPT codes be implemented" on the first day of January each year.[55] Currently, the system divides the established codes between six sections that will differentiate among the various types of procedures. These six sections include:

(1) Evaluation and management (E/M);
(2) Anesthesiology;
(3) Surgery;
(4) Radiology, including *nuclear medicine* and diagnostic *ultrasound*;
(5) Pathology and laboratory; and
(6) Medicine, excluding anesthesiology.[56]

The E/M section is used to describe the type of service, place of service, and patient's status.[57] Figure 2-2 displays the subdivisions between E/M codes.

50 Ibid, p. 18.
51 Ibid, p. 18.
52 Ibid, p. 18.
53 Ibid, p. 18.
54 "Understanding Health Insurance: A Guide to Billing and Reimbursement" By Michelle A. Green and JoAnn C. Rowell, Twelfth Edition, Stamford, CT: Cengage Learning, 2013, p. 218-219.
55 "Understanding Health Insurance: A Guide to Billing and Reimbursement" By Michelle A. Green and JoAnn C. Rowell, Twelfth Edition, Stamford, CT: Cengage Learning, 2013, p. 218-219.
56 "Current Procedural Terminology: Professional Edition 2012" By Michelle Abraham, et al., 4th Edition, Revised Chicago, IL: American Medical Association, 2011, p. x.
57 Ibid, p. 4.

Figure 2-2: EM Code Subdivisions[58]



Determining coding for each E/M service requires the provider to determine a level of complexity, establish a diagnosis, or select a care management option. A code's complexity level is determined by the number of options available, the amount of and complexity of a patient's medical record and history, and the risk of complications, morbidity, mortality, and/or comorbidity with the patient's current condition. The third determinant may also include the diagnosis or the selected care management option. Table 2-3 below displays the various categorical classifications that are associated with each level of complexity.

Table 2-3: Assignment of Complexity Level for E/M Services[59]

Level of Complexity	Number of Options Available	Amount of, and Complexity of, the Data to be Reviewed	Risks Associated with a Particular Case
Straightforward	Minimal	None-Minimal	Minimal
Low Complexity	Limited	Limited	Low
Moderate Complexity	Multiple	Moderate	Moderate
High Complexity	Extensive	Extensive	High

In addition to the Category I *CPT* codes above, there are also Category II and III *CPT* codes that are considered supplementary. Category II codes are optional and account for performance assessment and quality improvement activities. They use a four digit numerical code to describe

58 Ibid, p. 11-41.
59 "Current Procedural Terminology: Professional Edition 2012" By Michelle Abraham, et al., 4th Edition, Revised, Chicago, IL: American Medical Association, 2011, p. 10.

the activity and use a fifth character letter to describe the patient's characteristics.[60] Currently the sections of Category II codes are as follows:

(1) Composite measures;
(2) Patient Management;
(3) Patient History;
(4) Physical Examination;
(5) Diagnostic/Screening Processes or Results;
(6) Therapeutic, Preventative, or Other Interventions;
(7) Follow-up or Other Outcomes;
(8) Patient Safety; and
(9) Structural Measures.[61]

Category III *CPT* codes are temporary and are assigned to emerging medical technologies, services, and procedures as needed.[62]

Additionally, there are often occasions where multiple combinations of *HCPCS* and *CPT* codes apply to a particular procedure.[63] Despite the many ways providers may code for a procedure, they are not permitted to separate, or *unbundle*, codes for different components of a comprehensive procedure if a code exists for the entire procedure.[64] CMS developed the National Correct Coding Initiative (NCCI) in an effort to prevent improper coding (for example, unbundling *CPT* codes in an effort to receive higher payments) and standardize national coding procedures.[65] The NCCI policy manual lists *HCPCS* and *CPT* codes that cannot be reported together unless a NCCI-associated modifier is used in a clinically appropriate manner.[66] NCCI denies claims when certain pairs of codes are reported together because one of the two codes may represent a component procedure to the procedure described by the other code, or because the two described procedures cannot possibly be performed together.[67] Additionally, some procedures that are integral to more comprehensive procedures (for example, wound irrigation is essential to the comprehensive treatment of all wounds) do not have *CPT* codes at all, and, therefore, should not be reported separately.[68]

Other Commonly Used Procedural Coding System: National Drug Codes (NDC) and Current Dental Terminology (CDT)

The *National Drug Codes* (NDC) is a coding system that provides a list of all the pharmaceutical products that are considered to be final marketed drugs and have been submitted to the Food and Drug Administration (FDA) in the electronic listing format by a labeler. Published and

60 "CPT Category II Codes" American Medical Association, 2015, http://www.ama-assn.org/ama/pub/physician-resources/solutions-managing-your-practice/coding-billing-insurance/cpt/about-cpt/category-ii-codes.page? (Accessed 2/21/15).
61 Ibid.
62 Ibid.
63 "National Correct Coding Initiative Policy Manual for Medicare Services" Correct Coding Solutions, LLC, Version 15.3, August 31, 2009, p. I-1.
64 Ibid, p. xii.
65 "National Correct Coding Initiatives Edits: Overview" Centers For Medicare & Medicaid Services, 2009, http://www.cms.hhs.gov/NationalCorrectCodInitEd/ (Accessed 10/07/09).
66 "National Correct Coding Initiative Policy Manual for Medicare Services" Correct Coding Solutions, LLC, Version 15.3, August 31, 2009, p. I-2.
67 Ibid.
68 Ibid, p. I-3.

maintained by the FDA, the codes use a unique ten digit, three-segment number as the universal identifier for each product.[69] The identifier provides information about the labeler (first segment), product information (second segment), and trade package size and type (third segment). Originally the NDC was updated twice a month; however as of February 1, 2013, the FDA began updating the NDC daily.[70]

The *Current Dental Terminology* (CDT) is a coding system used to achieve uniformity, consistency, and specificity in the reporting of all dental procedures in order to properly process claims.[71] The CDT is revised annually by the American Dental Association's Code Maintenance Committee (CMC) to ensure that the code accurately reflects the most current procedures for reimbursement and liability purposes.[72]

Modifiers

Modifiers are two-digit codes added to five-digit *CPT* codes to clarify the services and procedures performed.[73] Modifiers may be added to *CPT* codes for a number of reasons, including that the procedure was performed more than once, performed by more than one physician, or discontinued because of threats to a patient's health.[74] The AMA updates the list of modifiers on a continuous basis.[75] The expansion of modifiers presents the potential for some of the same operational and financial challenges as does the expansion of *CPT* codes.[76] A provider's costs may increase if billing time increases and the need for staff training arises.[77] However, as with expansions to the *CPT* coding system, an increase in the number of modifiers may lead to increased revenue because the added modifiers may lead to reimbursement for procedures and services not previously covered.[78]

Step 4: Documentation to Capture the Charge

Upon completion of the coding and documentation process, "the revenue cycle moves from the clinical side to the business side."[79] Capturing the charge entails the transfer of a provider's coding and documentation to the actual bill.[80] Providers are tasked with recording the appropriate procedure and diagnosis codes on an encounter form, and their business staff is responsible for

69 "National Code Directory" U.S. Food and Drug Administration, 2015, http://www.fda.gov/Drugs/InformationOnDrugs/ucm142438.htm (Accessed 2/21/15).
70 Ibid.
71 "CDT: Code on Dental Procedures and Nomenclature" American Dental Association, 2014, http://www.ada.org/en/publications/cdt/ (Accessed 2/21/15).
72 Ibid.
73 "Understanding Health Insurance: A Guide to Billing and Reimbursement" By Michelle A. Green and JoAnn C. Rowell, Twelfth Edition, Stamford, CT: Cengage Learning, 2013, p. 231.
74 Ibid, p. 231-241.
75 Ibid, p. 231.
76 "Switching to ICD-10: The Impact on Physicians" By Lindsay Law and Mary Ann Porucznik, American Academy of Orthopedic Surgeons/American Association of Orthopedic Surgeons, AAOS.org, February 2009, http://www.aaos.org/news/aaosnow/feb09/reimbursement1.asp (Accessed 8/9/09).
77 Ibid.
78 Ibid.
79 "Financial Management of the Medical Practice" By Max Reiboldt, Second Edition, The Coker Group, American Medical Association, 2002, p. 13.
80 Ibid.

ensuring that the encounter form is accurate before using it to bill patients and third-party insurers.[81]

Electronic Charge Capture

To improve *charge capture* and revenue generation, the more technologically advanced practices have begun using personal digital assistants to capture charges.[82] The electronic capture systems are then tied into the practice's practice management system, a computer system designed to collect registration and insurance information, facilitate billing and collections, and perform other operational functions so that charges can be downloaded and posted electronically.[83] These systems help reduce errors that may occur in the capture process, and they reduce the time between service and charge entry.[84]

Capturing Revenue for Office- and Hospital-Based Professional Practices

Office-based professional practices can capture inpatient charges in a variety of ways. Typically, if a practice has not adopted an electronic charge capture system as described previously, it may rely on the older method of charge capture, which requires the physician to actually note every consult or procedure he or she performs on a paper form.[85] Other practices hire staff to review hospital charts onsite for all patients seen by the practice's physicians.[86] In addition, to capture charges when the office-based practice is closed, some providers have set up a phone message system to which the physician can call, order to record the relevant patient information, and from which the staff performs the relevant billing actions when the office reopens.[87]

Hospital-based professionals typically capture charges in much the same way as their office-based counterparts, using either paper forms or electronic charge capture devices, although their bills are then submitted to the hospital's billing department.[88]

Steps 5 & 6: Patient and Insurance Billing

Once a provider has properly coded and documented the services provided, its staff must ensure the accuracy of the charge captures in order to facilitate accurate and timely billing of patients and third-party insurers.[89] Many providers implement practice management systems, process

81 "Financial Management of the Medical Practice" By Max Reiboldt, Second Edition, The Coker Group, American Medical Association, 2002, p. 13; "The Physician Billing Process: Avoiding Potholes in the Road to Getting Paid" By Deborah L. Walker, Sara M. Larch, and Elizabeth W. Woodcock, Englewood, CO: Medical Group Management Association, 2004, p. 57.

82 "Senate Votes 69-30 to Approve Legislation that Would Halt Medicare Physician Payment Cut" By Kaiser Daily Health Report, July 10, 2008, http://www.kaisernetwork.org/daily_reports/rep_index.cfm?hint=3&DR_ID=53221 (Accessed 10/16/08); "The Physician Billing Process: Avoiding Potholes in the Road to Getting Paid" By Deborah L. Walker, Sara M. Larch, and Elizabeth W. Woodcock, Englewood, CO: Medical Group Management Association, 2004, p. 51.

83 "The Physician Billing Process: Avoiding Potholes in the Road to Getting Paid" By Deborah L. Walker, Sara M. Larch, and Elizabeth W. Woodcock, Englewood, CO: Medical Group Management Association, 2004, p. 51, 170.

84 "The Physician Billing Process: Avoiding Potholes in the Road to Getting Paid" By Deborah L. Walker, Sara M. Larch, and Elizabeth W. Woodcock, Englewood, CO: Medical Group Management Association, 2004, p. 51.

85 Ibid., p. 48.

86 Ibid, p. 51.

87 Ibid, p. 51.

88 "Capturing Charges on the Go: Billing Software Saves Money When it Complements Hospitalists' Workflow" By Susan FitzGerald, ACP Hospitalist.org, May 2009, http://www.acphospitalist.org/archives/2009/05/software.htm (Accessed 8/26/09).

89 "Financial Management of the Medical Practice" By Max Reiboldt, Second Edition, The Coker Group, American Medical Association, 2002, p. 13.

claims electronically, work to maintain relationships with payors, develop internal information system processes, and develop other steps to ensure the effectiveness of the billing process.[90] Without an effective billing process, the revenue cycle will breakdown, money will be lost, and the full financial potential of the practice will not be realized.[91]

Primary Insurance Billing

A provider may submit a bill of exchange, a written document drafted by a party ordering payment from a third party, through their central billing department to the primary insurer. These bills are almost always submitted electronically.[92] Notably, as of 2005, Medicare began refusing to accept paper claims for any physician practice with more than 9 FTEs and any institution with more than 24 FTEs. As a result, many providers began utilizing clearinghouses or electronic data interchanges. These two types of entities assess each claim for errors and securely forward the bill to the correct payor. Clearinghouses also offer a service where they transform paper claims into the appropriate electronic format.[93]

Secondary Insurance Billing & Patient Responsibility

Once copayments and deductibles have been paid by the patient and primary payors have been billed, any remaining amount owed can be billed to a secondary payor. Some patients may have secondary insurance from their spouse or parent, an alternative public payor system for which the patient is eligible, or through supplemental insurance that covers any gaps left from the primary insurance coverage. The procedures and scope of coverage and benefits differ based on the secondary insurance party. After the copayment has been deducted and the insurers have determined their coverage, any amount left may be billed to the patient.[94] It is important to note that when a patient is covered by a participating public payor, the provider may not bill a person the amount to close the gap between what the provider was charged and what the payor was allowed to bill for that service.[95]

Step 7: Account Follow-Up, Claims Resolutions, and Collections

Submitting claims to third-party payors and sending bills to patients are not always sufficient to ensure timely payment, and follow-up on overdue accounts is often necessary to correct billing errors or to encourage payment by those who refuse to pay or cannot pay in a timely manner.[96] Thus, the revenue cycle is complete with the successful performance of the account follow-up and collection process.[97] A practice's past due accounts should be continually monitored, and

90 Ibid.
91 Ibid, p. 14; Details on billing to particular payors are included in Current Reimbursement Environment.
92 "Healthcare Valuation: The Four Pillars of Healthcare" By Robert James Cimasi, MHA, ASA, FRICS, MCBA, AVA, CM&AA, Vol. I, Hoboken, NJ: Wiley & Sons, Inc., 2014, p. 103.
93 "Say Goodbye to Paper: Noncompliant Medicare Claims Oct. 1" By Joyce Frieden, Family Practice News, September 1, 2005, p. 6.
94 "Healthcare Valuation: The Four Pillars of Healthcare" By Robert James Cimasi, MHA, ASA, FRICS, MCBA, AVA, CM&AA, Vol. I, Hoboken, NJ: Wiley & Sons, Inc., 2014, p. 104.
95 "State Plans for Medical Assistance," Social Security Act, Section 1902(n)(3)(B) (1997) (modified by "Balanced Budget Act of 1997" Pub. L. No. 105-33, § 4714, 111 Stat. 251, 509 (1997)).
96 "Prohibition on Balance Billing Qualified Medicare Beneficiaries (QMBs)" Centers for Medicare & Medicaid Services, MLN Matters Number: SE1128, Revised, July 25, 2012, p. 2.
97 Ibid.

when attempting to collect payment, it should use frequent phone calls, e-mails, and collection letters and other forms of communication, as needed.[98]

Use of Lockboxes

Instead of handling the collection and processing of payments themselves, providers may decide to use a *lockbox* service. For a fee, lockbox services open a provider's mail, collect payments, and deposit payments into the provider's account.[99] A lockbox service is convenient in that it saves the practice the time and resources of performing these procedures themselves. However, if the lockbox service is slow to process the payments, a payor who has properly paid its bill may receive another statement from the provider requesting payment, thereby creating more work for the provider and frustration for the patient.[100]

Accounting for Bad Debt

Regardless of the amount of effort a provider puts into the collection process, some account balances may never be collected. In these instances, providers will likely write the "balance off the accounts receivable as bad debt."[101] At this time, the provider must then decide whether to send the account to an outside collection agency, which will attempt to recover the balance for a fee, or give up all attempts at recovery because it may cost more to further pursue payment than to receive the outstanding amount.[102]

CHANGING NATURE OF THE REVENUE CYCLE

Experts predict that competitive pressure, as well as newly adopted and pending revenue cycle management regulations, will force providers to assess their revenue cycle management systems, resulting in system upgrades and the purchase of new systems over the next several years.[103] Since payment flows and the calculations of reimbursements and balances after insurance will make the revenue cycle more complicated,[104] providers with older revenue cycle management systems may need to upgrade these systems in order to improve patient satisfaction and convenience and to allow providers to more efficiently manage their revenue cycles.[105] Patient satisfaction, convenience, and increased efficiency will result from, among other things, the patient's ability to pre-register, schedule, and pay for their services by way of their provider's website.[106] Similarly, providers will benefit from new systems that improve efficiency by way of checking the payor's rules to ensure that the services to be performed are covered by the payor, automatically creating bills from the electronic medical record, bypassing clearinghouses and

98 "The Revenue Cycle," By Max Reiboldt and the Coker Group, in Financial Management of the Medical Practice, 2nd ed., Chicago, IL: American Medical Association, 2002, p. 14.
99 "The Physician Billing Process: Avoiding Potholes in the Road to Getting Paid" By Deborah L. Walker, Sara M. Larch, and Elizabeth W. Woodcock, Englewood, CO: Medical Group Management Association, 2004, p. 80.
100 Ibid.
101 Ibid, p. 137.
102 Ibid, p. 137.
103 "Essentials of the U. S. Hospital IT Market" By HIMSS Analytics, Fourth Edition, 2009, http://www.himssanalytics.org/docs/4thEditionEssentialsNGRCMfinal.pdf (Accessed 8/21/09); "Revenue Cycle Management-Storm Clouds on the Horizon" By Mike Davis, Future Healthcare, 2007, http://www.futurehealthcareus.com/?mc=revenue-cycle&page=fin-viewresearch (Accessed 8/21/09).
104 "Hospital Revenue Cycle Operations: Opportunities Created by the ACA" By Mathew Bayley, et al., McKinsey Healthcare Systems and Services Practice (May 2013), p. 51.
105 "Essentials of the U. S. Hospital IT Market" By HIMSS Analytics, Fourth Edition, 2009, http://www.himssanalytics.org/docs/4thEditionEssentialsNGRCMfinal.pdf (Accessed 8/21/09).
106 "Revenue Cycle Management-Storm Clouds on the Horizon" By Mike Davis, Future Healthcare, 2007, http://www.futurehealthcareus.com/?mc=revenue-cycle&page=fin-viewresearch (Accessed 8/21/09).

submitting claims directly to payors, enabling providers to receive electronic funds transferred directly from the payor to the provider's bank, and allowing providers to integrate their financial and clinical data.[107]

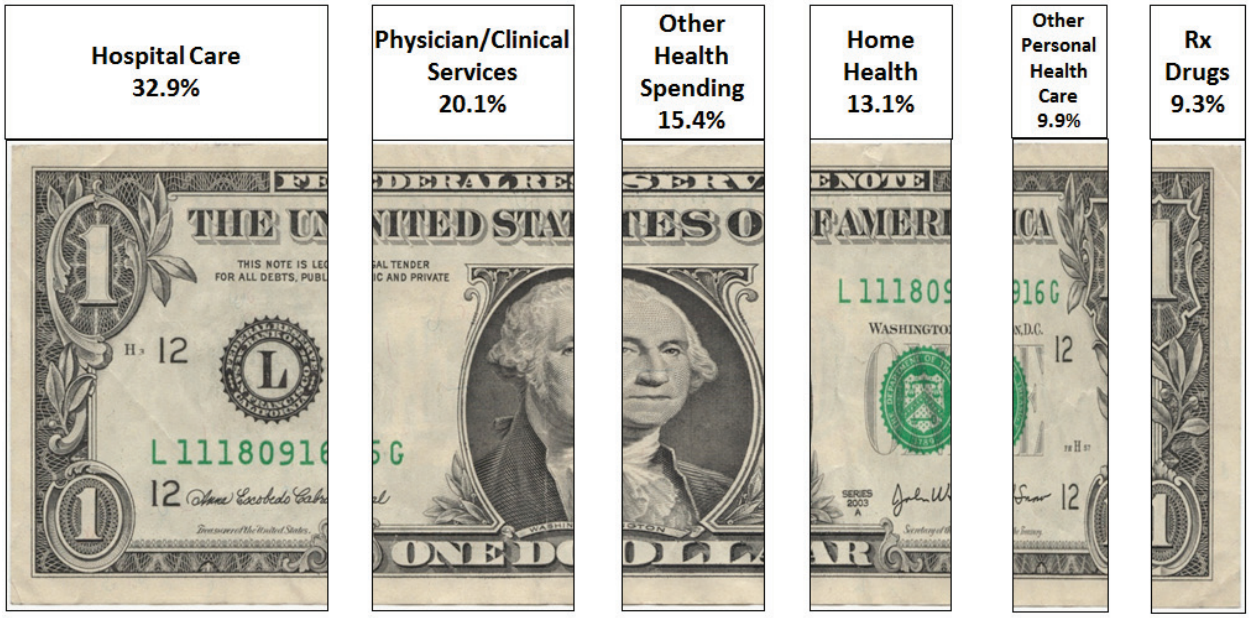
CURRENT REIMBURSEMENT ENVIRONMENT

The *Healthcare reimbursement* environment is composed of an elaborate set of relationships between healthcare providers, payors, and patients. The nature of any particular relationship between these entities is characterized by:

(1) The type of service provided;
(2) The location where that service is provided;
(3) The type of payor for the service; and
(4) The type of reimbursement model utilized.

The most recent breakdown of national health expenditures by type of service is illustrated in Figure 2-3: Allocation of Healthcare Expenditures by Type of Service, below.

Figure 2-3: Allocation of Healthcare Expenditures by Type of Service[108]



107 "Revenue Cycle Management-Storm Clouds on the Horizon" By Mike Davis, Future Healthcare, 2007, http://www.futurehealthcareus.com/?mc=revenue-cycle&page=fin-viewresearch (Accessed 8/21/09).

108 "National Health Expenditures by Type of Service and Source of Funds, CY 1960-2013" Centers for Medicare & Medicaid Services, http://www.cms.gov/Research-Statistics-Data-and-Systems/Statistics-Trends-and-Reports/NationalHealthExpendData/Downloads/NHE2013.zip (Accessed 2/24/2015). Other Personal Health Care includes dental and other professional health services, as well as durable and non-durable medical equipment. Other Health Spending includes administration and net cost of health insurance, public health activity, research, as well as structures and equipment.

A variety of payors are responsible for organizing the payment of these various healthcare services. The most recent breakdown of National Health Consumption Expenditures by type of payor is illustrated in Table 2-4: Allocation of National Health Consumption Expenditures by Payor, below.

Table 2-4: Allocation of National Health Consumption Expenditures by Payor[109]

Payor	Percentage of National Health Consumption Expenditures
Private Insurance	35%
Medicare	21%
Medicaid	16%
Other Health Insurance Programs	4%
Other Third Party Payors, Programs, and Public Health Activity	11%
Out of Pocket	12%
Total	100%

These healthcare payors are discussed in detail, below.

PUBLIC PAYORS

As the baby boomer generation becomes eligible for Medicare, public payor spending is expected to grow at a greater rate than private payor spending. From 2016 to 2023, Medicare spending is projected to grow over 7% per year compared to 5.4% for private payors.[110] Spending by public payors already represents a significant portion of the healthcare industry, with estimated payments by public programs surpassing 40% of all national health expenditures (NHE) in 2014.[111] This prevalence of public payors in the healthcare marketplace typically tends to set the benchmark for private reimbursement rates.[112] Among these influential public payors are Medicare, Medicaid, State Children's Health Insurance Program (SCHIP), TRICARE, Civilian Health and Medical Program of the Department of Veteran Affairs (CHAMPVA), workers' compensation, and Indian Health Services (IHS).

109 "Table 03 National Health Expenditures; Levels and Annual Percent Change, by Source of Funds: Selected calendar Years 1960-2013" in "NHE Tables" Centers for Medicare & Medicaid Services, December 9, 2014, http://www.cms.gov/Research-Statistics-Data-and-Systems/Statistics-Trends-and-Reports/NationalHealthExpendData/Downloads/Tables.zip (Accessed 2/25/15). Note that other health insurance Programs include Children's Health Insurance Program (Titles XIX and XXI), Department of Defense, and Department of Veterans Affairs. Further, Other Third Party Payors, Programs, and Public Health Activity includes worksite health care, other private revenues, Indian Health Service, workers' compensation, general assistance, maternal and child health, vocational rehabilitation, other federal programs, Substance Abuse and Mental Health Services Administration, other state and local programs, and school health.

110 "National Health Expenditure Projections 2013-2023: Forecast Summary" Centers for Medicare & Medicaid Services, September 17, 2014, http://www.cms.gov/Research-Statistics-Data-and-Systems/Statistics-Trends-and-Reports/NationalHealthExpendData/NationalHealthAccountsProjected.html (Accessed 1/27/15).

111 "Table 3: National Health Expenditures; Aggregate and per Capita Amounts, Percent Distribution and Annual Percent Change by Source of Funds: Calendar Years 2007-2023"in "National Health Expenditure Projections 2013-2023" Centers for Medicare & Medicaid Services, September 17, 2014, http://www.cms.gov/Research-Statistics-Data-and-Systems/Statistics-Trends-and-Reports/NationalHealthExpendData/NationalHealthAccountsProjected.html (Accessed 1/27/15).

112 "Bargaining in the Shadow of a Giant: Medicare's Influence on Private Payment Systems" by Jeffrey Clemens and Joshua D. Gottlieb, National Bureau of Economic Research, October 2013, p. 3.

Medicare

Overview

Medicare was created in 1965 as Title XVIII of the *Social Security Act* (SSA).[113] The program, originally known as the *Health Insurance for the Aged and Disabled Act*, is an entitlement program available to individuals over the age of sixty-five.[114] During the 1970s, benefits were extended to include the disabled and individuals with end-stage renal disease (ESRD).[115] Medicare is divided into four parts, as described in Table 2-5: The Four Parts of Medicare, below:

Table 2-5: The Four Parts of Medicare[116]

Medicare Part	Statutory Reference	Description
Part A	42 U.S.C. § 1395c, et seq. (2013)	Covers inpatient care
Part B	42 U.S.C. § 1395j, et seq. (2013)	Covers outpatient visits
Part C	42 U.S.C. § 1395w-21, et seq. (2013)	Managed Care replacement of Parts A and B
Part D	42 U.S.C. § 1395w-101, et seq. (2013)	Covers prescription drug benefits

Medicare Part A

Medicare Part A, also known as Medicare Hospital insurance, pays for institutional inpatient services in acute care hospitals, critical access hospitals (CAHs), and skilled nursing facilities (SNFs), as well as some hospice and home health services, although physician services that are provided in a hospital are covered under Medicare part B.[117] For those individuals aged 65 or older who paid (or whose spouse paid) Medicare taxes while they were working, Medicare Part A does not have a monthly premium. However, there is a deductible associated with hospital stays, which increases with the duration of the hospital stay according to the following schedule:[118]

(1) $1,184 (total) for the first 60 days;
(2) $296 per day for days 61-90;
(3) Patient pays all charges for days 91-150, or can elect to use *lifetime reserve days* (of which each beneficiary receives 60 to be used once in their life) at $592 per day; and
(4) Patient pays all charges for days past the 150th continuous day of hospitalization.

113 "Compilation of the Social Security Laws" Social Security Administration, 2009, http://www.socialsecurity.gov/OP_Home/ssact/title18/1800.htm (Accessed 6/19/09).
114 Ibid.
115 Ibid.
116 "Understanding Health Insurance: A Guide to Billing and Reimbursement" By Michelle A. Green and JoAnn C. Rowell, Twelfth Edition, Stamford, CT: Cengage Learning, 2013, p. 487; "The Medicare Part D Prescription Drug Benefit" The Henry J. Kaiser Family Foundation, September 2014, p. 1, http://files.kff.org/attachment/medicare-prescription-drug-benefit-fact-sheet (Accessed 3/2/15).
117 "Understanding Health Insurance: A Guide to Billing and Reimbursement" By Michelle A. Green and JoAnn C. Rowell, Twelfth Edition, Stamford, CT: Cengage Learning, 2013, p. 490.
118 Ibid, p. 488, 491.

Medicare Part B

Medicare Part B pays for institutional outpatient services, physician services, and some other services that are not covered by Medicare Part A.[119] Beneficiaries of Medicare Part B are responsible for the following costs:[120]

(1) A monthly premium of $104.90 (which may increase, based on the beneficiary's income);
(2) An annual deductible of $147;
(3) Co-insurance of 20% after the deductible is met (except on recommended preventive services);
(4) Co-insurance of 20% on all occupational, physical, and speech-language therapy services;
(5) Co-insurance of 20% of the Medicare-approved amount for durable medical equipment (DME); and
(6) Co-insurance of 50% of most outpatient mental health services.

Medigap

Medicare Supplementary Insurance (MSI, also known as *Medigap*) is a type of health plan that is offered by private insurance companies.[121] *Medigap* plans cover the out-of-pocket expenses paid by beneficiaries of Medicare Parts A and B (e.g., costs for services not covered by Medicare, normal deductible, or co-insurance costs).[122] These plans (of which there are 12) require beneficiaries to pay a monthly premium, which is determined by the private payor.[123] Some *Medigap* plans, known as Medicare SELECT, require beneficiaries to use a network of providers in order to receive the benefits of the plan. Due to this restriction, Medicare SELECT plans typically have lower monthly premiums than other *Medigap* plans.[124]

Medicare Part C

In general, Medicare Part C plans (also known as Medicare Advantage, or MA) are paid a capitated amount to provide all Part A and B Medicare benefits.[125] In order to determine the plan's reimbursement, MA plans submit bids based on their estimated costs per enrollee, and these bids are compared to geographic benchmark amounts that are set by a formula established by statute. The geographic benchmarks represent the maximum amount Medicare will pay a plan in any geographic area.[126] If the plan's bid is higher than the benchmark, then the enrollees must pay a premium to participate in that particular plan. If the plan's bid is lower than the

119 "Medicare Primer" by Patricia A. Davis et al., Congressional Research Service, July 12, 2011, p. 9, http://greenbook.waysandmeans.house.gov/sites/greenbook.waysandmeans.house.gov/files/2011/documents/R40425_gb.pdf (Accessed 3/2/15).
120 "Understanding Health Insurance: A Guide to Billing and Reimbursement" By Michelle A. Green and JoAnn C. Rowell, Twelfth Edition, Stamford, CT: Cengage Learning, 2013, p. 492.
121 "What's Medicare Supplement Insurance (Medigap)?" Centers for Medicare & Medicaid Services, http://www.medicare.gov/supplement-other-insurance/medigap/whats-medigap.html (Accessed 3/2/15).
122 Ibid.
123 "Understanding Health Insurance: A Guide to Billing and Reimbursement" By Michelle A. Green and JoAnn C. Rowell, Twelfth Edition, Stamford, CT: Cengage Learning, 2013, p. 496.
124 Ibid.
125 "Medicare Advantage Fact Sheet" The Henry J. Kaiser Family Foundation, November 25, 2013, http://kff.org/medicare/fact-sheet/medicare-advantage-fact-sheet/ (Accessed 4/22/14).
126 Ibid.

benchmark, then the plan receives a rebate which must be used to provide supplement benefits to enrollees.[127] Subsequently, payments to plans are adjusted based upon the risk profile of the plan's enrollees, which is determined according to the CMS Hierarchical Condition Category (CMS-HCC) methodology.[128] The individual's risk score is determined by assessing the individual enrollee's diagnoses, disability status, age, sex, and Medicaid status, which are provided to CMS by the insurer.[129] All diagnoses for risk adjustment purposes must be documented in a medical record, coded in accordance with guidelines, and assigned based on dates of service within the data collection period.[130] In 2014, the average monthly MA plan premium was $49. [131]

MA plan beneficiaries may choose among the following plan types:[132]

(1) A Medicare health maintenance organization (HMO);
(2) A Medicare medical savings account (MSA), wherein Medicare pays into an account that the beneficiary draws upon to pay for covered healthcare services until a (relatively high) deductible has been met, after which point the private insurer pays for the cost of healthcare services;
(3) A Medicare special needs plan, which is designed for individuals who need advanced chronic care management services;
(4) A preferred provider organization (PPO); and
(5) A private fee-for-service (PFFS) plan.

Medicare Part D

Medicare Part D provides optional coverage for prescription drugs, and can be added on to other Medicare health insurance plans.[133] Medicare beneficiaries who opt into Medicare Part D coverage pay a monthly premium (on top of any monthly premium associated with their base Medicare plan), which is based on the beneficiary's annual income and ranges from $0 to $66.60.[134] Currently, Medicare Part D beneficiaries may fall into the Medicare Part D *coverage gap,* which is the difference between the Medicare Part D plan's initial coverage limit and the threshold for catastrophic coverage.[135] Between these two values, Medicare Part D beneficiaries are responsible for a greater share of the cost of prescription drugs. The *Patient Protection and Affordable Care Act* (ACA) gradually closes the coverage gap, requiring Medicare Part D plans

127 Ibid.
128 "Medicare Managed Care Manual – Chapter 7" Centers for Medicare & Medicaid Services, June 7, 2013, http://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/downloads/mc86c07.pdf (Accessed 4/29/14), § 50.
129 "Medicare Advantage Fact Sheet" The Henry J. Kaiser Family Foundation, November 25, 2013, http://kff.org/medicare/fact-sheet/medicare-advantage-fact-sheet/ (Accessed 4/22/2014); "Medicare Managed Care Manual – Chapter 7" Centers for Medicare & Medicaid Services, June 7, 2013, http://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/downloads/mc86c07.pdf (Accessed 4/29/214), §§ 70.2.3, 70.2.4, 110, 120.
130 "Medicare Managed Care Manual – Chapter 7" Centers for Medicare & Medicaid Services, June 7, 2013, http://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/downloads/mc86c07.pdf (Accessed 4/29/14), § 40.
131 "Medicare Advantage 2014 Spotlight: Plan Availability and Premiums" By Marsha Gold et al., Kaiser Family Foundation, November 25, 2013, p. 4, http://kff.org/medicare/issue-brief/medicare-advantage-2014-spotlight-plan-availability-and-premiums/ (Accessed 5/29/14).
132 "Understanding Health Insurance: A Guide to Billing and Reimbursement" By Michelle A. Green and JoAnn C. Rowell, Twelfth Edition, Stamford, CT: Cengage Learning, 2013, p. 493-494.
133 "The Medicare Part D Prescription Drug Benefit" The Henry J. Kaiser Family Foundation, September 2014, http://files.kff.org/attachment/medicare-prescription-drug-benefit-fact-sheet (Accessed 3/2/15), p. 1.
134 "Understanding Health Insurance: A Guide to Billing and Reimbursement" By Michelle A. Green and JoAnn C. Rowell, Twelfth Edition, Stamford, CT: Cengage Learning, 2013, p. 494-495.
135 "The Medicare Part D Prescription Drug Benefit" The Henry J. Kaiser Family Foundation, September 2014, http://files.kff.org/attachment/medicare-prescription-drug-benefit-fact-sheet (Accessed 3/2/15), p. 2.

to cover 50% of said costs in 2011, and growing to total coverage of costs associated with the coverage gap, in 2020.[136]

Reimbursement and Billing

Medicare reimburses providers using a combination of *fee-for-service (FFS),* managed care arrangements, and payments from health savings accounts (HSA).[137] Medicare does not process or pay claims directly, but contracts with insurance companies to perform these services for them, instead.[138] *Fiscal intermediaries* are insurance companies that handle claims for hospitals, skilled nursing facilities, intermediate care facilities, long-term care facilities, and home health agencies.[139] By contrast, *carriers* process claims for physicians, providers, and suppliers.[140] In addition, private companies provide medical and hospital coverage to enrollees of MA (Part C).[141]

Under federal law, all providers and suppliers must submit claims if they provide a Medicare-covered service to a beneficiary enrolled in Medicare Part B.[142] Medicare should be billed as the primary payor when:

(1) An employee has chosen not to enroll in, or has recently dropped, his or her coverage in a group health plan;
(2) An employee is not yet eligible for group health plan coverage or has depleted his or her benefits under the plan;
(3) The insurance plan only covers the self-employed;
(4) The insurance plan is an individual plan and was not obtained through a group;
(5) The patient has coverage through TRICARE;
(6) The patient is younger than sixty-five, is covered by Medicare due to a disability or ESRD, and does not have employer-sponsored health insurance;
(7) The patient is younger than sixty-five, has ESRD, and is covered by an employer sponsored health insurance plan, but the patient has been eligible for Medicare for more than thirty months;
(8) The patient has left a company through which they were covered under a group health plan and has coverage under federal Consolidated Omnibus Budget Reconciliation Act *(COBRA)*; or
(9) The patient has both Medicare and Medicaid.[143]

136 "Understanding Health Insurance: A Guide to Billing and Reimbursement" By Michelle A. Green and JoAnn C. Rowell, Twelfth Edition, Stamford, CT: Cengage Learning, 2013, p. 495.
137 "From Patient to Payment: Insurance Procedures for the Medical Office, Third Edition" By Cynthia Newby, Columbus, Ohio: Glencoe/McGraw-Hill, 2002, p. 141-142.
138 Ibid, p. 140.
139 Ibid, p. 140.
140 "From Patient to Payment: Insurance Procedures for the Medical Office, Third Edition" By Cynthia Newby, Columbus, Ohio: Glencoe/McGraw-Hill, 2002, p. 140.
141 "Medicare Advantage Fact Sheet" The Henry J. Kaiser Family Foundation, November 25, 2013, http://kff.org/medicare/fact-sheet/medicare-advantage-fact-sheet/ (Accessed 4/22/14).
142 "Understanding Health Insurance: A Guide to Billing and Reimbursement" By Michelle A. Green and JoAnn C. Rowell, Twelfth Edition, Stamford, CT: Cengage Learning, 2013, p. 500.
143 "Understanding Health Insurance: A Guide to Billing and Reimbursement" By Michelle A. Green and JoAnn C. Rowell, Twelfth Edition, Stamford, CT: Cengage Learning, 2013, p. 505.

Medicare administrative contractors are required to pay *clean claims,* i.e., those with the requisite data needed to process and pay the claim, within thirty days from receipt, and must pay interest on those clean claims paid after thirty days.[144] Federal regulation also mandates that MA organizations pay 95 percent of clean claims submitted by nonparticipating providers in thirty days and pay interest on clean claims that are not paid prior to this deadline.[145] In addition, MA organizations must include a prompt payment provision in their contracts with participating providers, although the organization and the participating provider are free to agree upon its terms.[146] Typically, if an electronic claim is submitted, providers can receive Medicare reimbursement in fourteen days.[147]

As mentioned previously, Medicare pays for services provided by physicians, allied health professionals, nurse practitioners, and other paraprofessionals, with few exceptions.[148] In particular, Medicare makes certain distinctions for reimbursement based on the site of service of particular allied health practices.

A unique aspect of the Medicare reimbursement system is the participating physician program, which originated with the *1984 Deficit Reduction Act*.[149] Under the program, Medicare and physicians enter into participating provider (PAR) agreements by which the providers agree to accept the reimbursement amount set by the Medicare physician *fee schedule* (MPFS), as payment in full for every claim.[150] The physician may bill the patient for the patient's share of the co-insurance and the patient's deductible, but it cannot balance bill the patient, that is, attempt to collect the difference between its usual fee and Medicare's lower allowed charge.[151]

Like any other third-party payor system, Medicare beneficiaries may be subject to premiums, deductibles, and co-insurance, all of which vary according to their coverage, income, and services sought.[152]

Participating Providers (PARs)—Medicare Allowable Charge

Medicare reimburses providers at different rates depending on whether or not they agree to become *participating providers (PARs)*. In 2011, approximately 96% of all physicians billing

144 Ibid, p. 88.
145 "Prompt Payment by MA Organization" Vol. 42 CFR. Section 422.520 (October 1, 2014).
146 Ibid.
147 "80.2.1.2 – Payment Floor Standards" in "Medicare Claims Processing Manual: Chapter 1 – General Billing Requirements" Centers for Medicare & Medicaid Services, August 1, 2014, http://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/Downloads/clm104c01.pdf (Accessed 1/28/15).
148 "Medicare Benefit Policy Manual" Centers For Medicare & Medicaid Services, Department of Health and Human Services, August 7, 2009, Accessed at http://www.cms.hhs.gov/manuals/Downloads/bp102c15.pdf (Accessed 9/21/09), p. 150-250.
149 "Paying a Visit to the Doctor: Current Financial Protections for Medicare Patients When Receiving Physician Services" by Cristina Boccuti, The Henry J. Kaiser Family Foundation, April 2014, p. 5, https://kaiserfamilyfoundation.files.wordpress.com/2014/04/8573-paying-to-see-your-doctor.pdf (Accessed 2/3/2015).
150 "From Patient to Payment: Insurance Procedures for the Medical Office, Third Edition" By Cynthia Newby, Columbus, Ohio: Glencoe/McGraw-Hill, 2002, p. 142.
151 "Medicare Enrollment and Claim Submission Guidelines" Centers for Medicare & Medicaid Services, August 2014, p. 5, http://www.cms.gov/Outreach-and-Education/Medicare-Learning-Network-MLN/MLNProducts/downloads/MedicareClaimSubmissionGuidelines-ICN906764.pdf (Accessed 2/3/2015).
152 "Understanding Health Insurance: A Guide to Billing and Reimbursement" By Michelle A. Green and JoAnn C. Rowell, Twelfth Edition, Stamford, CT: Cengage Learning, 2013, p. 492-495.

Medicare were PARs.[153] In order to enroll in Medicare, providers must be assigned a specific National Provider Identifier (NPI) by the National Plan and Provider Enumeration System (NPPES), and enter into a PAR agreement through a CMS-855 form.[154] By entering a PAR agreement, a physician agrees to accept the MPFS reimbursement as payment in full for a given service, which ensures that after a Medicare beneficiary meets their deductible, their coinsurance will not exceed 20% of the Medicare charge for their services.[155] To encourage physicians to enter into PAR agreements, Congress has developed special incentives including: [156]

(1) Direct payment of all claims;
(2) A 5% higher fee schedule than for non-participating providers (non-PARs);
(3) Inclusion in Medicare provider directories; and
(4) Electronic access to Medicare beneficiaries' supplemental insurance status.

> In 2011, 96 percent of all physicians billing Medicare were participating providers.
>
> ***Centers for Medicare and Medicaid Services, December 2011.***

Nonparticipating Providers (non-PARs)

Nonparticipating providers (non-PARs) are providers that have not agreed to accept the Medicare reimbursement amount for every claim. Still, non-PARs are allowed to accept Medicare assignment on a claim-by-claim basis,[157] subject to a *limiting charge* requirement.[158] When a non-PAR provides services to a Medicare beneficiary, the beneficiary is usually responsible for full charge of the service. The non-PAR must then file a claim with Medicare, which reimburses the beneficiary for Medicare's share of the charge.[159]

Nonparticipating Providers Accepting Medicare Assignment on a Claim-by-Claim Basis—95 Percent of Medicare Allowable Charge (80 Percent Medicare, 20 Percent Patient)

Non-PARs that accept assignment on a claim-by-claim basis are subject to an allowable fee that is 5 percent less than the allowable fee that PARs are paid for similar services.[160] For example, if the Medicare allowable fee schedule for a PAR pays $100 for a service, Medicare would pay the PAR 80 percent of the allowable fee, or $80, and the patient would be responsible for paying the

153 "Table VII.20: Medicare Part B Participating Physicians and Other Practitioners by State Selected Years" in "Data Compendium 2011" Centers For Medicare & Medicaid Services, December 2011, https://www.cms.gov/Research-Statistics-Data-and-Systems/Statistics-Trends-and-Reports/DataCompendium/2011_Data_Compendium.html (Accessed 2/3/15).
154 "Difference between the Medicare Provider Numbers" WPS Medicare j5 MAC Part B, August 16, 2012, http://www.wpsmedicare.com/j5macpartb/resources/new_providers/providernumber.shtml (Accessed 9/18/213).
155 "Paying a Visit to the Doctor: Current Financial Protections for Medicare Patients When Receiving Physician Services" by Cristina Boccuti, The Henry J. Kaiser Family Foundation, April 2014, https://kaiserfamilyfoundation.files.wordpress.com/2014/04/8573-paying-to-see-your-doctor.pdf (Accessed 2/3/15), p. 5.
156 "Understanding Health Insurance: A Guide to Billing and Reimbursement" By Michelle A. Green and JoAnn C. Rowell, Twelfth Edition, Stamford, CT: Cengage Learning, 2013, p. 497-498.
157 See the Nonparticipating Providers Accepting Medicare Assignment on a Claim-by-Claim Basis section.
158 "Paying a Visit to the Doctor: Current Financial Protections for Medicare Patients When Receiving Physician Services" by Cristina Boccuti, The Henry J. Kaiser Family Foundation, April 2014, 6, https://kaiserfamilyfoundation.files.wordpress.com/2014/04/8573-paying-to-see-your-doctor.pdf (Accessed 2/3/15), p. 6.
159 Ibid.
160 "Understanding Health Insurance: A Guide to Billing and Reimbursement" By Michelle A. Green and JoAnn C. Rowell, Twelfth Edition, Stamford, CT: Cengage Learning, 2013, p. 498.

PAR the remaining 20 percent, or $20.[161] However, a non-PAR accepting assignment on the same claim will have an allowable fee of 5 percent less, or $95 for the same service.[162] Then, Medicare would pay the non-PAR 80 percent of the non-PAR fee schedule of $95, or a payment of $76 and the patient would be responsible for paying the non-PAR the remaining 20 percent, or $19.[163]

Although Medicare reimbursement differences can lead to a non-PAR being reimbursed more for a service than a PAR, a non-PAR's prices are decreased by *limiting charges* and increasing costs for patients, which may decrease a non-PAR's competitive advantage.[164]

Nonparticipating Providers Rejecting Medicare Assignment—115 Percent of 95 Percent of Medicare Allowable Charge (100 Percent from Patient)

A non-PAR may also treat Medicare patients without accepting the claim for assignment. When a non-PAR decides not to accept assignment on a particular claim, he or she may only charge a maximum of 15 percent above the non-PAR fee.[165] For example, if the Medicare allowable fee schedule for a PAR pays $100 for a particular service, Medicare would pay a non-PAR accepting assignment on a claim for the same type of service an allowable fee of 5 percent less, or $95. However, a non-PAR that chooses to submit a Medicare claim for the same type of service but chooses not to accept assignment may bill the patient an amount equal to 115 percent of the allowable fee for non-PARs.[166] Thus, the provider could charge a fee equal to 115 percent of $95, or $109.25. The ability to charge more than the Medicare allowable fee is offset by the increased risk that the provider faces from fact that he or she must collect the entire billable amount from the patient.

Physician Reimbursement and Billing: The Resource Based Relative Value Scale (RBRVS)

Medicare reimbursement is based on a standardized physician payment schedule based on a resource-based relative value scale (RBRVS), which determines payments based on the value of the resources necessary to provide a particular service.[167]

History and Background

The RBRVS was introduced in 1988 as a mechanism to control the cost of physicians' services borne by the Medicare program. William C. Hsiao from the Harvard School of Public Health

161 "Medicare Enrollment and Claim Submission Guidelines" Centers for Medicare & Medicaid Services, August 2014, http://www.cms.gov/Outreach-and-Education/Medicare-Learning-Network-MLN/MLNProducts/downloads/MedicareClaimSubmissionGuidelines-ICN906764.pdf (Accessed 2/3/15), p. 6-7.

162 "Understanding Health Insurance: A Guide to Billing and Reimbursement" By Michelle A. Green and JoAnn C. Rowell, Twelfth Edition, Stamford, CT: Cengage Learning, 2013, p. 498.

163 "Medicare Enrollment and Claim Submission Guidelines" Centers for Medicare & Medicaid Services, August 2014, http://www.cms.gov/Outreach-and-Education/Medicare-Learning-Network-MLN/MLNProducts/downloads/MedicareClaimSubmissionGuidelines-ICN906764.pdf (Accessed 2/3/215), p. 6-7.

164 "Understanding Health Insurance: A Guide to Billing and Reimbursement" By Michelle A. Green and JoAnn C. Rowell, Twelfth Edition, Stamford, CT: Cengage Learning, 2013, p. 497-498.

165 "CCH Medicare Explained" By Pamela K. Carron and Nicole T. Stone, Chicago, IL: CCH, 2012, p. 413.

166 "CCH Medicare Explained" By Pamela K. Carron and Nicole T. Stone, Chicago, IL: CCH, 2012, p. 413.

167 "Overview of the RBRVS" American Medical Association, http://www.ama-assn.org/ama/pub/physician-resources/solutions-managing-your-practice/coding-billing-insurance/medicare/the-resource-based-relative-value-scale/overview-of-rbrvs.shtml (Accessed 10/5/09).

developed it from the results of a 1988 study that was conducted in order to address the growing inequity between reimbursement rates for procedural services and those for cognitive clinical services, as well as the rapid increase in Medicare spending.[168] The system also was intended to bring medical practice payment more in line with a PPS, whereby reimbursement is based on a predetermined, fixed amount, and away from a purely FFS system.[169] The RBRVS system was implemented in 1992, and it is updated annually by the CMS.[170]

> The RBRVS was created by William C. Hsiao in 1988 in order to (1) address the growing inequity of reimbursement rates for procedural services for cognitive clinical services and (2) address the rapid increases in Medicare spending.
>
> ***Sarah E. Johnson, MD, and Warren P. Newton, MD, MPH, March 2002.***

Hsiao's Research

Dr. Hsiao's research consisted of examining components of providing care, such as physician work, practice costs, and the opportunity costs associated with training.[171] Through a series of surveys, the Hsiao study determined the relative value of the service-specific work component by establishing ways of quantifying work, including the time spent before, during, and after a procedure, as well as measuring the intensity of the work.[172] By conducting interviews with physicians, Hsiao and his team were able to develop a common scale describing and quantifying the resource costs needed to provide physician services across all fields of medicine.[173]

Transition from Customary Prevailing and Reasonable (CPR) to Prospective Payment System with Resource-Based Relative Value Scale

The *Omnibus Reconciliation Acts* of 1989 and 1990 implemented a new fixed-fee schedule for Medicare services.[174] The MPFS became effective January 1, 1992, and replaced the previous customary prevailing and reasonable (CPR) charge system with the RBRVS.[175] CPR payments were based on fees charged by providers by specialty within particular regions of the country, whereas the RBRVS fee schedule is a list of predetermined payments for healthcare services provided to patients.[176] The RBRVS was intended to place greater emphasis on time spent with a patient when assessing health, diagnosing conditions, and listening to complaints, thereby distributing Medicare payments more equitably among specialists, who traditionally received higher payments, and primary care physicians.[177]

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168 "Resource-based Relative Value Units: A Primer for Academic Family Physicians" By Sarah E. Johnson, and Warren P. Newton, Family Medicine, Vol. 34, No. 3 (March 2002), p. 172-173.

169 "Overview: Prospective Payment Systems, General Information" Centers For Medicare & Medicaid Services, Aug. 17, 2009, http://www.cms.hhs.gov/prospmedicarefeesvcpmtgen/ (Accessed 10/2/09).

170 "Medicare Physician Payment Updates and the Sustainable Growth Rate (SGR) System" by Jim Hahn, Congressional Research Service, June 12, 2014, http://greenbook.waysandmeans.house.gov/sites/greenbook.waysandmeans.house.gov/files/R40907_gb.pdf (Accessed 3/2/15), p. 1-2.

171 "Resource-based Relative Value Units: A Primer for Academic Family Physicians" By Sarah E. Johnson, and Warren P. Newton, Family Medicine, Vol. 34, No. 3 (March 2002), p. 172-173.

172 Ibid.

173 Ibid.

174 "Medicare Physician Payment Updates and the Sustainable Growth Rate (SGR) System" by Jim Hahn, Congressional Research Service, June 12, 2014, p. 1-2, http://greenbook.waysandmeans.house.gov/sites/greenbook.waysandmeans.house.gov/files/R40907_gb.pdf (Accessed 3/2/215).

175 "Understanding Health Insurance: A Guide to Billing and Reimbursement" By Michelle A. Green and JoAnn C. Rowell, Twelfth Edition, Stamford, CT: Cengage Learning, 2013, p. 333.

176 Ibid.

177 "RBRVS: How New Physician Fee Schedule Will Work -Resource-Based Relative Value Scale Payment System" By Paul L. Grimaldi, Healthcare Financial Management, Vol. 45, No. 9 (Sept 1991), p. 15.

Utilizing Relative Value Units (RVU) When Determining Fees and Costs

The MPFS constitutes a list of payment rates for different services based on their particular *HCPCS* codes.[178] The MPFS bases its payments on a single cross-specialty RBRVS with payment determined by a procedure's relative value units (RVUs).[179]

There are three RVU components: one for physician work, one for practice expense, and one for malpractice costs. These components can be broken down as follows:

(1) **Work.** The estimated value of the time, effort, expertise, and intensity of the service—approximately 55 percent of the RVU value.
(2) **Practice expense.** The estimated value of overhead and other expenses necessary to run the practice—approximately 42 percent of the RVU value.
(3) **Professional liability insurance.** The estimated value of malpractice cost for the service—approximately 3 percent of RVU value.[180]

These RVU components, as well as total RVU, are often adjusted using modifiers. Local geographic differences are accounted for by multiplying each RVU component by its corresponding geographic practice cost index (GPCI). By multiplying *total RVU* (the sum of geographically adjusted components) by a conversion factor (CF), the dollar amount of governmental reimbursement may be determined.[181]

The formula for calculating the Medicare physician reimbursement amount for a specific procedure and location is as follows:[182]

$$\text{Payment} = [(\text{wRVU} * \text{GPCI work}) + (\text{RVU PE} * \text{GPCI PE}) + (\text{RVU malpractice} * \text{GPCI malpractice})] * \text{CF}$$

RVUs are updated annually by committees from the AMA, as described in the RVU Updates section below. The three RVU components, GPCI, and CF are discussed further in the following sections.

Work Component

The work RVU component represents a physician's contribution of time and effort to the completion of a procedure. For example, a colonoscopy will have a higher work RVU than an intermediate office visit because the colonoscopy requires more time and skill.[183] The higher the value of the code, the more skill, time, and work it takes to complete.

178 "Physician Services Payment System" MedPAC Payment Basics, October 2008, http://www.medpac.gov/documents/MedPAC_Payment_Basics_08_Physician.pdf (Accessed 9/24/09).
179 Ibid.
180 "Gauging Emergency Physician Productivity: Are RVUs the Answer" By John Proctor, American College of Emergency Physicians, www.acep. org/practres.aspx?id=30306 (Accessed 4/1/09).
181 "Physician Services Payment System" MedPAC Payment Basics, October 2008, http://www.medpac.gov/documents/MedPAC_Payment_Basics_08_Physician.pdf (Accessed 9/24/09).
182 "Medicare Program; Revisions to Payment Policies Under the Physician Fee Schedule for Calendar Year 2006 and Certain Provisions Related to the Competitive Acquisition Program of Outpatient Drugs and Biological Under Part B; Final Rule" Federal Register Vol. 70, No. 223 (November 21, 2005), p. 70120.
183 "The Basics: Relative Value Units (RVUS)" National Health Policy Forum, The George Washington University, February 2009, http://www.nhpf.org/library/the-basics/Basics_RVUs_02-12-09.pdf (Accessed 4/1/09).

Practice Expense Component

The practice expense RVU component is based on numerous expenses that are incurred as a cost of providing the service or overhead of the practice, including the costs associated with office space, supplies, equipment, and non-administrative staff.[184] The practice expense RVU component is calculated using a bottom-up methodology in which direct costs (for example, costs that can be assigned, such as the cost of supplies) are calculated and indirect costs (for example, costs that cannot be assigned but are the costs of owning a practice, such as the cost of having a waiting room) are allocated.[185]

The practice expense RVU component may calculated differently, depending on whether services were provided in a facility setting (for example, a hospital), or in a *non-facility* setting (for example, a freestanding center) because of differences in the cost of operation.[186] The formula discussed previously can therefore be rewritten as:

Facility Payment Amount =
Payment = [(Work RVU * Work GPCI) + (Facility PE RVU * PE GPCI) + (MP RVU * MP GPCI)] * [Conversion Factor adjusted for budget neutrality]

Nonfacility Payment Amount =
Payment = [(Work RVU * Work GPCI) + (Nonfacility PE RVU * PE GPCI) + (MP RVU * MP GPCI)] * [Conversion Factor adjusted for budget neutrality][187]

Services that are billed by a *non-facility* receive a higher practice expense RVU component than services billed by a facility because the practice expenses are higher for a physician office than for a hospital.[188] When a service is billed by a *non-facility*, the practice expense RVU component compensates the physician's practice for the costs of owning and operating a practice (i.e., clinical personnel, equipment, and supplies).[189] However, when the service is billed by a facility, the practice does not incur these costs, and as such the practice expense RVU component is reduced.[190]

184 "Gauging Emergency Physician Productivity: Are RVUs the Answer" By John Proctor, American College of Emergency Physicians, www.acep. org/practres.aspx?id=30306 (Accessed 4/1/09); "Introduction to Relative Value Units (RVUs) and How Medicare Reimbursement is Calculated" American College of Radiation Oncology, 2009, http://www.acro.org/washington/RVU.pdf (Accessed 04/01/09); "Physician Services Payment System" MedPAC Payment Basics, October 2008, http://www.medpac.gov/documents/MedPAC_Payment_Basics_08_Physician.pdf (Accessed 9/24/09).

185 "Introduction to Relative Value Units (RVUs) and How Medicare Reimbursement is Calculated" American College of Radiation Oncology, 2009, http://www.acro.org/washington/RVU.pdf (Accessed 04/01/09).

186 "Introduction to Relative Value Units (RVUs) and How Medicare Reimbursement is Calculated" American College of Radiation Oncology, 2009, http://www.acro.org/washington/RVU.pdf (Accessed 04/01/09).

187 "Medicare Program; Revisions to Payment Policies Under the Physician Fee Schedule, Clinical Laboratory Fee Schedule, Access to Identifiable Data for the Center for Medicare and Medicaid Innovation Models & Other Revisions to Part B for CY 2015; Final Rule" Federal Register Vol. 79, No. 219, p. 67552; "Physician Fee Schedule" Centers for Medicare & Medicaid Services, February 4, 2015, http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/PhysicianFeeSched/ (Accessed 2/27/2015).

188 "The Basics: Relative Value Units (RVUS)" National Health Policy Forum, The George Washington University, February 2009, http://www.nhpf.org/library/the-basics/Basics_RVUs_02-12-09.pdf (Accessed 4/1/09).

189 Ibid.

190 "Resource-based Relative Value Units: A Primer for Academic Family Physicians" By Sarah E. Johnson, and Warren P. Newton, Family Medicine, Vol. 34, No. 3, (March 2002), p. 172-173; "The Basics: Relative Value Units (RVUS)" National Health Policy Forum, The George Washington University, February 2009, http://www.nhpf.org/library/the-basics/Basics_RVUs_02-12-09.pdf (Accessed 4/1/09).

Malpractice Expense Component

Section 1848(c) of the SSA, "Payment for Physician Services," requires CMS to develop resource-based malpractice RVU components as part of the method for physician reimbursement.[191] These RVUs correspond to the relative malpractice practice expense for medical procedures.[192] These values are updated at least every five years and typically comprise the smallest component of the RVU.[193] Due to the variation in malpractice costs among states and specialties, the malpractice component must be weighted geographically and across specialties.[194]

Geographic Practice Cost Index

The Geographic Practice Cost Index (GPCI) accounts for the geographic differences in the cost of maintaining a practice. Every Medicare payment locality has a GPCI for the work, practice, and malpractice component.[195] A locality's GPCI is determined by taking into consideration median hourly earnings of workers in the area and the average cost of office rental, medical equipment and supplies, and other miscellaneous expenses.[196] There were eighty-nine GPCI payment localities in the 2014 PFS final rule.[197]

Conversion Factor

The conversion factor (CF) is a monetary amount that is multiplied by the RVU from a locality to determine the payment amount for a given service.[198] This conversion factor is updated yearly by a formula that takes into account: (1) the previous year's conversion factor; (2) the estimated percentage increase in the Medicare Economic Index for the year (which accounts for inflationary changes in office expenses and physician earnings); and (3) an update adjustment factor.[199] All physician services, except anesthesia services, use a single conversion factor.[200]

191 "Interim Report on Malpractice RVUs for the CY 2010 Medicare Physician Fee Schedule Proposed Rule" By Margaret O'Brien-Strain, Sean McClellan, and Steve Frances Acumen LLC, June 2009, http://www.cms.gov/PhysicianFeeSched/05_Malpractice_Report.asp (Accessed 07/30/09), p.1.

192 Ibid.

193 "Interim Report on Malpractice RVUs for the CY 2010 Medicare Physician Fee Schedule Proposed Rule" By Margaret O'Brien-Strain, Sean McClellan, and Steve Frances Acumen LLC, June 2009, http://www.cms.gov/PhysicianFeeSched/05_Malpractice_Report.asp (Accessed 07/30/09), p. 1; "Introduction to Relative Value Units (RVUs) and How Medicare Reimbursement is Calculated" American College of Radiation Oncology, 2009, http://www.acro.org/washington/RVU.pdf (Accessed 04/01/09).

194 "Interim Report on Malpractice RVUs for the CY 2010 Medicare Physician Fee Schedule Proposed Rule" By Margaret O'Brien-Strain, Sean McClellan, and Steve Frances Acumen LLC, June 2009, http://www.cms.gov/PhysicianFeeSched/05_Malpractice_Report.asp (Accessed 07/30/09), p. 11.

195 "Physician Fee Schedule Look-Up, Overview" Centers For Medicare & Medicaid, January 7, 2009, http://www.cms.hhs.gov/PFSLookup/ (Accessed 7/30/09); "Physician Reimbursement Under Medicare" By Alan M. Scarrow, Neurosurgical Focus, Vol. 12, No. 4 (April, 2002), p. 2.

196 "Physician Reimbursement Under Medicare" By Alan M. Scarrow, Neurosurgical Focus, Vol. 12, No. 4 (April, 2002), p. 2.

197 "Medicare Program; Revisions to Payment Policies Under the Physician Fee Schedule, Clinical Laboratory Fee Schedule & Other Revisions to Part B for CY 2014; Final Rule" Fed. Reg. Vol. 78, No. 237 (December 10, 2013), p. 74384.

198 "Physician Reimbursement Under Medicare" By Alan M. Scarrow, Neurosurgical Focus, Vol. 12, No. 4 (April, 2002), p. 2.

199 "2009 Master Medicare Guide" CCH Health Editorial, Chicago, IL: Wolters Kluwer, 2009, p. 901.

200 Ibid, p. 900.

The CF is part of an annual update made to the MPFS by CMS based on an updated formula mandated in the *Balanced Budget Act of 1997*, which, until recently, included application of the sustainable growth rate (SGR) when determining MPFS rates.[201] Based on inflation, Medicare enrollment, growth of GDP, and regulatory developments, the SGR represented a spending target set for total annual expenditures under Medicare on Part B services, and annual adjustments were made to the MPFS based on whether actual spending came in above or below the target.[202] If actual spending was above the target, payment update rates were adjusted down; likewise, if actual spending was below the target, payment update rates were adjusted up.[203]

The SGR formula indicated downward adjustments to the MPFS every year since 2002; however, CMS averted the adjustment in 2003, and the United States Congress intervened and overrode the MPFS decreases to the CF for the past several years, sometimes replacing scheduled cuts with increases in payment.[204] On April 1, 2014, President Obama signed the *Protecting Access to Medicare Act of 2014,* which prevented a 24.4% cut to reimbursement for physicians' services to Medicare beneficiaries, replacing the cut with a 0.5% increase.[205] The law also provides for a 0% update to the 2015 MPFS through March 31, 2015.[206] The trends of CF and SGR updates, as compared to the actual physician fee schedule update, are represented below in Table 2-6: Annual Updates to the MPFS CF (CMS Final Rule v Congressional Action), 2002–2015.

Table 2-6: Annual Updates to the MPFS CF (CMS Final Rule v Congressional Action), 2002–2015

Year	Physician Fee Schedule Update Under CMS Final Rule	Physician Fee Schedule Update After Congressional Actions
2002	-4.8%[207]	N/A
2003	-4.4%[208]	1.6%*[209]
2004	-4.5%[210]	1.5%[211]
2005	1.5%[212]	1.5%[213]

(continued)

201 "CMS Proposes Payment, Policy Changes for Physicians Services to Medicare Beneficiaries in 2010" Centers For Medicare & Medicaid Services, Press Release (July 1, 2009), http://www.cms.hhs.gov/apps/media/press/release.asp?Counter=3469 (Accessed 10/09/09).
202 "The Sustainable Growth Rate Formula for Setting Medicare's Physician Payment Rates" Congressional Budget Office, Economic and Budget Issue Brief, September 6, 2006, http://www.cbo.gov/ftpdocs/75xx/doc7542/09-07-SGR-brief.pdf (Accessed 10/09/09).
203 Ibid.
204 "CMS Proposes Payment, Policy Changes for Physicians Services to Medicare Beneficiaries in 2010" Centers For Medicare & Medicaid Services, Press Release (July 1, 2009), p. 1, http://www.cms.hhs.gov/apps/media/press/release.asp?Counter=3469 (Accessed 10/09/09).
205 "President Obama Signs the Protecting Access to Medicare Act of 2014" Centers for Medicare & Medicaid Services, April 2, 2014, http://www.cms.gov/outreach-and-education/outreach/ffsprovpartprog/downloads/2014-04-02-standalone.pdf (Accessed 11/17/14).
206 Ibid.
207 "Medicare Program; Revisions to Payment Policies and Five-Year Review of and Adjustments to the Relative Value Units Under the Physician Fee Schedule for Calendar Year 2002: Final Rule with Comment Period" Federal Register Vol. 66, No. 212 (November 1, 2001), p. 55312.
208 "Medicare Program; Revisions to Payment Policies Under the Physician Fee Schedule for Calendar Year 2003 and Inclusion of Registered Nurses in the Personnel Provision of the Critical Access Hospital Emergency Services Requirement for Frontier Areas and Remote Locations" Federal Register, Vol. 67, No. 251 (December 31, 2002), p. 80018.
209 "Medicare Program; Physician Fee Schedule Update for Calendar Year 2003: Final Rule" Federal Register Vol. 68, No. 40 (February 28, 2003), p. 9567; [The revision of the SGR calculation is permitted due to the passage of the Consolidated Appropriations Resolution of 2003, section 402] "Consolidated Appropriations Resolution, 2003" Pub. L. No. 108-7, § 402, 117 Stat. 548 (February 20, 2003).
210 "Medicare Program; Revisions to Payment Policies under the Physician Fee Schedule for Calendar Year 2004" Federal Register Vol. 68, No. 216 (November 7, 2003), p. 63196.
211 "Medicare Program; Changes to Medicare Payment for Drugs and Physician Fee Schedule Payments for Calendar Year 2004: Interim Final Rule with Comment Period" Federal Register Vol. 69, No. 4 (January 7, 2004), p. 1095; "Medicare Prescription Drug, Improvement, and Modernization Act of 2003" Pub. L. No. 108-173, § 601, 117 Stat. 2300 (December 8, 2003).
212 "Medicare Program; Revisions to Payment Policies under the Physician Fee Schedule for Calendar Year 2005" Federal Register Vol. 69, No. 219 (November 15, 2004), p. 66236.
213 "Medicare Prescription Drug, Improvement, and Modernization Act of 2003" Pub. L. No. 108-173, § 601, 117 Stat. 2300 (December 8, 2003).

Year	Physician Fee Schedule Update Under CMS Final Rule	Physician Fee Schedule Update After Congressional Actions
2006	-4.4%[214]	0.0%[215]
2007	-5.0%[216]	0.0%[217]
2008	-10.1%[218]	0.5%[219]
2009	1.1%[220]	1.1%[221]
2010 (Jan - May)	-21.2%[222]	0.0%[223]
2010 (June-Dec)		2.2%[224]
2011	-24.9%[225]	0.0%[226]
2012	-27.4%[227]	0.0%[228]
2013	-26.5%[229]	0.0%[230]
2014	-20.1%[231]	0.5%[232]
2015 (Jan-March)	-21.2%[233]	0.0%[234]

*Enacted for March 1, 2003 - December 1, 2003

214 "Medicare Program; Revisions to Payment Policies Under the Physician Fee Schedule for Calendar Year 2006 and Certain Provisions Related to the Competitive Acquisition Program of Outpatient Drugs and Biologicals Under Part B" Federal Register Vol. 70, No. 223 (November 21, 2005), p. 70116.

215 "Deficit Reduction Act of 2005" Pub. L. No. 109-171, § 5104, 120 Stat. 40-41 (February 8, 2006).

216 "Medicare Program; Revisions to Payment Policies, Five-Year Review of Work Relative Value Units, Changes to the Practice Expense Methodology Under the Physician Fee Schedule, and Other Changes to Payment Under Part B; Revisions to the Payment Policies of Ambulance Services Under the Fee Schedule for Ambulance Services; and Ambulance Inflation Factor Update for CY 2007" Federal Register Vol. 71, No. 231 (December 1, 2006), p. 69624.

217 "Tax Relief and Health Care Act of 2006" Pub. L. No. 109-432, § 101, 120 Stat. 2975 (December 20, 2006).

218 "Medicare Program; Revisions to Payment Policies Under the Physician Fee Schedule, and Other Part B Payment Policies for CY 2008; Revisions to the Payment Policies of Ambulance Services Under the Ambulance Fee Schedule for CY 2008; and the Amendment of the E-Prescribing Exemption for Computer Generated Facsimile Transmissions" Federal Register Vol. 72, No. 227 (November 27, 2007), p. 66222.

219 "Medicare, Medicaid, and SCHIP Extension Act of 2007" Pub. L. No. 110-173, § 101, 121 Stat. 2493 (December 29, 2007).

220 "Medicare Program; Payment Policies under the Physician Fee Schedule and Other Revisions to Part B for CY 2009" Centers for Medicare and Medicaid Services, Federal Register Vol. 73, No. 224 (November 19, 2008), p. 69726.

221 "Medicare Improvements for Patients and Providers Act of 2008" Pub. L. No. 110-275, § 131, 122 Stat. 2520 (July 15, 2008).

222 "Medicare Program; Payment Policies under the Physician Fee Schedule and Other Revisions to Part B for CY 2010" Federal Register Vol. 74, No. 226 (November 25, 2009), p. 61738.

223 "Department of Defense Appropriations Act, 2010" Pub. L. No. 111-118, § 1011, 123 Stat. 3473-3474.

224 "Preservation of Access to Care for Medicare Beneficiaries and Pension Relief Act of 2010" Pub. L. No. 111-192, § 101, 124 Stat. 1280 (June 25, 2010).

225 "Medicare Program; Payment Policies under the Physician Fee Schedule and Other Revisions to Part B for CY 2011; Final Rule" Federal Register Vol. 75, No. 228 (November 29, 2010), p. 73283.

226 "Medicare Program; Payment Policies Under the Physician Fee Schedule and Other Revisions to Part B for CY 2011; Corrections: Correction on Final Rule with Comment Period" Federal Register Vol. 76, No. 7 (January 11, 2011), p. 1670; "Medicare and Medicaid Extenders Act of 2010" Pub. L. No. 111-309, § 101, 124 Stat. 3285-3286.

227 "Medicare Program; Payment Policies Under the Physician Fee Schedule, Five-Year Review of Work Relative Value Units, Clinical Laboratory Fee Schedule: Signature on Requisition, and Other Revisions to Part B for CY 2012; Final Rule" Federal Register Vol. 76, No. 228 (November 28, 2011), p. 73277.

228 "Temporary Payroll Tax Cut Continuation Act of 2011" Pub. L. No. 112-78, § 301, 125 Stat. 1283-1284 (December 23, 2011); extended by "Middle Class Tax Relief and Job Creation Act" Pub. L. No. 112-96, § 3003, 126 Stat. 186-187 (February 22, 2012).

229 "Medicare Program; Revisions to Payment Policies Under the Physician Fee Schedule, DME Face-to-Face Encounters, Elimination of the Requirement for Termination of Non-Random Prepayment Complex Medical Review and Other Revisions to Part B for CY 2013; Final Rule" Federal Register Vol. 77, No. 222 (November 16, 2012), p. 69138.

230 "American Taxpayer Relief Act of 2012" Pub. L. No. 112-240, § 601, 126 Stat. 2345 (January 2, 2013).

231 "Medicare Program; Revisions to Payment Policies Under the Physician Fee Schedule, Clinical Laboratory Fee Schedule & Other Revisions to Part B for CY 2014; Final Rule" Federal Register Vol. 78, No. 237 (December 10, 2013), p. 74398.

232 "Pathway for SGR Reform Act of 2013" Pub. L. No. 113-67, § 1101, 127 Stat. 1165, 1196 (December 26, 2013); "Protecting Access to Medicare Act of 2014" Pub. L. No. 113-93, § 101, 128 Stat. 1041 (April 1, 2014).

233 "Medicare Program; Revisions to Payment Policies Under the Physician Fee Schedule, Clinical Laboratory Fee Schedule, Access to Identifiable Data for the Center for Medicare and Medicaid Innovation Models & Other Revisions to Part B for CY 2015; Final Rule" Federal Register Vol. 79, No. 219 (November 13, 2014), p. 67742.

234 "Protecting Access to Medicare Act of 2014" Pub. L. No. 113-93, § 101, 128 Stat. 1041 (April 1, 2014).

In April of 2015, Congress passed the *Medicare Access and CHIP Reauthorization Act of 2015* (MACRA), the first section of which is dedicated to repealing the SGR.[235] In place of the SGR, Congress enacted a series of pre-determined updates, which vary based on the payment model used by the provider.[236] MACRA mandates an annual conversion factor update of 0.5%, beginning in July 2015 and ending in December 2019, followed by a 0.0% annual update from 2020 to 2025, followed by a 0.25% annual update from 2026 forward.[237] However, for providers who qualify as participants in an *alternative payment model* (APM), the annual update to the conversion factor for 2026 forward is 0.75%.[238]

Chronic Care Management

As noted in the Reimbursement and Billing section above, Medicare uses a fee-for-service (FFS) system when reimbursing providers. In the 2015 MPFS, CMS finalized a rule that allows primary care providers to bill for chronic care management (CCM), effectively opening a new category of services to be reimbursed under Medicare's FFS system. CCM, as defined by CMS, includes the following services:[239]

(1) The provision of 24/7 access to a provider who will address a patient's acute chronic care needs;
(2) Continuity of care with a designated provider with whom the patient is able to get successive routine appointments;
(3) Systematic assessment of a patient's medical, functional, and psychological needs;
(4) Ensuring the timely receipt of all recommended preventive care services;
(5) Medication reconciliation with review of adherence and potential interactions;
(6) Oversight of patient self-management of medications;
(7) Management of care transitions between providers of healthcare services;
(8) Coordination with home and community based clinical service providers required to support a patient's psychosocial needs and functional deficits; and
(9) Enhanced opportunities to communicate with the provider regarding the patient's care.

In order to bill for CCM, these services must be furnished to patients with multiple chronic conditions that (1) are expected to last at least one year (or until the death of the patient) and (2) put the patient at significant risk of death, acute decompensation, or functional decline.[240] The provider must spend at least 20 minutes on the services listed above in order to bill for CCM, and the services can only be billed once per patient, per month.[241] Providers will be able to bill, on average, $40.39 per Medicare beneficiary, per month for CCM services in the first quarter of 2015 (after this point, changes in the SGR and Congressional action will dictate the

235 "Medicare Access and CHIP Reauthorization Act of 2015" H.R. 2, January 6, 2015, p. 1-2; "Summary: H.R.2—114th Congress (2015-2016)" Congress.gov, April 16, 2015, https://www.congress.gov/bill/114th-congress/house-bill/2 (Accessed 4/22/2015).
236 Ibid.
237 "Medicare Access and CHIP Reauthorization Act of 2015" H.R. 2, January 6, 2015, p. 3-4.
238 Ibid; For more information about MACRA, see Chapter 6: Healthcare Reform, of Volume 1: An Era of Reform.
239 "Medicare Program; Revisions to Payment Policies Under the Physician Fee Schedule, Clinical Laboratory Fee Schedule & Other Revisions to Part B for CY 2014; Final Rule" Federal Register Vol. 78, No. 237 (December 10, 2013), p. 74417-74418.
240 "Medicare Program; Revisions to Payment Policies Under the Physician Fee Schedule, Clinical Laboratory Fee Schedule, Access to Identifiable Data for the Center for Medicare and Medicaid Innovation Models & Other Revisions to Part B for CY 2015; Final Rule" Federal Register Vol. 79, No. 219 (November 14, 2014), p. 67716.
241 Ibid.

reimbursement rates).[242] A 2014 analysis showed that, at $40.39 per Medicare beneficiary, per month, a family physician with an average number of patients that qualify for CCM services could generate nearly $240,000 in annual revenue by billing for CCM services.[243] As such, the introduction of Medicare reimbursement for CCM services may blend traditional FFS reimbursement with elements of value-based purchasing (VBP), by incentivizing physicians to provide for a patient's overall level of health.[244]

Chapter Appendix A, found at the end of this chapter, shows historic changes in Medicare payments charged by various physician specialties.

RVU Updates

RVUs are updated annually by CMS, with significant input and advice from the *AMA/Specialty Society Relative Value Scale Update Committee (RUC)*.[245] The *RUC* is a somewhat controversial panel of 31 physicians from different specialties who recommend updates to the values of various RVU's under the *Physician Fee Schedule*.[246] Of the 31 physicians comprising the *RUC*, 21 physicians represent major medical specialties. Four additional seats are reserved for internal medicine subspecialty practitioners, one primary care practitioner, and one for any other specialty.[247] The remaining six slots are occupied by:

(1) The *RUC* Chair;
(2) The Co-Chair of the *RUC Health Care Professionals Advisory Committee Review Board*;
(3) The chair of the *Practice Expense Review Board*;
(4) A representative of the AMA;
(5) A representative of the American Osteopathic Association; and
(6) *Current Procedural Terminology (CPT) Editorial Panel*.[248]

The panel convenes three times per year to discuss and make recommendations regarding a multitude of medical and surgical procedures.[249] There has been significant controversy surrounding the *RUC's* level of impartiality and the extent to which CMS's relies on their recommendations.[250] Critics of the *RUC* process have suggested that CMS gives the *RUC* too much influence in the RBRVS decision-making process. Historically, CMS has followed

242 "Providing and Billing Medicare for Chronic Care Management: 2015 Medicare Physician Fee Schedule Final Rule" Pershing Yoakley & Associates, PC, November 2014, p. 4.
243 Ibid.
244 Ibid.
245 "Gauging Emergency Physician Productivity: Are RVUs the Answer?" By John Proctor, ACEP Reimbursement Committee, Posted on American College of Emergency Physicians, www.acep.org/practres.aspx?id=30306 (Accessed 08/14/12).
246 "AMA/Specialty Society RVU Update Committee: The RUC is… The RUC is Not…" American Medical Association, June 16, 2007; "The RVS Update Committee" American Medical Association, December 8, 2014, http://www.ama-assn.org/ama/pub/physician-resources/solutions-managing-your-practice/coding-billing-insurance/medicare/the-resource-based-relative-value-scale/the-rvs-update-committee.page? (Accessed 2/23/15).
247 "The RVS Update Committee" American Medical Association, December 8, 2014, http://www.ama-assn.org/ama/pub/physician-resources/solutions-managing-your-practice/coding-billing-insurance/medicare/the-resource-based-relative-value-scale/the-rvs-update-committee.page? (Accessed 2/23/215).
248 Ibid.
249 "AMA/Specialty Society RVS Update Committee (RUC)" By Barbara S. Levy, AMA/Specialty Society RVS Committee Chair, American Medical Association, March 5, 2010, p.4.
250 "Letter From AAFP to CMS Regarding the RUC" By Lori Heim, American Academy of Family Physicians, To Donald Berwick, Centers For Medicare & Medicaid Administrator, October 8, 2010.

90 percent of the recommendations provided by the *RUC* regarding physician reimbursements, basing at least 20 percent of physician payments on *RUC* recommendations.[251]

RUC challengers have also alleged that, as the majority of *RUC* members are selected by medical-specialty trade groups, the *RUC* has facilitated disparities between specialty and primary reimbursement rates.[252] The *American Academy of Family Physicians* (AAFP), the most vocal opponent to the *RUC*, wrote to CMS urging them to follow a 2006 Medicare Payment Advisory Commision (MedPac) Report to Congress, which suggested lowering reliance on the *RUC* by forming a group of less financially invested experts to identify over-valued services and work with the *RUC* to increase transparency and encourage provider efficiency.[253]

Professional Component Versus Ancillary Services and Technical Component

The MPFS differentiates between two distinct revenue streams: the professional services component and the ancillary services and *technical component* (ASTC).[254] To use the performance of diagnostic services as an example, a provider performs the *technical component* when he or she executes functions such as taking an x-ray or administering an electrocardiogram.[255] Providers then perform the professional component when they interpret the results of those tests or write reports.[256] Providers must use the appropriate procedure code modifiers on submitted claims to distinguish between the services they performed and those performed by others, such as the hospital, technicians, or other staff, because a provider may only bill for services he or she provides.[257]

Imaging Reimbursement

Reimbursement for diagnostic imaging services is often split into a professional component (PC), representing the physician's efforts in interpreting a test, and a *technical component* (TC), representing the use of an imaging device itself (e.g. an MRI machine).[258] Adding another layer of complexity, the reimbursement methodology changes depending on where the diagnostic imaging services are performed. For example, if the imaging services are performed in a physician practice, both the PC and the TC are billed using the MPFS.[259] However, if the

251 "A Small Group of Physicians has a Big Say in What you Get Paid: What Every Physician Should Know about the RUC" By Kent J, Moore, et al., Family Practice Management, February 2008; "AMA/Specialty Society RVU Update Committee: The RUC is… The RUC is Not…" American Medical Association, June 16, 2007.

252 "Missing Productivity Gains in Medicare Physician Fee Schedule: Where are They?" By Jerry Cromwell, et al., Medical Research and Review, June 16, 2010, p.2-3; "RUC Physician Fee Lawsuit Dismissed" By Andis Robeznieks, Modern Healthcare, May 11, 2012, http://www.modernhealthcare.com/article/20120511/MODERNPHYSICIAN/305119989 (Accessed 2/23/15).

253 "Letter From AAFP to CMS Regarding the RUC" By Lori Heim, American Academy of Family Physicians, To Donald Berwick, Centers For Medicare & Medicaid Administrator, October 8, 2010; "Missing Productivity Gains in Medicare Physician Fee Schedule: Where are They?" By Jerry Cromwell, et al., Medical Research and Review, June 16, 2010, p. 3, 15.

254 "2009 CCH Medicare Explained" Edited By Pam Carron et al., Chicago, IL: Wolters Kluwer, 2009, p. 306.

255 Ibid.

256 "Professional and Technical Component Modifiers" By Donna Tyler, The American College of Obstetricians and Gynecologists, 2009, http://www.acog.org/departments/dept_notice.cfm?recno=6&bulletin=4672 (Accessed 8/19/09).

257 "2009 CCH Medicare Explained" Edited By Pam Carron et al., Chicago, IL: Wolters Kluwer, 2009, p. 306; "2009 Master Medicare Guide" CCH Health Editorial, Chicago, IL: Wolters Kluwer, 2009, p. 917.

258 "Medicare Coverage of Imaging Services" Medicare Learning Network, Centers for Medicare & Medicaid Services, June 2013, http://www.cms.gov/Outreach-and-Education/Medicare-Learning-Network-MLN/MLNProducts/downloads/Radiology_FactSheet_ICN907164.pdf (Accessed 11/11/2014), p.1.

259 Ibid, p. 2.

imaging services are performed in a hospital, the PC is billed using the MPFS, while the TC is billed using the appropriate hospital PPS, depending on whether the patient had been admitted.[260]

Over the last several years, reimbursement for many diagnostic imaging procedures has suffered drastic cuts, many of which particularly target imaging services delivered in a *"non-facility"* setting (e.g. services delivered in a physician practice).[261] One source of payment reduction for imaging services is the equipment utilization rate. CMS uses the utilization rate to calculate PE RVUs, reasoning that the more often a fixed piece of equipment is used, the lower the expense per use (and therefore, lower reimbursement for the use of that equipment). For most equipment, CMS assumes a utilization rate of 50% (i.e. the equipment is in use 50% of the time the provider is open for business).[262] However, the *American Taxpayer Relief Act* mandated that CMS assume a utilization rate of 90% for imaging equipment that costs more than $1 million.[263] With this higher utilization rate, imaging services receive less reimbursement per use of the equipment. Radiologists have argued that 90% utilization is nearly unattainable, citing surveys which place average utilization rates for imaging equipment much closer to CMS's original assumption of 50%.[264] In response, CMS has stated that the agency now lacks the authority to change the assumed utilization rate, due to the *American Taxpayer Relief Act*.[265]

In addition to the 90% utilization rate assumption for equipment that costs more than $1 million (effectively reducing payments for imaging services that utilize such equipment), Medicare also reduces reimbursement for certain repeated imaging services delivered by the same physician to the same patient on the same day (coded using modifier 51), known as the Multiple Procedure Payment Reduction (MPPR).[266] Aside from the highest paying service (which receives the normal Medicare payment), further services delivered to the same patient in the same session on the same day by the same physician are reimbursed at 75% of the normal Medicare payment.[267]

CMS Anti-Markup Rule

If a provider orders a diagnostic test from another supplier, he or she may bill Medicare for the *technical component* of that diagnostic test, even though he or she didn't perform the *technical component*.[268] However, that provider may not *mark-up* the bill he or she submits for Medicare

260 "Medicare Claims Processing Manual: Chapter 13 – Radiology Services and Other Diagnostic Procedures" Centers For Medicare & Medicaid Services, April 18, 2014, p. 5-8.
261 "Medicare Cuts Imaging Reimbursement Again – But There is Good News Too" by Jon Geise, 3d health, Inc., February 24, 2014, p. 2, http://www.3dhealthinc.com/blog/medicare-cuts-imaging-reimbursement-again-but-there-is-good-news-too (Accessed 11/11/14).
262 "Medicare Program; Revisions to Payment Policies Under the Physician Fee Schedule, Clinical Laboratory Fee Schedule, Access to Identifiable Data for the Center for Medicare and Medicaid Innovation Models & Other Revisions to Part B for CY 2015; Proposed Rule" Federal Register Vol. 79, No. 133 (July 11, 2014), p. 40327.
263 "Medicare Program; Revisions to Payment Policies Under the Physician Fee Schedule, Clinical Laboratory Fee Schedule & Other Revisions to Part B for CY 2014; Final Rule" Federal Register Vol. 78, No. 237 (December 10, 2013), p. 74238-74239; "Equipment Utilization Rate Changes Adversely Affect Patients and Radiologists" American College of Radiologists, 2013, http://www.acr.org/~/media/ACR/Documents/PDF/Advocacy/Fed%20Relations/EquipmentUtilizationAssumptionRateIssueBrief.pdf (Accessed 11/12/14).
264 "Equipment Utilization Rate Changes Adversely Affect Patients and Radiologists" American College of Radiologists, 2013, http://www.acr.org/~/media/ACR/Documents/PDF/Advocacy/Fed%20Relations/EquipmentUtilizationAssumptionRateIssueBrief.pdf (Accessed 11/12/14) , p. 2.
265 "Medicare Program; Revisions to Payment Policies Under the Physician Fee Schedule, Clinical Laboratory Fee Schedule & Other Revisions to Part B for CY 2014; Final Rule" Federal Register Vol. 78, No. 237 (December 10, 2013), p. 74238-74239.
266 "Pub 100-04 Medicare Claims Processing: Transmittal 2395" Centers for Medicare & Medicaid Services, January 26, 2012, https://www.cms.gov/Regulations-and-Guidance/Guidance/Transmittals/downloads/R2395CP.pdf (Accessed 11/21/2014), p. 3.
267 Ibid.
268 "CMS 2008 Rulemaking Focuses on Curbing Self-Referred Imaging" By Thomas W. Greeson & Heather M. Zimmerman, American Journal of Roentgenology, Vol. 190 (February 2008), http://www.ajronline.org/cgi/reprint/190/2/275.pdf (Accessed 09/15/09), p. 277.

reimbursement above the amount he or she paid for the test to reflect additional professional component costs associated with reading and interpreting the test.[269] Additionally, the 2008 MPFS expanded this *anti-markup* provision to both professional and *technical component* revenue generated by tests performed outside the office of the billing physician.[270] There are two exceptions that allow the billing physician to avoid the *anti-markup rule*:[271]

(1) The *technical component* is supervised by a physician who performs *substantially all* (that is, 75 percent or more) of his or her professional services for the billing physician, physician organization, or supplier; and,
(2) The *technical component* is conducted and supervised in the *same building* as the medical office of the ordering physician or authorized non-physician provider is located.

Therefore, even in a group practice, the *technical component* must be performed in the same building where the ordering physician provides services, rather than the *technical component* being performed at a separate diagnostic testing facility, in order to avoid the *anti-markup* rule.[272]

Incidentally, an increasingly volatile regulatory environment surrounding physician ownership is being driven by competition over who should benefit from ASTC revenues. Federal legislators consistently have advocated against physicians earning profits, which compounds the problem of declining reimbursement under the MPFS for the professional component of diagnostic imaging services, which has not kept up with inflation indices and has resulted in consistent decreases in physician professional component fee reimbursement yield.[273] To attempt to counteract this trend, physicians have attempted to invest in ASTC revenue stream enterprises, for example, ASCs; independent diagnostic testing facilities, surgical hospitals, physical therapy, etc.[274] However, there have been incessant legislative and regulatory efforts undertaken at the federal and state levels, in large part due to massive lobbying initiatives by oligopoly hospitals and their trade associations, to prevent this trend by restricting physician investment in ASTC revenue stream enterprises.[275] These measures have served to relegate independent physicians in private practice to receiving only professional fee component revenues or to acquiesce by accepting employee status under the substantial control of hospital systems or large corporate players.[276] In cases in which physicians receive only the professional fee component, many physician owners

269 Ibid.
270 "Medicare Program; Revisions to Payment Policies Under the Physician Fee Schedule, and Other Part B Payment Policies for CY 2008; Revision to the Payment Policies of Ambulance Services under the Ambulance Fee Schedule for CY 2008; and the Amendment of the E-Prescribing Exemption for Computer Generated Facsimile Transmissions" Federal Register Vol. 72 No. 227(November 27, 2007), p. 66307.
271 "30.2.9—Payment to Physician or Other Supplier for Diagnostic Tests Subject to the Anti-Markup Payment Limitation—Claims Submitted to A/B MACs (B)" in "Medicare Claims Processing Manual: Chapter 1 – General Billing Requirements" Centers for Medicare & Medicaid Services, February 20, 2015, http://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/Downloads/clm104c01.pdf (Accessed 3/2/2015).
272 Ibid.
273 "Down on the Farm: The Attack on Physician Ownership" By Robert James Cimasi, SurgiStrategies, May 1, 2008, http://www.surgistrategies.com/articles/physician-ownership-law-asc-cimasi.html# (Accessed 10/08/09); "Specialty Hospitals, Ambulatory Surgery Centers, and General Hospitals: Charting a Wise Policy Course" By Michael D. Maves, American Medical Association, The Council on Health Care Economics and Policy: Sept. 10, 2004, http://content.healthaffairs.org/content/24/3/868.full.pdf (Accessed 5/20/2010), p. 24.
274 "Down on the Farm: The Attack on Physician Ownership" By Robert James Cimasi, SurgiStrategies, May 1, 2008, http://www.surgistrategies.com/articles/physician-ownership-law-asc-cimasi.html# (Accessed 10/08/09).
275 "Down on the Farm: The Attack on Physician Ownership" By Robert James Cimasi, SurgiStrategies, May 1, 2008, http://www.surgistrategies.com/articles/physician-ownership-law-asc-cimasi.html# (Accessed 10/08/09).
276 Ibid.

are finding it very difficult to recover both the operating and capital expenses associated with running a practice.

Facility-Based Reimbursement Rates

Medicare reimburses providers at different rates depending on whether payments are being made under Part A or Part B (that is, inpatient or outpatient), and reimburses outpatient procedures at different rates based on the site of service.

Hospital Inpatient Services

CMS reimburses hospitals under Medicare Part A for two different payments, the *operating payment* and the *capital payment*.[277] The *operating payment* covers operating expenses, such as the cost of radiological isotopes, supplies, nurse salaries, etc., while the *capital payment* covers costs for depreciation, interest, rent, and property-related insurance and taxes.[278] The hospital submits the bill for all inpatient services, and any associated outpatient services, to a Medicare Claims Administration Contractor, who then categorizes the bill into a *Medicare Severity Diagnosis Related Group* (MS-DRG) classification.[279] The MS-DRG classification system divides possible diagnoses into approximately 500 groups depending on the patient's diagnosis, the resources used to treat the condition, and the severity of the condition.[280] In order to calculate the *operating payment*, each MS-DRG is assigned a specific DRG weight, which is then multiplied by the *base payment rate*. The *base payment rate* is comprised of a *labor-related portion*, and a *non-labor related portion*. The *labor-related portion* is adjusted by a wage index to reflect geographic differences in cost of labor, while the *non-labor related portion* is adjusted by a cost-of-living adjustment.[281] The DRG-adjusted *base payment rate* is then modified by certain policy adjustments, including:[282]

(1) Indirect costs of graduate medical education (IME) payments;
(2) Disproportionate share hospital (DSH) payments;
(3) Hospital value based purchasing payments (VBP) or penalties;
(4) Hospital readmissions reduction program penalties (HRR); and
(5) High cost outlier payments, among others.

277 "Acute Care Hospital Inpatient Prospective Payment System; Payment System Fact Sheet Series" Medicare Learning Network, Centers for Medicare & Medicaid Services, April 2013, http://www.cms.gov/Outreach-and-Education/Medicare-Learning-Network-MLN/MLNProducts/downloads/AcutePaymtSysfctsht.pdf (Accessed 6/3/14), p. 5.
278 Ibid.
279 Ibid, p. 2.
280 "Diagnosis-related group (DRG)," By Charlyn Stanberry, American Health Lawyers Association, 8/10/2012, p. 1, http://www.healthlawyers.org/hlresources/Health%20Law%20Wiki/Diagnosis-related%20group%20(DRG).aspx (Accessed 6/3/14).
281 "Acute Inpatient PPS" Centers for Medicare & Medicaid Services, August 4, 2014, http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/AcuteInpatientPPS/index.html (Accessed 3/2/15).
282 "Acute Care Hospital Inpatient Prospective Payment System; Payment System Fact Sheet Series," Medicare Learning Network, Centers for Medicare & Medicaid Services, April 2013, http://www.cms.gov/Outreach-and-Education/Medicare-Learning-Network-MLN/MLNProducts/downloads/AcutePaymtSysfctsht.pdf (Accessed 6/3/14), p. 4.

The formulas for calculating the operating and capital cost components of the IPPS payment are as follows:

Operating Cost Payment = DRG Relative Weight x [(Wage Index x Labor Related Portion) + Nonlabor Related Portion x Cost of Living Adjustment] x (1 + IME + DSH ± VBP - HRR)[283]

Capital Cost Payment = DRG Relative Weight x (Capital Base Rate x Capital Wage Index x Cost of Living Adjustment) x (1 + DSH + IME)[284]

Hospital Outpatient Departments

When physicians provide services and perform procedures in their offices, they are reimbursed under the MPFS for both their professional services as well as the *technical component* of those services. When procedures are provided in hospital outpatient departments (HOPDs) or ambulatory surgery centers (ASCs), however, they are reimbursed under both the MPFS (for the physician services) and the associated payment schedule, which reimburses for the cost of facilities, equipment, supplies, and staff for services provided in a HOPD or ASC.[285] For services provided in a HOPD, Outpatient *Prospective Payment System* (OPPS) payments are classified by service groups called Ambulatory Payment Classifications (APC), each of which includes services that are clinically similar to one another and require similar resources.[286] Each APC has a relative weight that reflects the geometric mean cost of services in that group.[287] These APCs are multiplied by a conversion factor (CF) and adjusted for geographic variance in order to arrive at the HOPD payment. The formula for calculating the HOPD payment is as follows:

HOPD Payment = (CF x APC relative weight) x [Labor Related Portion (60%) Adjusted by Hospital Wage Index + Non labor Related Portion (40%) Unadjusted] + (Special Exception Payments)[288]

283 "Acute Care Hospital Inpatient Prospective Payment System" Centers for Medicare & Medicaid Services, Medicare Learning Network, http://www.cms.gov/Outreach-and-Education/Medicare-Learning-Network-MLN/MLNProducts/downloads/AcutePaymtSysfctsht.pdf (Accessed 2/21/2015), p. 4. Note that outlier payments and adjustments for transfers are not included in the displayed formula.

284 Ibid.

285 "Ambulatory Surgical Centers Payment System" MedPAC Payment Basics, October 2008, http://www.medpac.gov/documents/MedPAC_Payment_Basics_08_ASC.pdf (Accessed 09/24/09), p. 1.

286 "Final 2009 Policy, Payment Changes for Hospital Outpatient Departments and Ambulatory Surgery Centers," Centers For Medicare & Medicaid Services, October 30, 2008, http://www.cms.gov/apps/media/press/factsheet.asp?Counter= 3335&intNumPerPage=10&checkDate=&checkKey=&srchType=1&numDays= 3500&srchOpt=0&srchData=&keywordType=All&chkNewsType=6&intPage=&showAll=&pYear=&year=&desc=false&cboOrder=date (Accessed 9/24/09).

287 "Hospital Outpatient Prospective Payment System" Payment Fact Sheet Series, Centers for Medicare & Medicaid Services, January 2014, http://www.cms.gov/Outreach-and-Education/Medicare-Learning-Network-MLN/MLNProducts/downloads/HospitalOutpaysysfctsht.pdf (Accessed 1/28/15), p. 4.

288 Ibid, p. 4-6.

Ambulatory Surgery Centers

For services performed in an ASC, Medicare pays the lower of: (1) the actual charge or (2) the ASC payment rate, according to the Ambulatory Surgical Center Fee Schedule (ASCFS).[289] ASC payment rates are calculated by multiplying the ASC conversion factor (CF) by the ASC relative payment weights, which are based on the relative weights assigned to procedures under the OPPS for HOPDs.[290] CMS implemented this payment methodology for ASCs in 2008. Due to the need to ensure budget neutrality between the old ASC payment system and the revised system, CMS reduces the OPPS relative payment weights before applying them to the ASCFS. In 2014, the ASC relative weights were 7.7% lower than those used in the OPPS.[291] In addition to the reduction of the payment weights, the ASCFS and the OPPS use different methodologies to update their respective CFs, resulting in the ASC CF generally having smaller updates than the OPPS CF.[292] As a result of these discrepancies, payments for most ambulatory procedures are, according to MedPac, overall 81% higher in HOPDs than in freestanding ASCs.[293]

In order to take advantage of this increased reimbursement to HOPDs, physician offices and physician-owned ASCs may wish to integrate with hospitals, and apply for *provider-based status*.[294] There are separate requirements for *provider-based billing*, i.e., the ability to charge a HOPD rate and a physician professional component, based upon the site of the entity seeking provider based status (on and off the hospital's campus), as well as the type of contract for which provider based status is sought (joint ventures and management contracts).[295] However, all of these sites and contracts have the following requirements in common:

(1) The provider applying for provider based status must be operated under the same license as the main facility, except for certain circumstances;
(2) The provider applying for provider based status and the main facility must be clinically integrated;
(3) The provider applying for provider based status and the main facility must be financially integrated; and
(4) The entities must make their affiliation known to the public.[296]

However, there have been various suggestions and rules regarding the repeal of this payment discrepancy. The OIG stated in its 2015 Work Plan that it would review the "appropriateness of Medicare's methodology for setting ambulatory surgical center payment rates under the revised payment system," and that it would determine if a payment disparity exists between ASCs and

289 "Ambulatory Surgical Center Fee Schedule: Payment System Fact Sheet Series" Centers for Medicare & Medicaid Service, April 2014, http://www.cms.gov/Outreach-and-Education/Medicare-Learning-Network-MLN/MLNProducts/downloads/AmbSurgCtrFeepymtfctsht508-09.pdf (Accessed 8/6/14), p. 5.
290 "Ambulatory Surgical Center Fee Schedule: Payment System Fact Sheet Series" Centers for Medicare & Medicaid Service, April 2014, http://www.cms.gov/Outreach-and-Education/Medicare-Learning-Network-MLN/MLNProducts/downloads/AmbSurgCtrFeepymtfctsht508-09.pdf (Accessed 8/6/14), p. 5.
291 "Chapter 5—Ambulatory Surgery Center Services" in "Report to the Congress: Medicare Payment Policy" Medicare Payment Advisory Commission, March 2014, p. 123.
292 "Payment Disparities Persist, but ASCs Gain Some Ground under Medicare's Proposed 2015 Payment Rule" Ambulatory Surgery Center Association, July 22, 2014, http://www.ascassociation.org/ASCsGainGroundin2015ProposedRule (Accessed 1/28/15).
293 "Chapter 5—Ambulatory Surgery Center Services" in "Report to the Congress: Medicare Payment Policy" Medicare Payment Advisory Commission, March 2014, p. 121-122.
294 "Requirements for a Determination that a Facility or an Organization has Provider-Based Status" 42 C.F.R. § 413.65(d)-(h) (November 6, 2014).
295 Ibid.
296 Ibid.

HOPDs for similar surgical procedures.[297] Similarly, MedPac has recommended that CMS collect ASC cost data to determine whether the utilization of alternative price indices would be more accurate in determining an appropriate proxy for ASC costs.[298] Despite these suggestions, in its final payment rule for 2015, CMS stated that it would not use the hospital *market basket* as the inflation index for ASCs, but it would consider collecting ASC cost data to assist in determining the appropriate inflation index to use; however, CMS does not believe the collection of such data would be productive.[299]

There are a few procedures performed in ASCs that are not reimbursed through the standard payment methodology. CMS began paying ASCs for "new, office-based procedures" (which are generally performed in physician offices) in 2008.[300] In an effort to prevent physicians from moving their practices out of their offices and into ASCs, CMS determined that it would reimburse for these services performed in an ASC at a rate that is the lower of the ASC rates (that is, the percentage of the OPPS rate) or the practice expense portion of the MPFS payment rate that would apply to the procedure if it had been performed in a physician's office.[301] Based on the same objective of discouraging shifting procedures to ASCs, CMS also excludes from the revised ASC payment rates reimbursement for separately payable radiology services and reimbursement for drugs, instead applying the same reimbursement policy as for office-based procedures.[302]

Critical Access Hospitals

Outpatient services that are delivered at a Critical Access Hospital (CAH) are reimbursed under a methodology that is separate from the reimbursement for outpatient services delivered at a normal hospital, which are reimbursed under the OPPS. The CAH designation was created to ensure that Medicare beneficiaries in remote areas would have access to healthcare services, by providing hospitals that receive the designation with improved reimbursements.[303] When paying for outpatient services delivered at a CAH, instead of using the OPPS payment rates, Medicare pays the CAH 101% of their reasonable costs.[304] In addition, the Medicare beneficiary is responsible for a coinsurance payment in the amount of 20% of the CAH's charge for the service, regardless of what Medicare will eventually pay.[305] An investigation by the Office of the Inspector General (OIG) in October of 2014 found that, due to this discrepancy, Medicare beneficiaries were paying, on average, 47% of the cost of outpatient services delivered at

297 "Work Plan: Fiscal Year 2015" Office of Inspector General - U.S. Department of Health and Human Services, October, 2014, https://oig.hhs.gov/reports-and-publications/workplan/#current (Accessed 11/6/2014) p. 27.
298 "Report to the Congress: Medicare Payment Policy" Medicare Payment Advisory Commission, March, 2014, http://www.medpac.gov/-documents-/reports (Accessed 11/6/2014) p. 123.
299 "Medicare and Medicaid Programs: Hospital Outpatient Prospective Payment and Ambulatory Surgical Center Payment Systems and Quality Reporting Programs; Physician-Owned Hospitals; Data Sources for Expansion Exception; Physician Certification of Inpatient Hospital Services; Medicare Advantage Organizations and Part D Sponsors; CMS-Identified Overpayments Associated with Submitted Payment Data; Final Rule" Federal Register Vol. 79, No. 217 (November 10, 2014), p. 66939.
300 "Ambulatory Surgical Centers Payment System" MedPAC Payment Basics, October 2008, http://www.medpac.gov/documents/MedPAC_Payment_Basics_08_ASC.pdf (Accessed 09/24/09), p. 2.
301 Ibid.
302 Ibid.
303 "Medicare Beneficiaries Paid Nearly Half of the Costs for Outpatient Services at Critical Access Hospitals" by Daniel R. Levinson, Inspector General, Office of the Inspector General, U.S. Department of Health and Human Services, October 2014, p. 1.
304 "Critical Access Hospital: Rural Health Fact Sheet Series" Centers for Medicare and Medicaid Services, September 2014, http://www.cms.gov/Outreach-and-Education/Medicare-Learning-Network-MLN/MLNProducts/downloads/CritAccessHospfctsht.pdf (Accessed 3/2/15) , p. 2.
305 Ibid.

CAHs.[306] The OIG concluded that CMS should seek legislative authority to change how coinsurance payments for outpatient services at CAHs are calculated.[307]

Inpatient vs. Outpatient Reimbursement

Depending on whether a hospital admits a patient or provides treatment to the patient without admitting them (i.e., providing services in observation), a hospital may bill Medicare for services using the IPPS or the OPPS. As described above, the IPPS calculates payment based on the average cost of a patient with a specific diagnosis, while the OPPS calculates payment based on the services provided to a specific beneficiary.

Because of these differing methodologies, hospitals may have an incentive to admit patients or leave them in observation status based on the patient's complexity, rather than the duration of their hospital stay.[308] If a patient will require relatively few services (and a correspondingly short stay), the hospital may seek to admit them, then bill Medicare for services using the IPPS. Thus the hospital still receives the standard IPPS payment for an average patient with a given diagnosis, while incurring comparatively low costs. Alternatively, if a patient will require a relatively high number of services (and a correspondingly longer stay), the hospital may not admit them, leaving the patient in observation status for a prolonged period. Because the OPPS pays for beneficiaries on a per-service basis, and because patients in observation are billed using the OPPS, hospitals could receive significantly higher payments by performing as many services as possible on patients in observation.[309]

In July of 2013, the Office of the Inspector General (OIG) published research that reinforced the idea that a hospital could reap significant financial rewards by admitting patients who required relatively short stays. The OIG found that in 2012, Medicare paid an average of $5,142 per inpatient stay lasting one night or fewer (which the report defined as a short inpatient stay).[310] Conversely, Medicare paid an average of $1,741 per observation stay.[311] Furthermore, the OIG found that when patients were treated for the same medical problems, Medicare still paid more for short inpatient stays than for observation stays.[312]

The Two Midnight Rule

In order to standardize how hospitals classify their patients (thus addressing the issue of hospitals admitting patients based on revenue projections rather than medical necessity, as described above), CMS issued the final version of the *two-midnight* rule in August of 2013, which states:[313]

306 "Medicare Beneficiaries Paid Nearly Half of the Costs for Outpatient Services at Critical Access Hospitals" by Daniel R. Levinson, Inspector General, Office of the Inspector General, U.S. Department of Health and Human Services, October 2014, p. 7.
307 Ibid, p. 13.
308 "Two-midnight rule a double-edged sword" by Tammy Worth, Healthcare Finance News, October 22, 2013, http://www.healthcarefinancenews.com/news/two-midnight-rule-double-edged-sword?single-page=true (Accessed 8/12/14).
309 "Memorandum Report: Hospitals' Use of Observation Stays and Short Inpatient stays for Medicare Beneficiaries" by Stuart Wright, Office of Inspector General, To Marilyn Tavenner, Centers for Medicare & Medicaid Services, https://oig.hhs.gov/oei/reports/oei-02-12-00040.pdf (Accessed 8/12/14) , p. 2.
310 Ibid, p. 12.
311 Ibid, p. 12.
312 "Memorandum Report: Hospitals' Use of Observation Stays and Short Inpatient stays for Medicare Beneficiaries" by Stuart Wright, Office of Inspector General, To Marilyn Tavenner, Centers for Medicare & Medicaid Services, https://oig.hhs.gov/oei/reports/oei-02-12-00040.pdf (Accessed 8/12/14) , p. 12-13.
313 "Admissions" 42 CFR § 412.3(e)(1) (October 1, 2013).

> "[if a] physician expects to keep the patient in the hospital for only a limited period of time that does not cross 2 midnights, the services are generally inappropriate for inpatient admission and inpatient payment under Medicare Part A…"

Similarly, the rule states that admission, and the corresponding payment under the IPPS, is appropriate for patients that could be expected to stay in the hospital for a period of time spanning more than two midnights.[314] As of October 1, 2013, claims for services that do not comply with this rule could be denied, if the claim were reviewed.[315] Therefore, as a result of this rule, hospitals may stand to lose significant revenue.[316] Some hospital groups have spoken out against the *two-midnight rule*, leading CMS to enact a *Probe and Educate* program through March 2015, during which CMS auditors will attempt to educate hospitals.[317] Auditors will deny claims that do not comply with the *two-midnight rule,* but auditors will not conduct post-payment reviews of claims for admissions between October 1, 2013 and March 31, 2015.[318]

Skilled Nursing Facility Reimbursement

Medicare only covers about 22 percent of all nursing home expenditures,[319] as neither Medicare Parts A or B cover *custodial care*, i.e., care that helps residents with daily activities.[320] Reimbursement for nursing home expenditures are further restricted because Medicare Part A (the primary payor for covered skilled nursing services) only pays for daily skilled nursing or rehabilitation services when they fall under following scenario: (1) the patient had a prior stay in a general acute care hospital for three consecutive days; (2) admission to a skilled nursing facility was within a short time period after hospital discharge; (3) the patient is receiving treatment for the same condition that was being treated in the hospital; and (4) a medical professional certified the need for daily skilled nursing or rehabilitative care.[321] Even with these limitations, Medicare still paid skilled nursing facilities about $26.4 billion in 2010.[322]

In the interest of controlling program costs, Medicare Part A limits the amount of skilled nursing days covered to 100 days per *benefit period.* While Medicare covers the first 20 days at 100 percent of costs, a co-payment of $144.50 per day is required for days 21 through 100.[323] After the 100-day benefit is exhausted, the patient's Medicare Part B benefits will continue to reimburse for any physician services; however, the beneficiary will also be liable for all other

314 "Admissions" 42 CFR § 412.3(e)(1) (October 1, 2013).
315 "Selecting Hospital Claims for Patient Status Reviews: Admissions On or After October 1, 2013" Centers for Medicare & Medicaid Services, November 4, 2013, http://www.cms.gov/Research-Statistics-Data-and-Systems/Monitoring-Programs/Medical-Review/Downloads/SelectingHospitalClaimsforAdmissionsonorafterOctober1st2013forReviewForWebPostingCLEAN.pdf (Accessed 8/12/14).
316 "Two-midnight rule a double-edged sword" by Tammy Worth, Healthcare Finance News, October 22, 2013, http://www.healthcarefinancenews.com/news/two-midnight-rule-double-edged-sword?single-page=true (Accessed 8/12/14).
317 "Inpatient Hospital Reviews" Centers for Medicare & Medicaid Services, November 25, 2014, http://www.cms.gov/Research-Statistics-Data-and-Systems/Monitoring-Programs/Medicare-FFS-Compliance-Programs/Medical-Review/InpatientHospitalReviews.html (Accessed 2/18/15).
318 Ibid.
319 "Health Care Spending and the Medicare Program" Medicare Payment Advisory Commission, Data Book, June 2012, p. 6.
320 "CCH Medicare Explained: §244" Editor Pamela K. Carron and Nicole T. Stone, Chicago, IL: CCH, 2012, p. 60.
321 "CCH Medicare Explained: §230, §625" Editor Pamela K. Carron and Nicole T. Stone, Chicago, IL: CCH, 2012, p. 50-52, 301
322 "Skilled nursing facility services payment system" MedPAC, October 2011, http://www.medpac.gov/documents/MedPAC_Payment_Basics_11_SNF_v2.pdf (Accessed 8/17/12).
323 "Medicare & You 2012" Centers For Medicare & Medicaid Services, 2012, http://www.medicare.gov/publications/pubs/pdf/10050.pdf (Accessed 8/21/12), p. 35.

costs.[324] The costs of nursing home care, without the assistance of insurance coverage, are often prohibitive for many patients, as these costs range between $39,600 and $81,030.[325]

Medicare reimbursed skilled nursing facility services under a *cost-based payment system* prior to the July 1, 1998 implementation of the PPS. Under the PPS reimbursement system, skilled nursing facilities are reimbursed through:

> "…prospective, case-mix adjusted per diem payments that cover routine, ancillary, and capital-related costs, including most items and services for which payment was previously made under Medicare Part B. The per diem payment is based on Fiscal Year 1995 Part A & B costs adjusted using the [skilled nursing facility] market basket index, the case mix from resident assessments, and geographical wage variations."[326]

The *case-mix index* accounts for the different levels of care required by individual patients while the *market basket index* serves as an adjustment factor made for inflation.[327] In order to determine an appropriate *case-mix*, skilled nursing facilities assign patients into one of the 66 *Resource Utilization Groups* (RUGs),[328] and then divide patients into the following six major categories:

(1) *Special rehabilitation*;
(2) *Extensive services*;
(3) *Special care*;
(4) *Clinically complex*;
(5) *Impaired cognition*; and
(6) *Reduced physical function*.[329]

In order to address concerns that reimbursement payments for skilled nursing services were reduced by the implementation of the PPS, Congress enacted the *Balanced Budget Refinement Act* (BBRA) on November 29, 1999. As a result, Congress implemented a four percent across-the-board increase in payments to skilled nursing facilities for Fiscal Years 2001 and 2002, with a temporary 20 percent increase in payments for 15 RUGs that represented medically complex conditions, on April 1, 2001.[330] Congress then enacted additional legislation to further increase reimbursement rates to skilled nursing facilities. Under the *Benefits Improvement and Protection Act of 2000* (BIPA), the inflation update was increased to the *full market basket* in Fiscal Year

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324 "Medicare & You 2012" Centers For Medicare & Medicaid Services, 2012, http://www.medicare.gov/publications/pubs/pdf/10050.pdf (Accessed 8/21/12), p. 35; "Medicare Beneficiary Access to Skilled Nursing Facilities, 2001," Report OEI-02-01-00160, U.S. Office of Inspector General, July 2001, p.1; "Prospective Payment for Post-Acute Care: Current Issues and Long-Term Agenda," Report to the Congress: Medicare Payment Policy, MedPAC, March 2001, p. 91.

325 "Genworth 2012 Cost of Care Survey: Home Care Providers, Adult Day Health Care Facilities, Assisted Living Facilities and Nursing Homes" Genworth Financial, LLC and National Eldercare Referral Systems, LLC, 2012, p. 9.

326 "Medicare Beneficiary Access to Skilled Nursing Facilities, 2001," Report OEI-02-01-00160, U.S. Office of Inspector General, July 2001, p.2; "Prospective Payment for Post-Acute Care: Current Issues and Long-Term Agenda" Medicare Payment Advisory Commission, Report to the Congress: Medicare Payment Policy, 2001 Washington, D.C., March 2010, p. 90-92.

327 "Medicare Beneficiary Access to Skilled Nursing Facilities, 2001," Report OEI-02-01-00160, U.S. Office of Inspector General, July 2001, p. 2.

328 Resource Utilization Groups are based on patient characteristics, including services used, that estimate what resources a particular patient with similar characteristics may utilize. RUGs are used to adjust the daily rate for skilled nursing payments. "Skilled Nursing Facility Services Payment System" Medicare Payment Advisory Commission, Payment Basics, October 2011, p. 1-2.

329 "Skilled Nursing Facility Services Payment System" Medicare Payment Advisory Commission, Payment Basics, October 2011, p. 1-2.

330 "Balanced Budget Refinement Act of 1999" Pub. L. 106-113, § 101, 113 Stat. 1501, 1501A-324 (November 29, 1999).

2001, and the nursing component of the RUGs were increased by 16.6 percent.[331] Additionally, BIPA adjusted BBRA's 20 percent increase in payment for three of the fifteen RUGs (those for rehabilitation) to a 6.7 percent increase across 14 additional rehabilitation RUGs.[332]

Home Health Reimbursement

Home health services are reimbursed through Medicare Part A as directed by Section 1861 of the SSA. Specifically, Medicare Part A will reimburse for home healthcare for a patient only when:

(1) A physician has certified that home healthcare is necessary;
(2) The beneficiary has been confined to their home; and,
(3) The beneficiary requires services covered by Medicare, specifically:
    (a) Physical and occupational therapy;
    (b) Speech language pathology services;
    (c) Medical social services; and,
    (d) Home health aide services for personal care related to the treatment of the beneficiary's illness or injury.

Additionally, Medicare Part B covers the cost of medical supplies and durable medical equipment (DME).[333]

When Congress drafted this section of the *Social Security Act*, they intended to limit the coverage of care strictly to the *skilled* treatment of a specific illness or injury.[334] As a result, the SSA's coverage of home health services was constructed similarly to the reimbursement methodology for skilled nursing facilities by specifically denying coverage for *custodial care* and *personal comfort items.*

Originally, Medicare Part A benefits were limited to 100 home healthcare visits for Medicare beneficiaries discharged from a minimum three day stay at the hospital. If these visits were exhausted under Medicare Part A, the beneficiary gained additional coverage under Medicare Part B. Specifically, Medicare Part B provided coverage for an additional 100 home healthcare visits yearly, but required the beneficiary to pay a deductible. However, the *Omnibus Budget Reconciliation Act of 1980* eliminated the 100 visit limits for both Part A and Part B, removed the deductible requirement for Part B home health services, and waived the three day prior hospitalization requirement under Part A. This essentially transformed the Medicare home health benefits into an *unlimited benefit* serving both the short-term *recuperative care* after a hospital stay and the long-term *chronic needs* of patients.[335]

331 "Medicare Program; Provisions of the Benefits Improvement and Protection Act of 2000; Inpatient Payments and Rates and Costs of Graduate Medical Education: Interim Final Rule with Comment Period" Federal Register Vol. 66, No. 144 (June 13, 2001)., p. 32175.
332 "Medicare Beneficiary Access to Skilled Nursing Facilities, 2001," Report OEI-02-01-00160, U.S. Office of Inspector General, July 2001, p.3.
333 "What Part B covers," Medicare.gov, http://www.medicare.gov/what-medicare-covers/part-b/what-medicare-part-b-covers.html (Accessed 4/1/15).
334 "Testimony on the Balanced Budget Act Home Health Provisions by Nancy-Ann Min DeParle" Assistant Secretary for Legislation Department of Health and Human Services, March 31, 1998.
335 "Medicare from the Start to Today" By Tom Dowdal, National Bipartisan Commission of the Future of Medicare, http://rs9.loc.gov/medicare/history.htm (Accessed 8/29/12).

The 1983 implementation of the Medicare PPS for inpatient hospital services resulted in a large transition of healthcare services that once were provided in an inpatient setting instead being provided through an outpatient setting. The result of this was evident through the first half of the 1980's, as the percentage of Medicare patients discharged to home health facilities increased from 9.1 percent in 1981 to 17.9 percent in 1985.[336] In order to slow the surging home health costs, the *Balanced Budget Act* of 1997 implemented a PPS for home health services, as well as aggregate, *per patient cost caps,* on the amount agencies were reimbursed for home healthcare patients.[337]

On October 1, 2000, the PPS for home health was implemented,[338] causing home health agencies to be paid a *pre-determined pay rate* for each 60-day episode of care. This rate is based upon several elements, including:

(1) Patients' conditions and service usage;
(2) Geographic area;
(3) Case mix; and
(4) Number of visits.

If there were fewer than five visits within the 60-day episode of care period, the home health agency is paid instead by the *type of visit*.[339] The episode of care is then categorized by *labor* and *non-labor portions*. The *labor portion* of the pay rate is adjusted to account for geographic differences in labor inputs to home health services.[340] Any remaining elements in the episode of care are categorized as *non-labor portions*.[341] In addition to these established CMS payment rates, the ACA provided an additional three percent payment for episodes of care in rural areas between April 2010 and April 2015.[342]

Independent Diagnostic Testing Facilities (IDTF) Reimbursement

Independent Diagnostic Testing Facilities (IDTF), also known as *Freestanding Diagnostic Imaging Facilities*, offer diagnostic services that are independently performed outside of a physician's office or hospital. Medicare Part B reimburses IDTFs according the MPFS. Notably, the *Deficit Reduction Act of 2005* (DRA), signed into law on February 8, 2006, placed a cap on the *technical component* (which includes the *technical component* of the global fee, i.e., when the technical and professional components are reimbursed as one amount—*globally*) for various

336 "Basic Statistics About Home Care" National Association for Home Care and Hospice, November 2001, www.nahc.org/Consumer/hcstats.html (Accessed 6/5/2003), p. 6.
337 "Medicare Home Health Care: Prospective Payment System Could Reverse Recent Declines in Spending" GAO Report to the Chairman, Subcommittee on Health, Committee on Ways and Means, House of Representatives, September 2000, http://www.gao.gov/new.items/he00176.pdf (Accessed 7/13/07), p. 23.
338 "Home Health Prospective Payment System" Centers For Medicare & Medicaid Services, Payment System Fact Sheet Series, ICN 006816, December 2012, http://www.cms.gov/Outreach-and-Education/Medicare-Learning-Network-MLN/MLNProducts/downloads/HomeHlthProsPaymt.pdf (Accessed 3/3/2015), p. 2.
339 Type of Visit is characterized as skilled nursing care; physical, occupational, and speech therapy; medical social work; or, home health aide services. "Home Health Care Services Payment System" MedPAC, October 2014, Payment Basics, http://www.medpac.gov/documents/payment-basics/home-health-care-services-payment-system-14.pdf?sfvrsn=0 (Accessed 3/3/2015), p. 1.
340 "Balanced Budget Act of 1997" Pub. L. 105-33, § 4603, 111 Stat. 251, 467 (August 5, 1997); "Home Health Care Services Payment System" MedPAC, October 2014, Payment Basics, http://www.medpac.gov/documents/payment-basics/home-health-care-services-payment-system-14.pdf?sfvrsn=0 (Accessed 3/3/2015), p. 3.
341 Ibid.
342 "Home Health Care Services Payment System" MedPAC, October 2014, Payment Basics, http://www.medpac.gov/documents/payment-basics/home-health-care-services-payment-system-14.pdf?sfvrsn=0 (Accessed 3/3/2015), p. 3.

imaging services provided in either a physician's office or IDTF. Importantly, these services may also be provided in a hospital outpatient setting at the OPPS rate.[343] This cap on the *technical component* in physician office or IDTF settings, established by the DRA, which went into effect on or after January 1, 2007, applies to imaging services including:

(1) *X-ray*;
(2) *Ultrasound*;
(3) *Nuclear medicine*;
(4) *Magnetic resonance imaging* (MRI);
(5) *Computed tomography* (CT); and
(6) *Fluoroscopy*.[344]

Notably, the DRA-established cap does not include imaging services that are classified as diagnostic and screening mammography.[345]

Reimbursement to IDTFs has historically been perceived as more vulnerable to abuse than other services by health policy regulators. A 2012 Office of the Inspector General (OIG) study found that, despite accounting for only 2.2 percent of the Medicare beneficiaries receiving IDTF services, 90.1 percent of all IDTF services were provided by 9 percent of the IDTFs in the 20 highest CBSAs. Additionally, these 20 CBSAs allegedly submitted twice as many claims to Medicare that were marked as having at least two *questionable characteristics*.[346] As a result, CMS has increased the monitoring of IDTF billing; however, CMS postponed any further judgment regarding the imposition of a temporary moratorium on new IDTF Medicare enrollment.[347]

ESRD Reimbursement

Medicare has reimbursed providers of *dialysis* services for *end stage renal disease* (ESRD) based on a *composite rate* (CR), which is comprised of a *predetermined prospective payment* for each *dialysis* treatment they conduct, since 1983.[348] The CR covers the costs associated with a single *dialysis* treatment, which includes:

(1) Nursing;
(2) Diet counseling;
(3) Other clinical services;
(4) Social services;
(5) Supplies;
(6) Equipment;
(7) Certain *laboratory tests*; and
(8) Drugs.[349]

343 "Deficit Reduction Act of 2005" Pub. L. 109-171, § 5102, 120 STAT 4, 39 (February 8, 2006).
344 "Deficit Reduction Act of 2005" Pub. L. 109-171, § 5102, 120 STAT 4, 40 (February 8, 2006).
345 Ibid.
346 "Questionable Billing for Medicare Independent Diagnostic Testing Facility Services" By Timothy S. Brady, et al., Office of the Inspector General, OEI-09-09-00380, March 2012, http://oig.hhs.gov/oei/reports/oei-09-09-00380.pdf (Accessed 3/3/2015), p. 9-11.
347 Ibid, p. 14.
348 "Outpatient Dialysis Services Payment System" Payment Basics, Medicare Payment Advisory Committee, October 2014, http://www.medpac.gov/documents/payment-basics/outpatient-dialysis-services-payment-system.pdf?sfvrsn=0 (Accessed 3/3/2015), p. 1.
349 "Outpatient Dialysis Services Payment System" Payment Basics, Medicare Payment Advisory Committee, October 2014, http://www.medpac.gov/documents/payment-basics/outpatient-dialysis-services-payment-system.pdf?sfvrsn=0 (Accessed 3/3/2015), p. 1; "Outpatient Dialysis Services" Medicare Payment Advisory Commission, Report to the Congress: Medicare Payment Policy, 2006 Washington, D.C., March 2006, p. 105-129.

Additionally, the CR is adjusted to account for geographic differences in prices and *case-mix*.[350]

As of January 1, 2011, the basic *composite payment system* was replaced with a bundled ESRD *prospective payment system* (ESRD PPS) for Medicare outpatient ESRD facilities by §153(b) of the *Medicare Improvements for Patients and Providers Act* (MIPPA).[351] The new reimbursement model was fully implemented on January 1, 2014, having been transitioned in over a four-year period.[352] Providers were given the option to either: (1) fully implement the new reimbursement system on January 1, 2011 or (2) transition to the new reimbursement system under the four year transition model.[353] If the provider elected to transition under the four year model, they received a blended payment rate comprised of the initial *case-mixed adjusted composite payment rate* and the new ESRD PPS payment.[354]

The ESRD PPS bundled payment system includes services that were included in the CR as of 2010, such as *erythropoiesis stimulating* agents and any oral form of such agents; *injectable biologicals* used to treat anemia; *laboratory tests* and other items and services provided to beneficiaries for ESRD treatment; and other *injectable medications* that are furnished to ESRD beneficiaries and separately paid for under Medicare Part B.[355] Similar to other forms of payment, the bundled payment rate is adjusted for *patient case-mix*, *high cost patients*, and *low volume* facilities.[356] Various factors that adjust the ESRD PPS base rate are described and set forth below, in Table 2-7: *Factors Used to Adjust ESRD PPS Base Rate Payments*.

Table 2-7: Factors Used to Adjust ESRD PPS Base Rate Payments[357]

Adjustment Factor	Description
Patient-Level Adjustments for Case-Mix	Based on demographics that play a role in the cost of providing care, including: patient age; body surface area; low body mass index; onset of dialysis; and the following six specified co-morbidities: (1) Hereditary Hemolytic and Sickle Cell Anemia; (2) Monoclonal Gammopathy (in the absence of multiple Myeloma); (3) Myelodysplastic Syndrome; (4) Bacterial Pneumonia; (5) Gastrointestinal Bleeding; and (6) Pericarditis.
Facility-Level Adjustments	Facilities that are certified to furnish home or self-care dialysis training services will receive a training add-on payment. This adjustment applies to both peritoneal dialysis and hemodialysis training treatments.

350 "Outpatient Dialysis Services Payment System" Payment Basics, Medicare Payment Advisory Committee, October 2014, http://www.medpac.gov/documents/payment-basics/outpatient-dialysis-services-payment-system.pdf?sfvrsn=0 (Accessed 3/3/2015), p.2.

351 "ESRD Prospective Payment System (PPS) Overview" Centers for Medicare & Medicaid Services, August 19, 2014, http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/ESRDpayment/index.html?redirect=/ESRDPayment (Accessed 3/2/15).

352 "Medicare: ESRD Payment" Centers For Medicare & Medicaid Services, March 23, 2012, http://www.cms.gov/ESRDPayment (Accessed 2/18/10).

353 This option was not available to providers that began offering dialysis services on or after January 1, 2011, instead these providers were reimbursed at 100 percent of the ESRD PPS. "Medicare Program; End-Stage Renal Disease Prospective Payment System; Final Rule and Proposed Rule," Centers For Medicare & Medicaid Services, Federal Register Vol. 75, No. 155 (August 12, 2010), p. 49033-49034;

354 "Medicare Program; End-Stage Renal Disease Prospective Payment System; Final Rule and Proposed Rule," Centers For Medicare & Medicaid Services, Federal Register Vol. 75, No. 155 (August 12, 2010), p. 49083.

355 "Outpatient Dialysis Services Payment System" By The Medicare Payment Advisory Commission, October 2009, http://www.amcp.org/WorkArea/DownloadAsset.aspx?id=11180 (Accessed 3/2/15), p. 3.

356 Ibid.

357 "Medicare Program; End-Stage Renal Disease Prospective Payment System and Quality Incentive Program; Ambulance Fee Schedule; Durable Medical Equipment; and Competitive Acquisition of Certain Durable Medical Equipment, Prosthetics, Orthotics and Supplies; Final Rule," Centers For Medicare & Medicaid Services, Federal Register Vol. 76, No. 218 (November 10, 2011), p. 70230.

Adjustment Factor	Description
Adjustments for Pediatric Patients	Treatments provided to pediatric patients (i.e., individuals under the age of 18) are subject to a payment adjustment to reflect the higher total payments for pediatric composite rate and separately billable services compared to adult patients.
Outlier Adjustments	An additional outlier payment is applied when a beneficiary's payment per treatment for outlier services exceeds the predicted payment amount per treatment for the outlier services plus a fixed dollar amount. Outlier services include drugs, laboratory testing, and other items that facilities separately billed under the old payment system, such as ESRD-related medical and surgical supplies.

A pay-for-performance program was also implemented into the payment bundle system under MIPPA.[358]

Durable Medical Equipment Reimbursement

Medicare Part B reimburses approximately 28 percent of all spending on *durable medical equipment, prosthetics, orthotics, and other medical supplies* (DMEPOS) that is medically necessary and physician prescribed. CMS reimbursement varies based on the distinctions in the definition of DMEPOS. *Durable medical equipment (*DME) and *prosthetics and orthotics* (PO) have the largest scope of Medicare reimbursement. DME includes any equipment that: "(1) can withstand repeated use, (2) is used to serve a medical purpose, (3) generally is not useful in the absence of an illness or injury, and (4) is appropriate for use in the home."[359] PO are more limited to those devices that replace all or part of an internal body organ or body part, e.g., colostomy bags, artificial parts, and leg braces. Additionally, Medicare covers *some* supplies (S) that are not including in DME or PO, such as disposable surgical dressings.[360]

Medicare's reimbursement fee schedule for DMEPOS is developed from previous charges submitted to Medicare by suppliers. Medicare typically pays 80 percent of either (1) the supplier's actual charge or (2) the Medicare fee schedule for an item or service, whichever is less. The remaining 20 percent of the charge is covered through beneficiary coinsurance accounts. There are four specific *Medicare Administrative Contractors* that manage the payment of claims for DMEPOS Medicare billing.[361]

President Ronald Reagan signed The *National Association of Medical Equipment Services' Six-Point Plan* into law as a part of the *Omnibus Budget Act of 1987*. Taking effect in 1989, the *Six-Point Plan's* purpose was to stabilize Medicare reimbursements for DMEPOS and to increase the *rent/purchase cap*[362] from $120 to $150.[363] The *Six-Point Plan* classified DMEPOS into six categories, as follows:

358 "Outpatient Dialysis Services Payment System" By The Medicare Payment Advisory Commission, October 2009, http://www.amcp.org/WorkArea/DownloadAsset.aspx?id=11180 (Accessed 3/2/15), p. 3.
359 "Medicare Durable Medical Equipment: The Competitive Bidding Program" By Paulette C. Morgan, Congressional Research Service, Report to Congress, R41211, August 6, 2010, p. 1
360 Ibid.
361 "Medicare: Review of the First Year of CMS's Durable Medical Equipment Competitive Bidding Program's Round 1 Rebid" Government Accountability Office, GAO-12-693, May 2012, p. 6.
362 The maximum cost of DME of which Medicare will reimburse.
363 "The Home Care Evolution" Home Care Magazine, January 1, 2003, http://homecaremag.com/mag/medical_home_care_evolution/ (Accessed 5/29/07); "Reimbursement Challenges Hit Home" By David Gourley, RT for Decision Makers in Respiratory Care, (2006), p. 1-4.

(1) **Inexpensive or Other Routinely purchased DME (Rent or Purchase).** Defined as DME that does not exceed $150 or is acquired by purchase as least 75 percent of the time;
(2) **Items Requiring Frequent and Substantial Servicing (Rental Only).** Defined as DME items that require frequent and substantial servicing to avoid a risk to a patient's health, such as ventilators and aspirators;
(3) **General Prosthetic and Orthotic Devices and Supplies, Miscellaneous Supplies and Other Items (Purchase Only).** Where prosthetics are defined as devices that replace all or part of an internal body organ or its function, orthotic devices are defined as items used for the correction or prevention of skeletal deformities, and miscellaneous supplies include items such as sterile saline or water and blood glucose test strips;
(4) **Capped Rental Items (Rent or Purchase).** Defined as items that cost more than $150; are not routinely purchased; are not service intensive; are not customized; and are not oxygen or oxygen-related;
(5) **Oxygen (Rental Only) and Oxygen Equipment.** With oxygen equipment defined as stationary or portable gaseous and liquid systems; and
(6) **Customized Equipment (Including Customized Prosthetic and Orthotic Devices) (Purchase Only).** Defined as equipment uniquely constructed or modified to meet the needs of a specific patient.[364]

To this day, CMS still uses all of these six basic categories for DMEPOS reimbursement.[365]

The terms of beneficiary ownership of certain DMEPOS, including those defined in the *Six-Point Plan,* were altered under the *Deficit Reduction Act* (DRA) of 2005. Payments must be made on a monthly basis, not exceeding 13 months of continuous use, in order to be considered a rental item. In the event that the rental item is used for more than 13 continuous months, the title will be transferred from the supplier to the individual. An exception to this rule is made if the item is a power-driven wheelchair. Instead, power-driven wheelchairs are required to be offered for purchase at a lump sum price when the supplier furnishes the item. The DRA also changed the rules for maintenance and servicing of DME after the title is transferred to the individual, by stating that reasonable and necessary maintenance and servicing for capped rental items and certain oxygen-generating equipment is the responsibility of the supplier.[366]

The process of *competitive bidding*, whereby certain DMEPOS manufacturers (i.e., patient safety items, ambulatory aids, wheelchairs, and hospital beds) submit competing bids to Medicare based on the *charge per unit* and the lowest of which is granted a government DMEPOS contract, provides the DMEPOS provider with a unique opportunity to be a Medicare provider in one of ten different metropolitan areas.[367] CMS chooses two, sometimes more, suppliers from each *metropolitan statistical area* (MSA), until patient need is satisfied and CMS caps the number of *winning bidders*. *Competitive bidding,* mandated under §302 of the *Medicare*

364 "Region C DMERC: DMEPOS Supplier Manual" Palmetto GBA and Centers For Medicare & Medicaid Services, Spring 2007, p. 8.2-8.7.
365 "30 – General Payment Rules" in "Medicare Claims Processing Manual: Chapter 20 – Durable Medical Equipment, Prosthetics, Orthotics, and Supplies (DMEPOS)" Centers for Medicare & Medicaid Services, June 20, 2014, http://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/Downloads/clm104c20.pdf (Accessed 3/3/2015)..
366 "Deficit Reduction Act of 2005" Pub. L. 109-171, § 5101, 120 STAT 4, 37 (February 8, 2006).
367 "Medicare DME Bidding Program Set to Relaunch in 2010," By Chris Silva, American Medical News, May 4, 2009, http://www.ama-assn.org/amednews/2009/05/04/gvsd0504 (Accessed 11/10/09).

Prescription Drug, Improvement, and Modernization Act of 2003 (MMA),[368] was designed to reduce out-of-pocket costs to patients, as well as costs incurred by Medicare, by combatting provider fraud.[369] Identical products must be priced the same within an individual MSAs, however prices may vary between MSAs.

In general, all DME contract suppliers for Medicare must be licensed and accredited by an approved agency[370] before their bid is considered.[371] CMS requires any potential DME supplier to meet seven criteria:

(1) Be in good standing with the Medicare program and not under any current sanctions by Medicare or any governmental agency or accreditation or licensing organization;
(2) Have an active National Supplier Clearinghouse (NSC) number[372];
(3) Meet any local or state licensure requirements for the item being bid;
(4) Submit a bid as a prerequisite to becoming a winning supplier;
(5) Be accredited or have an application for accreditation pending in order to participate in bidding;
(6) Provide capacity estimates of the number of units for each item included in the product category that the supplier would be capable of furnishing under the program; and
(7) Agree to service the entire *competitive bidding area* (CBA) regardless of where the beneficiary is located, although the supplier will not be required to be capable of servicing 100 percent of the beneficiaries in that geographic area.[373]

Approximately 85 percent of DMEPOS suppliers enrolled in the Medicare program are small suppliers that generate gross revenue of $3.5 million or less in annual receipts.[374] CMS published their final rule on the *DMEPOS competitive bidding program* April 10, 2007, ensuring that small suppliers would be able to participate in, and access the *competitive bidding* market through

368 "Medicare Prescription Drug, Improvement, and Modernization Act of 2003" Pub. L. 108-173, § 302, 117 STAT. 2066, 2223 (December 8, 2003).

369 "Medicare Announces Competitive Acquisition Program for Certain Durable Medical Equipment, Prosthetics, Orthotics, and Supplies" Centers For Medicare & Medicaid Services, April 2, 2007, http://www.cms.hhs.gov/apps/media/press/release.asp?Counter=2097&intNumPerPage=10&checkDate=&checkKey=&srchType=&numDays=3500&srchOpt=0&srchData=&keywordType=All&chkNewsType=1%2C+2%2C+3%2C+4%2C+5&intPage=&showAll=&pYear=&year=&desc=&cboOrder=date (Accessed 08/16/12).

370 To obtain a CMS contract to supply DME, suppliers must meet quality standards established by CMS and be accredited by a CMS-approved independent national Accreditation Organization (AO), of which there are ten (approved by CMS in November 2006), including: (1) Accreditation Commission for Health Care, Inc.; (2) American Board for Certification in Orthotics & Prosthetics, Inc.; (3) Board of Certification/Accreditation International; (4) Commission on Accreditation of Rehabilitation Facilities; (5) Community Health Accreditation Program; (6) HealthCare Quality Association on Accreditation; (7) National Association of Boards of Pharmacy; (8) The Compliance Team, Inc.; (9) The Joint Commission; and, (10) The National Board of Accreditation for Orthotic Suppliers. "Medicare New Deemed Accreditation Organizations for Suppliers of Durable Medical Equipment, Prosthetics, Orthotics and Supplies (DMEPOS)" Centers for Medicare & Medicaid Services, March 2013, http://www.cms.gov/Medicare/Provider-Enrollment-and-Certification/MedicareProviderSupEnroll/Downloads/DeemedAccreditationOrganizationsCMB.pdf (Accessed 3/3/2015).

371 "Shaping Up for NCB," Miram Lieber, HomeCare, April 1, 2007, http://www.homecaremag.com/mag/medical_shaping_ncb/index.html, (May 8, 2007).

372 The National Supplier Clearinghouse (NSC) is the organization that enrolls and monitors the business information for DMEPOS suppliers in the Medicare program. NSC issues Medicare supplier numbers based on a suppliers single tax reporting or employee identification number and uses modifiers to identify geographic office locations. Although NSC is not directly involved in billing and claims, they supply DME Medicare Administrative Contractors with the overall NSC Master File to facilitate supplier eligibility for claims payment. "Durable Medicare Equipment Medicare Administrative Contractor: Workload Implementation Handbook" Centers For Medicare & Medicaid and the Medicare Contractor Management Group, March 1, 2007, p. 7-3.

373 "Medicare Program; Competitive Acquisition for Certain Durable Medical Equipment, Prosthetics, Orthotics, and Supplies (DMEPOS) and Other Issues" Federal Register Vol. 72, No. 68 (April 10, 2007), p. 18035-18039.

374 "Fact Sheet: Competitive Bidding Program for Certain Durable Medical Equipment, Prosthetics, Orthotics, and Supplies: Final Rule (CMS 1270-F)" Centers for Medicare & Medicaid Services, April 02, 2007, http://www.cms.hhs.gov/apps/media/press/factsheet.asp?Counter=2098&int NumPerPage=10&checkDate=&checkKey=&srchType=&numDays=3500&srchOpt=0&srchData=&keywordType=All&chkNewsType=6&intPage=&showAll=&pYear=&year=&desc=&cboOrder=date, (Accessed 8/16/12).

several provisions. First, the final rule set that winning bidders representing small supplier participation must meet the target percentage of 30 percent for each category. If this percentage is not met during a *competitive bidding* cycle, CMS must offer DMEPOS supplier contracts to those small suppliers that submitted bids higher than the winning bids, and represent the highest of the small supplier bids until either: (1) the 30 percent goal is met or (2) there are no additional small supplier bidders.[375] Additionally, the rule also facilitated participation in the bidding process by permitting small suppliers to form *networks* in order to "lower bidding costs, expand service options, or attain more favorable purchasing terms,"[376] so long as they comply with all federal and state laws, including antitrust laws.[377]

The first round of *competitive bidding* began in 2007, and the first round of contracts that were awarded took effect on July 1, 2008. This process successfully achieved an approximate 26 percent in savings as compared to prior Medicare expenditures on specific DMEPOS items.[378] However, partially due to problems with the implementation of the automatic bid submission system, MIPPA rescinded the contracts awarded in the first round of bidding; delayed the second round of bidding, which was scheduled for 2009; and made several other changes to the program.[379]

MIPPA made changes to the fee schedule in order to offset the cost of the implementation delays. Any item selected for *competitive bidding* before July 1, 2008 had their 2009 fee schedule payment amount reduced by 9.5 percent.[380] Beginning in October 2009, the *Round One Rebid* resulted in 1,217 new contracts, which became effective in January 2011, in nine MSAs for nine product categories.[381] Approximately 51 percent of the contracts were with small businesses, vastly exceeding the required target minimum of 30 percent (discussed above).[382] The *competitive bidding* program achieved a 35 percent savings in its *first* round, significantly reducing prices for beneficiaries in select areas.[383] Due to the *competitive bidding process* of MSAs included in the *Round One Rebid*, CMS has estimated that DMEPOS expenditures were reduced by $202.1 million (42 percent).[384] Additionally, their *real-time monitoring* also indicated significantly fewer instances of inappropriate mail-order claims.[385]

375 "Medicare Program; Competitive Acquisition for Certain Durable Medical Equipment, Prosthetics, Orthotics, and Supplies (DMEPOS) and Other Issues" Federal Register Vol. 72, No. 68 (April 10, 2007), p. 18058.
376 Ibid, p. 18058-18059.
377 Ibid, p. 18058-18059.
378 "Durable Medical Equipment Payment System" Medicare Payment Advisory Commission, October 2014, http://www.medpac.gov/documents/payment-basics/durable-medical-equipment-payment-system-14.pdf?sfvrsn=0 (Accessed 3/2/15), p. 2.
379 Ibid.
380 Ibid.
381 "DMEPOS Competitive Bidding" Centers For Medicare & Medicaid Services, April 18, 2012, http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/DMEPOSCompetitiveBid/index.html?redirect=/DMEPOSCompetitiveBid/ (Accessed 8/9/12); "Competitive Bidding Update – One Year Implementation Update" Centers For Medicare & Medicaid Services, April 17, 2012, http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/DMEPOSCompetitiveBid/Downloads/Competitive-Bidding-Update-One-Year-Implementation.pdf (Accessed 8/9/12), p. 2.
382 "Review of the First Year of CMS's Durable Medical Equipment Competitive Bidding Program's Round 1 Rebid" U.S. Government Accountability Office, May 2012, p. 19, http://www.gao.gov/assets/600/590712.pdf (Accessed 3/2/15).
383 "Durable Medical Equipment Payment System" Medicare Payment Advisory Commission, October 2014, p. 2, http://www.medpac.gov/documents/payment-basics/durable-medical-equipment-payment-system-14.pdf?sfvrsn=0 (Accessed 3/2/15).
384 "Review of the First Year of CMS's Durable Medical Equipment Competitive Bidding Program's Round 1 Rebid" U.S.Government Accountability Office, May 2012, http://www.gao.gov/assets/600/590712.pdf (Accessed 3/2/15), p. 55.
385 "Competitive Bidding Update – One Year Implementation Update" Centers For Medicare & Medicaid Services, April 17, 2012, http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/DMEPOSCompetitiveBid/Downloads/Competitive-Bidding-Update-One-Year-Implementation.pdf (Accessed 8/9/12), p. 7.

CMS, which is required to *re-complete* DMEPOS contracts every three years, set an expiration date on the *Round One Rebid contracts* (except for mail order diabetes products) of December 31, 2013. Additionally, they began conducting the *Round One Re-compete* in the spring of 2012 in the same geographic areas (MSAs) included in the *Round One Rebid*.[386]

The implementation of the ACA expanded the *Round Two* MSAs from 70 to 91 and required further expansion in subsequent re-competes, including the requirement that the entire country be eligible for *competitive bidding* by 2016.[387] Mail order items were also included as a product category for *Round Two competitive bidding*.[388] Absent any negative effects on access to supplies or beneficiary health indicators, the *Round Two competitive bidding* process mirrors the process used during *Round One*. The *Office of the Actuary* (OACT)[389] has predicted that *competitive bidding* may save the Medicare program about $25.7 billion and may save beneficiaries an additional $17.1 billion between 2013 and 2022.[390]

Medicare Shared Savings Program

The ACA, §3022, formally introduced the Federal Accountable Care Organization (ACO) model, i.e., the Medicare *Shared Savings* Program (MSSP), which amends Title XVIII of the SSA by adding §1899 to the end of the Title.[391] Federal ACOs are discussed more fully in this section, while Commercial ACOs are more fully described in the Commercial ACOs section of this chapter. ACOs are a healthcare organizations in which a set of providers, usually a combination of primary care physicians, nurse practitioners, specialists, and allied health practitioners, as well as hospitals, nursing homes, ASCs, or any other entity in the patient's continuum of care,[392] are held accountable under an ACO contract with a payor for the cost and quality of care delivered to a specific population. This differs from the *medical home* model, discussed in the Medical Home Model section below, because a separate entity focuses on coordinating all of a patient's healthcare providers, rather than placing this responsibility on the physicians of the *medical home* and their staff.[393]

The MSSP allows for the creation of Federal ACOs, and "promotes accountability for a patient population and coordinates items and services under parts A and B, and encourages investment in infrastructure and redesigned care processes for high quality and efficient service delivery."[394]

386 "DMEPOS Competitive Bidding Program Round 1 Recompete Announced" Centers For Medicare & Medicaid Services, April 17, 2012, http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/DMEPOS-Round-1-Recompete/index.html (Accessed 8/9/12).

387 "DMEPOS Competitive Bidding" Centers For Medicare & Medicaid Services, April 18, 2012, http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/DMEPOSCompetitiveBid/index.html?redirect=/DMEPOSCompetitiveBid/ (Accessed 8/9/12).

388 "DMEPOS Competitive Bidding" Centers For Medicare & Medicaid Services, April 18, 2012, http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/DMEPOSCompetitiveBid/index.html?redirect=/DMEPOSCompetitiveBid/ (Accessed 8/9/12).

389 The Office of the Actuary (OACT) is a department within CMS that, "[c]onducts and directs the actuarial program for CMS and directs the development of and methodologies for macroeconomic analysis of health care financing issues." "Office of the Actuary" Centers For Medicare & Medicaid Services, June 28, 2012, http://www.cms.gov/About-CMS/Agency-Information/CMSLeadership/Office_OACT.html (Accessed 9/11/12).

390 "Competitive Bidding Update – One Year Implementation Update" Centers For Medicare & Medicaid Services, April 17, 2012, p. 7, http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/DMEPOSCompetitiveBid/Downloads/Competitive-Bidding-Update-One-Year-Implementation.pdf (Accessed 8/9/12).

391 "Shared Savings Program" 42.U.S.C. §1395jjj(a) (March 23, 2010); "Patient Protection and Affordable Care Act: Pub. L. No 111-148, §3022, 124 Stat. 119, 395 (2010).

392 "Health Care Reform Requires Accountable Care Systems" By Stephen Shortell and Lawrence Casalino, Journal of the American Medical Association, Vol. 300 No. 1 (July 2, 2008), p. 95.

393 "Creating Accountable Care Organizations: The Extended Hospital Medical Staff" By Elliot Fisher et al, Health Affairs Vol. 26, No. 1 (December 5, 2006) http://content.healthaffairs.org/cgi/reprint/26/1/w44 (Accessed 05/20/10), p. w53.

394 "Shared Savings Program" 42 U.S.C. §1395jjj(a) (March 23, 2010).

Section 1899(d)(1)(A) of the SSA, provides that ACOs will be reimbursed under a FFS model as previously established for Medicare Part A and Part B.[395] While FFS reimbursement places little risk on providers, providers in an ACO have some discretion as to the amount of risk to assume in regard to incentive bonuses, i.e., *shared savings* payments.[396]

Under the MSSP, a participating ACO may receive bonuses for achieving resource use and quality targets over the course of a year, as well as potentially being subject to penalties, i.e., *shared losses*, for failing to meet these requirements.[397] Originally, there were two *risk models* for ACOs to receive *shared savings* payments or pay *shared losses*: (1) the *one-sided risk model* (Track 1) and (2) the *two-sided risk model* (Track 2). In December of 2014, CMS released a proposed rule for a third ACO *risk model* (Track 3), similar to the *two-sided risk model*.[398]

The *one-sided risk model* allows federal ACOs to *avoid risk* (i.e., no *shared losses*) during their initial three-year contract in exchange for a *smaller percentage* of the achieved *shared savings* distributed to the ACO.[399] The *two-sided risk model* offsets the additional *risk* of possible *shared losses* by allowing the ACO to partake in a *greater percentage* of the *shared savings* (i.e., patient expenditure reductions) they can demonstrate and document have been achieved.[400]

Under all *risk models*, CMS sets a spending benchmark for each ACO based upon the most recently available three years of Medicare Parts A and B expenditure data for the population of beneficiaries assigned to the ACO.[401] Then, CMS establishes a minimum savings rate (MSR) for each ACO, which is the minimal amount of savings the ACO must achieve in order to receive *shared savings*, akin to a corridor around the ACO's benchmark.[402] Under the December 2014 proposed rule, both Track 1 and Track 2 ACOs will have MSRs established based upon the size of their assigned populations, and this amount will vary between 2.0% and 3.9%, while Track 3 ACOs will have a fixed MSR of 2.0%.[403]

Similarly, CMS establishes a minimum loss rate (MLR) for each Track 2 ACO, which is the maximum amount of losses that an ACO may incur before becoming liable for sharing in its

395 "Medicare Program; Medicare Shared Savings Program: Accountable Care Organizations" Federal Register Vol. 76 No. 212 (November 2, 2011), p. 67904.

396 "Accountable Care Organizations: A new model for sustainable innovation" By Paul H. Keckley and Michelle Hoffman, Deloitte Center for Health Solutions, 2010, http://www.deloitte.com/assets/dcom-unitedstates/local%20assets/documents/us_Chs_accountable Careorganizations_041910.pdf (Accessed 2/24/15), p. 11.

397 "Methodology for Determining Shared Savings and Losses under the Medicare Share Savings Program" Medicare Learning Network, Centers for Medicare and Medicaid Services, April 2014, http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/sharedsavingsprogram/Downloads/ACO_Methodology_Factsheet_ICN907405.pdf (Accessed 2/24/15), p. 2.

398 "Medicare Program; Medicare Shared Savings Program; Accountable Care Organizations; Proposed Rule" Federal Register Vol. 79, No. 235 (December 8, 2014) p. 72808-72809; "CMS ACO Proposed Rule to Extend One-Sided Risk Track While Incentivizing Performance-Based Risk" McDermott Will & Emery, December 19, 2014, http://www.mwe.com/CMS-ACO-Proposed-Rule-to-Extend-One-Sided-Risk-Track-While-Incentivizing-Performance-Based-Risk-12-19-2014/ (Accessed 2/18/15).

399 "Medicare Program; Medicare Shared Savings Program: Accountable Care Organizations" Federal Register Vol. 76, No. 212 (November 2, 2011), p. 67985-67986.

400 Ibid, p. 67986-67987.

401 "Methodology for Determining Shared Savings and Losses under the Medicare Share Savings Program" Medicare Learning Network, Centers for Medicare and Medicaid Services, April 2014, http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/sharedsavingsprogram/Downloads/ACO_Methodology_Factsheet_ICN907405.pdf (Accessed 2/24/15), p. 3-4.

402 Ibid, p. 5-6.

403 "Medicare Program; Medicare Shared Savings Program; Accountable Care Organizations; Proposed Rule" Federal Register Vol. 79, No. 235 (December 8, 2014), p. 72807-72808, 72844-72845.

losses.[404] The MLR for each Track 2 ACO is established using the same methodology outlined above, while Track 3 ACOs will have a fixed MLR of 2.0%.[405]

The amount of *shared savings*, if any, is determined by comparing an ACO's quality performance to a specified set of metrics.[406] In Track 1, an ACO may earn up to 50% of its *shared savings*, based upon its performance as compared with these quality measure benchmarks, with a *shared savings* cap of 10% of the ACO's benchmark in that year.[407] Under the December 2014 proposed rule, ACOs may be able to participate in the MSSP under Track 1 for more than one three-year agreement period; however, Track 1 ACOs may only earn up to 40% of their *shared savings* in its second agreement period.[408]

Under Track 2, an ACO may earn up to 60% of its *shared savings*, based upon its performance as compared with quality measure benchmarks, with a *shared savings* cap of 15% of the ACO's benchmark in that year.[409] In addition, under Track 2, an ACO may share in up to 60% of the losses between the MLR and the actual amount of losses, with the actual percentage varying based upon the ACOs performance as compared with the same quality measure benchmarks.[410]

The maximum amount of losses for which Track 2 ACOs will be required to share in will vary based upon the ACO's year in the MSSP. Track 2 ACOs will be required to share in losses up to 5% of the ACO's benchmark in their first year, 7.5% of the ACO's benchmark in their second year, and 10% of the ACO's benchmark in their third year.[411]

The third *risk model* proposed by CMS in December 2014 works in a similar fashion to the *two-sided risk model*, but differs in the amount of *shared savings* and losses allocated toward the ACO. Specifically, Track 3 ACOS may earn up to 75% of the savings that they generate, based upon quality performance as compared with quality measure benchmarks, with a cap of 20% of the ACO's benchmark.[412] Similarly, Track 3 ACOs will be required to share between 45% and

404 "Methodology for Determining Shared Savings and Losses under the Medicare Share Savings Program" Medicare Learning Network, Centers for Medicare and Medicaid Services, April 2014, http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/sharedsavingsprogram/Downloads/ACO_Methodology_Factsheet_ICN907405.pdf (Accessed 2/24/15), p. 5.

405 "Medicare Program; Medicare Shared Savings Program; Accountable Care Organizations; Proposed Rule" Federal Register Vol. 79, No. 235 (December 8, 2014), p. 72807-72808, 72844-72845.

406 "Methodology for Determining Shared Savings and Losses under the Medicare Share Savings Program" Medicare Learning Network, Centers for Medicare and Medicaid Services, April 2014, http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/sharedsavingsprogram/Downloads/ACO_Methodology_Factsheet_ICN907405.pdf (Accessed 2/24/15), p. 6; "Medicare Shared Savings Program Quality measure Benchmarks for the 2014 and 2015 Reporting Years" Centers for Medicare & Medicaid Services, http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/sharedsavingsprogram/Downloads/MSSP-QM-Benchmarks.pdf (Accessed 2/24/15), p. 1.

407 "Methodology for Determining Shared Savings and Losses under the Medicare Share Savings Program" Medicare Learning Network, Centers for Medicare and Medicaid Services, April 2014, http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/sharedsavingsprogram/Downloads/ACO_Methodology_Factsheet_ICN907405.pdf (Accessed 2/24/15), p. 6; "Medicare Program; Medicare Shared Savings Program; Accountable Care Organizations; Proposed Rule" Federal Register Vol. 79, No. 235 (December 8, 2014), p. 72844-72845.

408 "Medicare Program; Medicare Shared Savings Program; Accountable Care Organizations; Proposed Rule" Federal Register Vol. 79, No. 235 (December 8, 2014), p. 72807-72805.

409 "Medicare Shared Savings Program: Shared Savings and Losses and Assignment Methodology – Specifications" Centers for Medicare and Medicaid Services, December 2014, p. 42, http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/sharedsavingsprogram/Downloads/Shared-Savings-Losses-Assignment-Spec-v2.pdf (Accessed 3/2/15); "Medicare Program; Medicare Shared Savings Program; Accountable Care Organizations; Proposed Rule" Federal Register Vol. 79, No. 235 (December 8, 2014), p. 72844-72845.

410 Ibid.

411 Ibid.

412 "Medicare Program; Medicare Shared Savings Program; Accountable Care Organizations; Proposed Rule" Federal Register Vol. 79, No. 235 (December 8, 2014), p. 72808-72809, 72844-72845; "CMS ACO Proposed Rule to Extend One-Sided Risk Track While Incentivizing Performance-Based Risk" McDermott Will & Emery, December 19, 2014, http://www.mwe.com/CMS-ACO-Proposed-Rule-to-Extend-One-Sided-Risk-Track-While-Incentivizing-Performance-Based-Risk-12-19-2014/ (Accessed 2/18/15).

75% of the losses between the MLR and the actual amount of losses, with the actual percentage varying upon the ACOs performance as compared with the quality measure benchmarks.[413] The maximum amount of losses for which Track 3 ACOs will be required to share in will be fixed at 15% of the ACO's benchmark.[414] Therefore, the one-sided model may be most appropriate for entities that are smaller and less mature in terms of their level of integration and coordination of care, while the two-sided models may be more attractive for more experienced ACOs that are willing to take on higher risks for potentially higher rewards.

Modifications to Medicare Resulting from the Affordable Care Act

The ACA, signed into law on March 23, 2010, included a number of modifications (some temporary, others permanent), to the Medicare program.

Modifications to Medicare Advantage

Among the most significant changes to Medicare in the 2010 healthcare reform legislation are the changes to the Medicare Advantage (MA) Program. The ACA implements provisions to bring MA spending back in line with Medicare FFS spending. These changes include altering the benchmark rates used in each county; altering the amount of money that may be paid as rebates to insurers; and utilizing quality measures to adjust benchmarks that determine MA rebate payment rate.

Benchmark rates were frozen in 2011 at 2010 levels, and are now being adjusted downward pursuant to the ACA's new benchmark policy.[415] Under the new ACA benchmark policy, all counties in the U.S. will be ranked according to their estimated per capita spending in the traditional Medicare program, as well as health plan quality indicators.[416] As stated above, MA plans submit bids that are then compared to these benchmarks, and MA plans with high quality scores (i.e., star rankings, discussed below) may have their benchmark values increased.

In addition, prior to the passage of the ACA, insurers received a rebate payment calculated at 75% of the difference between the plan's bid and the geographic area benchmark rate. However, the new ACA rebate policy reduces the rebate payment to between 50% and 70% of the difference between the plan's bid and the geographic area benchmark rate, depending upon the plan's star rankings.[417]

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413 "Medicare Program; Medicare Shared Savings Program; Accountable Care Organizations; Proposed Rule" Federal Register Vol. 79, No. 235 (December 8, 2014), p. 72844-72845.

414 Ibid, p. 72814, 72844-72845.

415 "Medicare Advantage Fact Sheet" The Henry J. Kaiser Family Foundation, May 2014, http://kaiserfamilyfoundation.files.wordpress.com/2013/06/8448.pdf (Accessed 2/25/15), p. 3.

416 "Medicare Advantage Program Payment System" Medicare Payment Advisory Council, October 2014, http://medpac.gov/documents/payment-basics/medicare-advantage-program-payment-system-14.pdf?sfvrsn=0 (Accessed 2/25/14), p. 1; "Realizing Health Reform's Potential: The Impact of Health Reform on the Medicare Advantage Program: Realigning Payment with Performance" By Brian Biles et al., The Commonwealth Fund, October 2012, http://www.commonwealthfund.org/~/media/Files/Publications/Issue%20Brief/2012/Oct/1637_Biles_impact_hlt_reform_Medicare_Advantage_rb.pdf (Accessed 4/28/14), p. 3-4.

417 "Realizing Health Reform's Potential: The Impact of Health Reform on the Medicare Advantage Program: Realigning Payment with Performance," By Brian Biles et al., The Commonwealth Fund, October 2012, http://www.commonwealthfund.org/~/media/Files/Publications/Issue%20Brief/2012/Oct/1637_Biles_impact_hlt_reform_Medicare_Advantage_rb.pdf (Accessed 4/28/14), p. 5; "Medicare Advantage Program Payment System" Medicare Payment Advisory Council, October 2014, http://medpac.gov/documents/payment-basics/medicare-advantage-program-payment-system-14.pdf?sfvrsn=0 (Accessed 2/25/14), p. 3.

Further, the ACA established a method by which MA plans were rewarded with bonus payments for performing well on the new MA star scale. CMS uses information from satisfaction surveys, plans, and healthcare providers to rate plans on overall performance, or star rankings. A plan may receive between 1 and 5 stars.[418] In general, higher star plans get percentage bonuses to their geographic benchmarks, thereby increasing the amount of rebate payments to those plans.[419] Further, the percentage amount that the plan receives as a rebate is altered by their star-score, with higher star plans receiving larger percentage payments.[420] The additional amount that the plan receives in rebates with the bonus payment adjustments, over the original rebate amount, is called the bonus payment. The ACA awards bonus payments to MA plans that receive 4 or more stars. As such, due to the combined effects outlined above, MA plans will likely experience reduced reimbursement.

Bonus Payments for Primary Care Services

The ACA provides for a 10% bonus payment for primary care services that are delivered by a variety of providers, including:[421]

(1) Primary care physicians;
(2) Certain nurse practitioners;
(3) Clinical nurse specialists; and
(4) Physician assistants.

In order to qualify for these bonus payments, primary care services must account for at least 60% of these providers' Medicare allowed charges.[422] Furthermore, the ACA also provides for a 10% increase in payments to general surgeons operating in health professional shortage areas (HPSAs).[423] These bonus payments are effective from 2011-2015.[424]

Medicare Disproportionate Share Hospital Payments

The Medicare Disproportionate Share Hospital (DSH) payments are meant to assist hospitals in providing care to low income Medicare beneficiaries, the uninsured, and the underinsured.[425] The 2010 healthcare reform reduces the DSH payments to 25% of the amount that otherwise

418 "5-Star special Enrollment Period," Centers for Medicare and Medicaid Services, http://www.medicare.gov/sign-up-change-plans/when-can-i-join-a-health-or-drug-plan/five-star-enrollment/5-star-enrollment-period.html (Accessed 4/30/14); "5-Star Plan Rankings," Centers for Medicare and Medicaid Services, http://www.cms.gov/Outreach-and-Education/Training/CMSNationalTrainingProgram/Downloads/2013-5-Star-Enrollment-Period-Job-Aid.pdf (Accessed 4/29/14).

419 "Realizing Health Reform's Potential: The Impact of Health Reform on the Medicare Advantage Program: Realigning Payment with Performance" By Brian Biles et al., The Commonwealth Fund, October 2012, http://www.commonwealthfund.org/~/media/Files/Publications/Issue%20Brief/2012/Oct/1637_Biles_impact_hlt_reform_Medicare_Advantage_rb.pdf (Accessed 4/28/14), p. 6; "Medicare Advantage Program Payment System" Medicare Payment Advisory Council, October 2014, http://medpac.gov/documents/payment-basics/medicare-advantage-program-payment-system-14.pdf?sfvrsn=0 (Accessed 2/25/14), p. 2-3.

420 Ibid.

421 "Pub 100-04 Medicare Claims Processing: Transmittal 2161" Centers for Medicare and Medicaid Services, February 25, 2011, https://www.cms.gov/Regulations-and-Guidance/Guidance/Transmittals/downloads/R2161CP.pdf (Accessed 3/2/15), p. 1, 3.

422 "Summary of Key changes to Medicare in 2010 Health Reform Law" Kaiser Family Foundation, http://www.kff.org/healthreform/upload/7948-02.pdf (Accessed 8/24/10), p. 4.

423 Ibid.

424 "Pub 100-04 Medicare Claims Processing: Transmittal 2161" Centers for Medicare and Medicaid Services, February 25, 2011, https://www.cms.gov/Regulations-and-Guidance/Guidance/Transmittals/downloads/R2161CP.pdf (Accessed 3/2/15), p. 1, 3.

425 "Medicare DSH Factsheet" American Hospital Association, January 10, 2014, https://www.google.com/url?sa=t&rct=j&q=&esrc=s&source=web&cd=2&ved=0CCQQFjAB&url=http%3A%2F%2Fwww.aha.org%2Fcontent%2F13%2Ffs-dsh.pdf&ei=oNvbU9CdBY-1yASd6ILICw&usg=AFQjCNFQXlF8OOU43lo4bDCE0mCldeZfZA&bvm=bv.72197243,d.aWw&cad=rja (Accessed 8/1/14), p. 1.

would be made beginning in 2014.[426] The remaining 75% of the DSH payments are reduced based on the reduction in the percent of individuals under the age of 65 who are uninsured, and then reallocated to hospitals based on the amount of uncompensated care that each hospital provides, relative to the total amount of uncompensated care for all DSHs.[427] Congress passed this payment reduction in part because of the theory that hospitals would have fewer uninsured or underinsured patients when the ACA was implemented, due to the ACA's provisions aimed at expanding health insurance coverage. Although a bill has been proposed to postpone the DSH payment reductions, in their current format, DSH payments will be reduced by over $22 billion between 2014 and 2019.[428]

Value Based Purchasing Programs

In an attempt to address the predicted rapid growth rate for the U.S. healthcare system, the Institute for Healthcare Improvement developed an innovative framework called the *Triple Aim* that focused on simultaneously improving the patient's experience of care, improving the health of populations, and reducing the per capita cost of care.[429] By addressing the payment structure and implementing concepts such as value based purchasing programs, CMS is able to link the quality of care to the Medicare payment system and address some of the suggested *triple aim* improvements that are needed to control the growing cost of care.[430]

Hospitals

The ACA provides for a variety of programs that alter Medicare payments to hospitals based on the quality of care that those hospitals provide. These include:[431]

(1) The Hospital Readmissions Reduction Program;
(2) The Hospital-Acquired Condition (HAC) Reduction Program; and
(3) The Hospital Value-Based Purchasing Program.

The Hospital Readmissions Reduction Program is intended to reduce the number of unintended readmissions for conditions such as acute myocardial infarction, heart failure, and pneumonia.[432] This program reduces DRG payment rates based on a hospital's ratio of expected readmissions to actual readmissions, with reductions of:

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426 "Summary of Key changes to Medicare in 2010 Health Reform Law" Kaiser Family Foundation, http://www.kff.org/healthreform/upload/7948-02.pdf (Accessed 8/24/10), p. 4.

427 "Disproportionate Share Hospital (DSH)" Centers for Medicare and Medicaid Services, August 4, 2014, http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/AcuteInpatientPPS/dsh.html (Accessed 2/4/15).

428 "Medicare DSH Factsheet" American Hospital Association, January 10, 2014, https://www.google.com/url?sa=t&rct=j&q=&esrc=s&source=web&cd=2&ved=0CCQQFjAB&url=http%3A%2F%2Fwww.aha.org%2Fcontent%2F13%2Ffs-dsh.pdf&ei=oNvbU9CdBY-1yASd6ILICw&usg=AFQjCNFQXlF8OOU43lo4bDCE0mCldeZfZA&bvm=bv.72197243,d.aWw&cad=rja (Accessed 8/1/14), p. 1.

429 "IHI Triple Aim Initiative," Institute for Healthcare Improvement, 2015, http://www.ihi.org/Engage/Initiatives/TripleAim/Pages/default.aspx (Accessed 2/27/15).

430 "Hospital Value Based Purchasing," Centers for Medicare and Medicaid Services, December 18, 2014, https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/hospital-value-based-purchasing/index.html?redirect=/hospital-value-based-purchasing/ (Accessed 2/27/15); "IHI Triple Aim Initiative," Institute for Healthcare Improvement, 2015, http://www.ihi.org/Engage/Initiatives/TripleAim/Pages/default.aspx (Accessed 2/27/15).

431 "Selected Medicare Hospital Quality Provisions Under the ACA" Association of American Medical Colleges, https://www.aamc.org/advocacy/medicare/153882/selected_medicare_hospital_quality_provisions_under_the_aca.html (Accessed 2/4/15).

432 "Readmissions Reduction Program" Centers for Medicare and Medicaid Services, August 4, 2014, http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/AcuteInpatientPPS/Readmissions-Reduction-Program.html (Accessed 2/4/15).

(1) 1% in fiscal year (FY) 2013;
(2) 2% in FY 2014; and
(3) 3% in FY 2015 and beyond.

Furthermore, as the severity of payment reductions increases, the program also scrutinizes a wider variety of conditions beginning in FY 2015.[433]

The HAC reduction program uses not only payment reductions, but also public reporting of quality measures to incentivize hospitals to improve patient safety. The HAC reduction program focuses on preventable conditions (e.g., infections) that patients develop while staying at an inpatient hospital (i.e., HACs), as well as general patient safety.[434] This program imposes a 1% payment reduction for hospitals in the top 25% for HACs, beginning in 2015.[435]

Contrary to the preceding two programs, which incentivize hospitals to improve patient well-being through payment reductions for poor performance, the Hospital Value-Based Purchasing (HVBP) Program provides hospitals with incentive payments in order to encourage improvement in four major areas:[436]

(1) Clinical process of care;
(2) Patient experience and satisfaction;
(3) Clinical outcomes (e.g., mortality measures for specified conditions); and
(4) Efficiency (e.g., spending per beneficiary).

Based on their performance in these *domains,* hospitals are given a *Total Performance Score* (TPS). The TPS has a direct, linear relationship with the hospital's value-based incentive payments.[437] However, these incentive payments are funded by a reduction in the *base payment rate* for all DRGs, which starts at a 1% reduction in FY 2013 and gradually increases to a 2% reduction by FY 2017.[438]

In addition to those value based programs implemented by the ACA, in 2008, Medicare ceased paying the extra costs associated with treating *never events*, particularly shocking medical errors that should never occur, such as wrong site surgery.[439]

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433 "Selected Medicare Hospital Quality Provisions Under the ACA" Association of American Medical Colleges, https://www.aamc.org/advocacy/medicare/153882/selected_medicare_hospital_quality_provisions_under_the_aca.html (Accessed 2/4/15); "Readmissions Reduction Program" Centers for Medicare and Medicaid Services, August 4, 2014, http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/AcuteInpatientPPS/Readmissions-Reduction-Program.html (Accessed 2/4/15).

434 "Fact sheets: Fiscal Year 2015 Results for the CMS Hospital-Acquired Condition Reduction Program and Hospital Value-Based Purchasing Program" Centers for Medicare and Medicaid Services, December 18, 2014, http://www.cms.gov/Newsroom/MediaReleaseDatabase/Fact-sheets/2014-Fact-sheets-items/2014-12-18-2.html?DLPage=1&DLSort=0&DLSortDir=descending (Accessed 2/27/15).

435 "Selected Medicare Hospital Quality Provisions Under the ACA" Association of American Medical Colleges, https://www.aamc.org/advocacy/medicare/153882/selected_medicare_hospital_quality_provisions_under_the_aca.html (Accessed 2/4/15); "Hospital-Acquired Condition (HAC) Reduction Program" Centers for Medicare & Medicaid Services, December 18, 2014, http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/AcuteInpatientPPS/HAC-Reduction-Program.html (Accessed 2/4/15).

436 "Fact sheets: Fiscal Year 2015 Results for the CMS Hospital-Acquired Condition Reduction Program and Hospital Value-Based Purchasing Program" Centers for Medicare & Medicaid Services, December 18, 2014, http://www.cms.gov/Newsroom/MediaReleaseDatabase/Fact-sheets/2014-Fact-sheets-items/2014-12-18-2.html?DLPage=1&DLSort=0&DLSortDir=descending (Accessed 2/27/15).

437 Ibid.

438 "Selected Medicare Hospital Quality Provisions Under the ACA" Association of American Medical Colleges, https://www.aamc.org/advocacy/medicare/153882/selected_medicare_hospital_quality_provisions_under_the_aca.html (Accessed 2/4/15).

439 "Letter From CMS to State Medicaid Director" By Herb Kuhn, Centers for Medicare & Medicaid Services, July 31, 2008, http://downloads.cms.gov/cmsgov/archived-downloads/SMDL/downloads/SMD073108.pdf (Accessed 2/23/15); "Never Events" Agency for Healthcare Research and Quality, October 2012, http://psnet.ahrq.gov/primer.aspx?primerID=3 (Accessed 2/23/15).

Physicians

The ACA also instructed CMS to create a value based purchasing program for physicians, which resulted in the Physician Value-Based Payment Modifier (PVBM). This program scores providers on measures of cost and quality of the care that they deliver, and adjust the payments these providers receive from Medicare accordingly, rewarding the providers with the best value care and punishing the providers with the worst.[440]

The PVBM is primarily based on the Physician Quality Reporting System (PQRS).[441] The PQRS is a program that CMS uses to encourage providers to report data on the quality of care which they provide, using incentive payments and payment reductions.[442] 2014 is the last year for physicians to receive a bonus payment for participating in the PQRS, consisting of a 0.5% increase in the physician's reimbursement.[443] After 2014, physicians who do not report quality measures via the PQRS will be penalized by a reduction in their Medicare payments. In 2015, this penalty is a 1.5% reduction of the physician's reimbursement, and from 2016 forward this penalty is a 2% reduction of the physician's reimbursement.[444]

After physician practices report data on the cost and quality of the care which they deliver through the PQRS, CMS grades each practice in terms of cost and quality in order to determine their payment modifier under the PVBM.[445] Groups are assigned a payment adjustment based on their cost and quality designations according to Table 2-8: *Physician Value Based Payment Modifier Adjustments,* shown below.

Table 2-8: Physician Value Based Payment Modifier Adjustments[446]

Level of Quality	Low Cost	Average Cost	High Cost
High Quality	+2.0x	+1.0x	0%
Average Quality	+1.0x	0%	-0.50%
Low Quality	0%	-0.50%	-1%

Note that downward adjustments are given percentage penalties, while upward adjustments are not. CMS first calculates the aggregate downward adjustments by combining the penalties to low-scoring groups with the penalties to groups that did not report performance metrics.[447] The savings generated by these aggregate reduced payments constitute a pool of funds which is divided among the high-scoring provider groups. To do this, CMS calculates the number of

440 "Medicare's Physician Value-Based Payment Modifier – Will the Tectonic Shift Create Waves?" By Alyna T. Chien, M.D. and Meredith B. Rosenthal, Ph.D., The New England Journal of Medicine, November 28, 2013, http://www.nejm.org/doi/full/10.1056/NEJMp1311957 (Accessed 5/19/14), p. 1.
441 "Summary of 2015 Physician Value-based Payment Modifier Policies" Centers for Medicare & Medicaid Services, January 24, 2014, https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/PhysicianFeedbackProgram/Downloads/CY2015Value ModifierPolicies.pdf (Accessed 6/20/14), p. 3.
442 "Physician Quality Reporting System" Centers for Medicare & Medicaid Services, June 9, 2014, http://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/PQRS/Index.html (Accessed 6/20/14), p. 1.
443 "Physician Quality Reporting System," 42 C.F.R. §414.90(c)(3) (December 10, 2013).
444 "Physician Quality Reporting System," 42 C.F.R. §414.90(e)(1) (December 10, 2013).
445 "The Physician Value-Based Payment Modifier under the 2014 Medicare Physician Fee Schedule" Centers for Medicare & Medicaid Services, December 3, 2013, http://www.cms.gov/Outreach-and-Education/Outreach/NPC/Downloads/NPC-PFS-VBP-12-03-13-Slides.pdf (Accessed 3/2/15), p. 15.
446 "Summary of 2015 Physician Value-based Payment Modifier Policies," Centers for Medicare & Medicaid Services, January 24, 2014, https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/PhysicianFeedbackProgram/Downloads/CY2015ValueModifier Policies.pdf (Accessed 6/20/14), p. 14.
447 Ibid.

shares to be awarded to the high value provider groups, with one share going to some groups, and two shares going to those groups that scored high in both cost and quality (see Table 2-7). The pool of funds derived from reduced payments to low scoring groups is then divided equally among these shares. Thus, when receiving their shares, provider groups that scored above average in overall value receive a bonus payment, provider groups that scored above average in both cost and quality (making them well above average in overall value) receive a double bonus payment, and the payments are funded by the forfeits of the low-scoring provider groups. Using this methodology, CMS ensures that the PVBM payment adjustments are budget neutral.[448]

Medicaid and State Children's Health Insurance Program

Overview

Medicaid is a state-administered health insurance program for low-income individuals and certain federally recognized eligibility groups.[449] Medicaid is funded by participating state governments that receive federal matching funds as long as they operate their Medicaid programs within parameters set by the federal government.[450]

These parameters determine mandatory eligibility groups and mandatory services (i.e., the groups and services the state must cover to receive federal Medicaid money).[451] The mandatory eligibility groups are as follows:[452]

(1) Families who meet their states' eligibility requirements for Temporary Assistance for Needy Families (TANF);
(2) Pregnant women and children under the age of 6 whose income is at or below 133% of the federal poverty level (FPL);
(3) Relatives or legal guardians who care for children under the age of 18 (i.e., caretakers);
(4) Those who receive Supplemental Security Income (SSI), or the aged, blind, and disabled who meet more restrictive requirements than those of the SSI program, depending on the state; and
(5) Individuals and couples living in medical institutions whose monthly income is up to 300% of the SSI.

448 "Summary of 2015 Physician Value-based Payment Modifier Policies," Centers for Medicare & Medicaid Services, January 24, 2014, https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/PhysicianFeedbackProgram/Downloads/CY2015ValueModifierPolicies.pdf (Accessed 6/20/14), p. 14.
449 "Federal Core Requirements and State Options in Medicaid: Current Policies and Key Issues" The Henry J. Kaiser Family Foundation, April 2011, https://kaiserfamilyfoundation.files.wordpress.com/2013/01/8174.pdf (Accessed 2/5/15), p. 1.
450 Ibid.
451 Ibid.
452 "Understanding Health Insurance: A Guide to Billing and Reimbursement" By Michelle A. Green and JoAnn C. Rowell, Twelfth Edition, Stamford, CT: Cengage Learning, 2013, p. 535.

Table 2-9: 2015 Federal Poverty Guidelines for the 48 Contiguous States[453]

Persons in family/household	Poverty Guideline
1	$11,770
2	$15,930
3	$20,090
4	$24,250
5	$28,410
6	$32,570
7	$36,730
8	$40,890
For each additional person over 8, add $4,160	

In addition to mandatory groups and services, states may also receive federal funds for covering other optional groups and services.[454] States have significant discretion regarding to whom they extend Medicaid benefits beyond the mandatory groups, and many states opt to extend benefits to individuals who are above the income cutoffs found in the mandatory groups.[455] For example, many states offer Medicaid coverage for children well above the mandatory federal minimum.[456]

Although the federal government determines the medical services that will be covered and paid for by the federal portion of the program, Medicaid programs vary widely from state to state, as state governments are free to add additional services or expand eligibility to additional groups.[457] The mandatory services that state Medicaid programs must provide in order to receive federal matching funds include the following:[458]

(1) Inpatient and outpatient hospital services;
(2) Outpatient hospital services and, depending on the state, rural health clinic and other ambulatory services;
(3) Other laboratory and x-ray services;
(4) Certified pediatric and family nurse practitioners' services;
(5) Nursing facility services for those aged 21 and over;
(6) Early and Periodic Screening, Diagnosis, and Treatment (EPSDT) for children under the age of 21;
(7) Family planning services and supplies;
(8) Physicians' services;
(9) Medical and surgical services of a dentist;
(10) Home health services for those who qualify for nursing facility services according to the state's Medicaid plan;
(11) Intermittent or part-time nursing services;
(12) Nurse midwife services;
(13) Pregnancy related services;
(14) Home health aides; and
(15) Medical supplies and appliances for use in the home.

453 "Annual Update of the HHS Poverty Guidelines" Federal Register Vol. 80, No. 14 (January 22, 2015), p. 3237. Note that the Poverty Guidelines in Alaska and Hawaii deviate from those of the 48 contiguous states.
454 "Medicaid Enrollment and Expenditures by Federal Core Requirements and State Options" By Brigette Courtot et al., The Henry J. Kaiser Family Foundation, January 2012, https://kaiserfamilyfoundation.files.wordpress.com/2013/01/8239.pdf (Accessed 2/5/15), p. 1.
455 Ibid..
456 Ibid, p. 4.
457 "From Patient to Payment: Insurance Procedures for the Medical Office, Third Edition" By Cynthia Newby, Columbus, OH: Glencoe/McGraw-Hill, 2002, p. 132.
458 "Understanding Health Insurance: A Guide to Billing and Reimbursement" By Michelle A. Green and JoAnn C. Rowell, Twelfth Edition, Stamford, CT: Cengage Learning, 2013, p. 537-538.

Optional services, by contrast, may include prescription drugs, dental services, durable medical equipment, personal care services, and home and community-based services.[459] It is important to look at a particular state's Medicaid coverage manual to determine which optional groups and services that state covers.

Medicaid Expansion

One of the central elements of the ACA was the expansion of Medicaid to cover a larger share of low income individuals. In general, the ACA's expansion extended Medicaid coverage to the majority of adults with incomes at or below 138% of the FPL.[460] Originally intended to be a nationwide change, a June 2012 Supreme Court decision made the Medicaid expansion optional for individual states.[461] As of January 27, 2015, 29 states, as well as the District of Columbia, had opted to expand Medicaid coverage under the ACA.[462] The federal government funds 100% of the expansion (i.e., the cost associated with the newly eligible individuals) through 2016, gradually decreasing to 90% in 2020 and beyond, for those states that opt to expand Medicaid.[463] In addition, it was thought that the expansion of Medicaid would change the basis for the supplemental payments to hospitals accepting Medicaid patients, known as disproportionate share payments, discussed more fully in the Medicaid Disproportionate Share Hospital (DSH) Payments section below.

Section 1115 Waivers

Before the passage of the ACA, the only way to obtain federal funds for Medicaid coverage of childless adults was through the use of a Section 1115 waiver.[464] Using these waivers, states could offer Medicaid coverage to childless adults, albeit with restrictions. Section 1115 waivers are required to be budget neutral for the federal government, and as such, the coverage that they provide often has limited benefits and higher cost-sharing for the beneficiaries.[465] Since the ACA has been passed, states that opt into the Medicaid expansion have been able to offer Medicaid coverage to childless adults without the use of a Section 1115 waiver.

However, some states (Arkansas, Iowa, Michigan, and Pennsylvania, as of November 2014), have effectively expanded Medicaid without meeting the federal rules under the ACA, instead implementing the expansion through the use of Section 1115 waivers.[466] In these states, this alternative approach to Medicaid expansion is perceived by some as being more politically viable than opting into the ACA Medicaid expansion, due to the partisan contention surrounding

459 "Medicaid Moving Forward" The Henry J. Kaiser Family Foundation, January 2015, http://files.kff.org/attachment/fact-sheet-medicaid-moving-forward (Accessed 2/5/15), p. 4.
460 "Status of State Action on the Medicaid Expansion Decision" The Henry J. Kaiser Family Foundation, January 27, 2015, http://kff.org/health-reform/state-indicator/state-activity-around-expanding-medicaid-under-the-affordable-care-act/ (Accessed 3/2/15).
461 "Medicaid Moving Forward" The Henry J. Kaiser Family Foundation, January 2015, http://files.kff.org/attachment/fact-sheet-medicaid-moving-forward (Accessed 2/5/15), p. 1.
462 "Status of State Action on the Medicaid Expansion Decision" The Henry J. Kaiser Family Foundation, January 27, 2015, http://kff.org/health-reform/state-indicator/state-activity-around-expanding-medicaid-under-the-affordable-care-act/ (Accessed 3/2/15).
463 "Medicaid Moving Forward" The Henry J. Kaiser Family Foundation, January 2015, http://files.kff.org/attachment/fact-sheet-medicaid-moving-forward (Accessed 2/5/15), p. 1.
464 "The ACA and Recent Section 1115 Medicaid Demonstration Waivers" The Henry J. Kaiser Family Foundation, November 2014, http://files.kff.org/attachment/the-aca-and-recent-section-1115-medicaid-demonstration-issue-brief (Accessed 2/5/15), p. 1.
465 Ibid.
466 "The ACA and Recent Section 1115 Medicaid Demonstration Waivers" The Henry J. Kaiser Family Foundation, November 2014, http://files.kff.org/attachment/the-aca-and-recent-section-1115-medicaid-demonstration-issue-brief (Accessed 2/5/15), p. 2.

the ACA.[467] As such, the 23 states which have not yet opted into the ACA's Medicaid Expansion have put a significant stress on hospitals that, heretofore, had received more significant amounts of Medicaid disproportionate share payments than would be available under the ACA. This topic is discussed more fully in the Medicaid Disproportionate Share Hospital (DSH) Payments section of this chapter.

Children's Health Insurance Program (CHIP)

In addition to Medicaid, each state, territory, and the District of Columbia have implemented the *Children's Health Insurance Program (CHIP),* a state-federal partnership that provides assistance to children and pregnant women in families whose income is above the threshold for Medicaid.[468] Enacted under the *Balanced Budget Act of 1997*, and formerly known as SCHIP, CHIP covered approximately 5.7 million children in June 2013, which is in addition to the number of children already covered under Medicaid (28 million in June 2013).[469]

> CHIP covered approximately 5.7 million children in June 2013 which is in addition to the number of children already covered under Medicaid (28 million in June 2013).
>
> ***Robin Rudowitz et al, March 2014.***

CHIP programs vary among states, which determine, within federal parameters, who may be eligible for CHIP funds, as well as other details such as benefits, payment levels, and administration.[470] As part of their autonomy over CHIP programs, states are free to set premiums and co-payment rates on a sliding scale based on income; funds are then matched by the federal government up to a certain capped amount.[471]

After temporary reauthorizations of the program in 2007 and 2009, the ACA most recently reauthorized federal CHIP funding through fiscal year 2015, leaving the long term life of the program open to debate.[472] If the program is extended beyond fiscal year 2015, the ACA mandates that the federal matching rate for CHIP financing increase by 23% (up to 100%) for fiscal years 2016-2019.

Billing and Reimbursement

Reimbursement for services provided to Medicaid patients are paid by states on either an FFS basis or under a pre-paid managed care arrangement.[473] The Medicaid program requires the use

467 Ibid, p. 1.
468 "The Children's Health Insurance Program (CHIP): Overview" Centers for Medicare & Medicaid Services, http://www.cms.hhs.gov/LowCostHealthInsFamChild/ (Accessed 10/6/09).
469 "Children's Health Coverage: Medicaid, CHIP and the ACA" by Robin Rudowitz et al, The Henry J. Kaiser Family Foundation, March 2014, p. 1, https://kaiserfamilyfoundation.files.wordpress.com/2014/03/8570-children_s-health-coverage-medicaid-chip-and-the-aca1.pdf (Accessed 2/5/15).
470 "The Children's Health Insurance Program (CHIP): Overview" Centers for Medicare & Medicaid Services, http://www.cms.hhs.gov/LowCostHealthInsFamChild/ (Accessed 10/6/09).
471 "Health Coverage of Children: The Role of Medicaid and SCHIP" By the Kaiser Commission on Medicaid and the Uninsured, November 2008, http://www.kff.org/uninsured/upload/7698_02.pdf (Accessed 10/6/09).
472 "Report to the Congress on Medicaid and CHIP" Medicaid and CHIP Payment and Access Commission, June 2014, http://www.macpac.gov/reports (Accessed 1/5/15), p. 6-7.
473 "Delivery Systems" Centers for Medicare & Medicaid Services, http://medicaid.gov/medicaid-chip-program-information/by-topics/delivery-systems/delivery-systems.html (Accessed 3/2/15).

of the CMS-1500 claim form when seeking FFS reimbursement.[474] Providers should consult their state's Medicaid managed care organization (MCO) billing manual in order to determine how to bill for non-capitated managed care services, as these procedures may vary by state.[475] Deadlines for filing a Medicaid claim range from two months to one year from the date of treatment.[476] Thus, it is important for providers to be familiar with their particular state's rules and deadlines for claim submission. Federal regulation requires states to promptly pay practitioners for *clean claims* submitted for services rendered to Medicaid recipients.[477] Under the regulation, states must pay 90 percent of *clean claims* in thirty days, 99 percent of *clean claims* within ninety days, and all other claims within twelve months of receipt unless limited exception apply.[478]

Each state is free to develop its own reimbursement process and payment rates, with three exceptions:

(1) For institutional services, payment may not exceed amounts that would be paid under Medicare payment rates;
(2) For DSH, hospitals that treat a disproportionate number of Medicaid patients, different limits apply; and
(3) For hospice care services, rates cannot be lower than Medicare rates.[479]

Accordingly, states may impose deductibles, co-insurance, or co-payments on certain recipients for particular services.[480] PARs in the Medicaid program must accept direct payments from Medicaid for services rendered as payment in full, and they may not bill patients the difference between their usual fee and the Medicaid reimbursement rate for covered benefits.[481] Medicaid reimburses on a lump-sum basis, meaning providers will receive one payment for several submitted claims.[482]

Medicaid is considered by many to be the *payor of last resort*.[483] As such, for Medicaid patients who also are covered by an insurance plan or another government program, including Medicare, TRICARE, CHAMPVA, or IHS, these plans or programs must be billed first.[484] Claims should only be submitted to Medicaid if one of the other payors denies responsibility for payment or

474 "Understanding Health Insurance: A Guide to Billing and Reimbursement" By Michelle A. Green and JoAnn C. Rowell, Ninth Edition, Clifton Park, NY: Delmar Cengage Learning, 2008, p. 483.
475 "Understanding Health Insurance: A Guide to Billing and Reimbursement" By Michelle A. Green and JoAnn C. Rowell, Twelfth Edition, Stamford, CT: Cengage Learning, 2013, p. 545.
476 "From Patient to Payment: Insurance Procedures for the Medical Office, Third Edition" By Cynthia Newby, Columbus, OH: Glencoe/McGraw-Hill, 2002, p. 135.
477 "Timely Claims Payment" 42 C.F.R. § 447.45(d) (October 1, 2013).
478 Ibid.
479 "Understanding Health Insurance: A Guide to Billing and Reimbursement" By Michelle A. Green and JoAnn C. Rowell, Twelfth Edition, Stamford, CT: Cengage Learning, 2013, p. 541.
480 "Medicaid Information by Topic" Centers for Medicare & Medicaid Services, http://medicaid.gov/medicaid-chip-program-information/by-topics/by-topic.html (Accessed 3/2/15).
481 "Understanding Health Insurance: A Guide to Billing and Reimbursement" By Michelle A. Green and JoAnn C. Rowell, Twelfth Edition, Stamford, CT: Cengage Learning, 2013, p. 542.
482 Ibid., p. 544.
483 "Deficit Reduction Act Important Facts for State Policymakers" Centers for Medicare & Medicaid Services, December 11, 2007, http://www.cms.gov/Regulations-and-Guidance/Legislation/DeficitReductionAct/downloads/tpl.pdf (Accessed 3/2/15), p. 1.
484 "Deficit Reduction Act Important Facts for State Policymakers" Centers for Medicare & Medicaid Services, December 11, 2007, http://www.cms.gov/Regulations-and-Guidance/Legislation/DeficitReductionAct/downloads/tpl.pdf (Accessed 3/2/15), p. 1.

reimburses at a rate that is less than Medicaid's fee schedule, or if Medicaid reimburses for procedures that are not covered by the other plans or programs.[485]

Medicaid Disproportionate Share Hospital (DSH) Payments

Similar to the Medicare DSH program, Medicaid Disproportionate Share Hospital (DSH) payments are a form of additional reimbursement under Medicaid for hospitals that care for a large number of Medicaid and uninsured patients (these hospitals are sometimes referred to as safety-net hospitals).[486] DSH payments are allotments from the federal government that augment basic Medicaid reimbursement, and under federal law, states are required to supplement DSHs in order to receive this additional Medicaid funding.[487] DSH payments are intended to supplement hospitals when costs are not adequately covered by traditional Medicaid and Medicare payments, by CHIP payments, or by other health insurance.[488]

Each state has its own methodology for calculating DSH payments, subject to two federal caps: (1) the federal funds that a state may spend on DSH payments may not exceed that state's annual DSH allotment and (2) Medicaid DSH payments to a particular facility may not exceed 100% of the costs incurred by the facility in serving Medicaid and uninsured patients for which the facility has not been otherwise compensated by Medicaid.[489]

Typically, a state's annual allotment of federal DSH funds is calculated using the state's federal DSH funds from the previous year, increased to account for inflation, and is capped at 12% of the state's total Medicaid medical assistance expenditures.[490] In order to receive its DSH allotment, a state must submit an annual report and a certified audit documenting payments made to DSHs, though the state has discretion over the hospitals to which it distributes DSH payments.[491] The only limits on this discretion are that: (1) a state may not distribute DSH payments to any hospital with a Medicaid utilization rate less than 1 percent; (2) the state *must* distribute DSH payments to all hospitals that have either a Medicaid inpatient utilization rate exceeding one standard deviation or more above the mean for all hospitals in the state, or a low-income utilization rate of more than 25 percent; and (3) all DSHs must retain at least two obstetricians with staff privileges who are willing to serve Medicaid patients.[492] If a state wants to distribute DSH payments to additional hospitals, it is free to do so; however, the state must

485 "Understanding Health Insurance: A Guide to Billing and Reimbursement" By Michelle A. Green and JoAnn C. Rowell, Twelfth Edition, Stamford, CT: Cengage Learning, 2013, p. 542.

486 "Disproportionate-Share Hospital Payment Reductions May Threaten The Financial Stability Of Safety-Net Hospitals" by Katherine Neuhausen et al., Health Affairs, June 2014, http://content.healthaffairs.org/content/33/6/988.full.pdf (Accessed 2/5/15), p. 1; "Medicaid Disproportionate Share Hospital (DSH) Payments: The Basics" National Health Policy Forum, The George Washington University, June 15, 2009, http://www.nhpf.org/library/the-basics/Basics_DSH_06-15-09.pdf (Accessed 10/05/09), p. 1.

487 "Medicaid Disproportionate Share Hospital (DSH) Payments: The Basics" National Health Policy Forum, The George Washington University, June 15, 2009, http://www.nhpf.org/library/the-basics/Basics_DSH_06-15-09.pdf (Accessed 10/05/09), p. 1

488 Ibid.

489 "How Do Medicaid Disproportionate Share Hospital (DSH) Payments Change Under the ACA?" The Henry J. Kaiser Family Foundation, November 2013, p. 1, https://kaiserfamilyfoundation.files.wordpress.com/2013/11/8513-how-do-medicaid-dsh-payments-change-under-the-aca.pdf (Accessed 2/5/15).

490 "Medicaid Program; Preliminary Disproportionate Share Hospital Allotments (DSH) for Fiscal Year (FY) 2014 and the Preliminary Institutions for Mental Diseases Disproportionate Share Hospital Limits for FY 2014" Federal Register Vol. 79, No. 40 (February 28, 2014), p. 11436.

491 "Medicaid Disproportionate Share Hospital Payments" by Alison Mitchell, Congressional Research Service, December 2, 2013, https://www.fas.org/sgp/crs/misc/R42865.pdf (Accessed 2/5/15), p. 23-24, 33.

492 "How Do Medicaid Disproportionate Share Hospital (DSH) Payments Change Under the ACA?" The Henry J. Kaiser Family Foundation, November 2013, https://kaiserfamilyfoundation.files.wordpress.com/2013/11/8513-how-do-medicaid-dsh-payments-change-under-the-aca.pdf (Accessed 2/5/15), p. 7.

distribute payments at a rate in line with the Medicaid DSH payment methodology or based on the hospital's low-income utilization rate.[493]

The ACA included a significant alteration to the Medicaid DSH program. The ACA mandated that aggregate federal Medicaid DSH funds be reduced each year from fiscal year 2014-2020, under the assumption that the ACA's other provisions would reduce the number of uninsured individuals in the U.S., and, as a result, there would be less need for DSH payments.[494] Furthermore, the *Middle Class Tax Relief and Job Creation Act of 2012* and the *American Taxpayer Relief Act of 2012* extended the DSH reductions through fiscal years 2021 and 2022.[495] The federal Medicaid DSH funds reduction starts at $500 million in fiscal year 2014, peaks at $5.6 billion in fiscal year 2019, and stays at $4 billion for fiscal years 2020-2022.[496] A preliminary analysis of the impact of the federal Medicaid DSH funds reduction in June 2014 found that the reduction increased the amount of uncompensated care that safety-net hospitals provided, potentially threatening their financial stability.[497]

Dual Eligibility

Some individuals who receive healthcare coverage from Medicare may also meet the eligibility criteria for Medicaid coverage. These individuals may utilize Medicaid to pay for additional services that are not covered by Medicare, e.g., nursing facility care beyond Medicare's 100 day limit.[498] Furthermore, dual eligible beneficiaries may utilize Medicaid to help cover Medicare's out-of-pocket expenses.[499] The individuals who are dually eligible for both Medicare and Medicaid (of which there are over 9 million) typically represent the poorest, sickest beneficiaries, and most expensive beneficiaries in either program.[500]

Any services that are covered by both Medicare and Medicaid are paid first by Medicare, after which point Medicaid coverage may apply to any remaining charges. This is due to the fact that Medicaid is always the payor of last resort.[501] Thus, if a Medicaid beneficiary has coverage through any other means, (e.g. Medicare, TRICARE, CHAMPVA, etc.), those other sources of coverage must be billed before Medicaid may be utilized.

493 "Medicaid Disproportionate Share Hospital (DSH) Payments: The Basics" National Health Policy Forum, The George Washington University, June 15, 2009, http://www.nhpf.org/library/the-basics/Basics_DSH_06-15-09.pdf (Accessed 10/05/09), p. 3.
494 "Medicaid Disproportionate Share Hospital Payments" by Alison Mitchell, Congressional Research Service, December 2, 2013, https://www.fas.org/sgp/crs/misc/R42865.pdf (Accessed 2/5/15), p. ii.
495 Ibid.
496 "How Do Medicaid Disproportionate Share Hospital (DSH) Payments Change Under the ACA?" The Henry J. Kaiser Family Foundation, November 2013, https://kaiserfamilyfoundation.files.wordpress.com/2013/11/8513-how-do-medicaid-dsh-payments-change-under-the-aca.pdf (Accessed 2/5/15), p. 2.
497 "Disproportionate-Share Hospital Payment Reductions May Threaten The Financial Stability Of Safety-Net Hospitals" by Katherine Neuhausen et al., Health Affairs, June 2014, http://content.healthaffairs.org/content/33/6/988.full.pdf (Accessed 2/5/15), p. 1.
498 See the Long Term Care section below.
499 "Understanding Health Insurance: A Guide to Billing and Reimbursement" By Michelle A. Green and JoAnn C. Rowell, Twelfth Edition, Stamford, CT: Cengage Learning, 2013, p. 541.
500 "State Demonstration Proposals to Integrate Care and Align Financing and/or Administration for Dual Eligible Beneficiaries" The Henry J. Kaiser Family Foundation, February 6, 2015, http://kff.org/medicaid/fact-sheet/state-demonstration-proposals-to-integrate-care-and-align-financing-for-dual-eligible-beneficiaries/ (Accessed 2/24/15).
501 "Understanding Health Insurance: A Guide to Billing and Reimbursement" By Michelle A. Green and JoAnn C. Rowell, Twelfth Edition, Stamford, CT: Cengage Learning, 2013, p. 542.

Long Term Care

Despite the fact that Medicaid is designed to be the payor of last resort, it is the United States' primary payor for long-term services and supports (LTSS), representing over 40% of the payments for long-term care services in 2009.[502] This is due, in part, to the fact that many long term services are not covered by Medicare or private insurance. Eligibility for Medicaid long-term care coverage for the elderly and disabled is often tied to the Supplemental Security Income (SSI) program, but states may set higher thresholds.[503] Furthermore, the elderly and disabled must have assets below a pre-determined threshold (some states use $2,000 for an individual) in order to be eligible for Medicaid long-term care coverage (similar to the eligibility criteria tied to the SSI, this threshold also varies by state).[504]

TRICARE (CHAMPUS)

Overview

TRICARE, formerly known as the *Civilian Health and Medical Program of the Uniformed Services (CHAMPUS),* is the Department of Defense's healthcare program for active duty military personnel; members of the National Guard and Reserves; retirees, their dependents, and survivors; and certain former spouses.[505] The program uses military healthcare as the main provider of services, and supplements it with civilian healthcare providers, facilities, pharmacies, and suppliers.[506] TRICARE covers approximately 9.5 million beneficiaries worldwide through a variety of plans, including FFS and managed care plans.[507]

Billing and Reimbursement

TRICARE reimburses providers for services rendered to beneficiaries using both FFS and managed care arrangements.[508] The allowable fee is determined using Medicare's RBRVS system, except TRICARE uses a slightly higher conversion factor and has made minimal modifications to the geographic regions.[509] TRICARE only renders payment for services provided by authorized providers, those providers that meet licensing and certification requirements, and those who have been certified to treat beneficiaries.[510] Providers seeking reimbursement must submit claims using the CMS-1500 claim form within one year from the date the services were rendered.[511]

502 "Medicaid and Long-Term Care Services and Supports" The Henry J. Kaiser Family Foundation, June 2012, https://kaiserfamilyfoundation.files.wordpress.com/2013/01/2186-09.pdf (Accessed 2/24/15), p. 1.
503 Ibid.
504 Ibid.
505 "Welcome" U.S. Department of Defense, http://www.tricare.mil/welcome.aspx (Accessed 3/2/15).
506 "Evaluation of the TRICARE Program: Fiscal Year 2014 Report to Congress" U.S. Department of Defense, February 25, 2014, p. 5
507 Ibid.
508 Ibid.
509 "Understanding Health Insurance: A Guide to Billing and Reimbursement" By Michelle A. Green and JoAnn C. Rowell, Twelfth Edition, Stamford, CT: Cengage Learning, 2013, p. 580.
510 "TRICARE Prime Fact Sheet," U.S. Department of Defense, February 2015, p. 2.
511 "Understanding Health Insurance: A Guide to Billing and Reimbursement" By Michelle A. Green and JoAnn C. Rowell, Twelfth Edition, Stamford, CT: Cengage Learning, 2013, p. 579-580.

TRICARE offers a variety of programs with different beneficiary cost-sharing requirements, including co-insurance, annual enrollment fees, co-pays, catastrophic caps, and deductibles.[512] PARs must accept the allowable fee as payment in full, which prohibits them from billing the patient for more than the allowable charge for covered services.[513] Nonparticipating, authorized providers may accept the allowable fee on a case-by-case basis, or they can refuse to accept the fee, and bill the patient an amount not exceeding 15 percent above the TRICARE fee schedule.[514] Excluded from the 15 percent *limiting charge* are claims from independent laboratory and diagnostic laboratory companies, claims for durable medical equipment, and claims from medical supply companies.[515] In order to be reimbursed by TRICARE, the beneficiary files a claim using DD Form 2642.[516] TRICARE is typically very efficient in its claims processing, with an average processing time under 26 days in fiscal year 2013.[517] However, providers that do not accept TRICARE's allowable fee schedule must attempt to collect the entire bill from the beneficiary.

TRICARE is a primary payor if a beneficiary qualifies for Medicaid coverage, but it assumes secondary payor status if a patient is covered by another primary health plan.[518] In addition, TRICARE will not pay for occupational injuries or diseases covered by workers' compensation laws unless these benefits have been exhausted.[519] As such, to ensure prompt payment, providers must understand the relationship among TRICARE and other insurance or health plans.

Civilian Health and Medical Program of the Department of Veteran Affairs (CHAMPVA)

Overview

The *Civilian Health and Medical Program of the Department of Veteran Affairs (CHAMPVA)* is the Department of Veterans Affairs' (VA) healthcare program for the spouses and children of veterans who meet certain eligibility requirements. The CHAMPVA program and the beneficiaries are both responsible for a portion of the beneficiaries' healthcare costs.[520] To be eligible for the program, a beneficiary must be the spouse or child of a veteran who was declared to have a permanent service connected disability; the surviving spouse or child of a veteran who died as a result of his or her service related disability; the surviving spouse or child of a veteran who, at the time of his or her death, was determined to be permanently or totally disabled due to a service connected disability; or in certain instances, the surviving spouse or child of a service member who died in the line of duty.[521]

512 "Evaluation of the TRICARE Program: Fiscal Year 2014 Report to Congress" U.S. Department of Defense, February 25, 2014, p. 5.
513 "TRICARE Standard and TRICARE Extra" U.S. Department of Defense, February 2015, p. 1.
514 Ibid.
515 "Understanding Health Insurance: A Guide to Billing and Reimbursement" By Michelle A. Green and JoAnn C. Rowell, Twelfth Edition, Stamford, CT: Cengage Learning, 2013, p. 581.
516 "TRICARE Prime Fact Sheet," U.S. Department of Defense, February 2015, p. 4.
517 "Evaluation of the TRICARE Program: Fiscal Year 2014 Report to Congress" U.S. Department of Defense, February 25, 2014, p. 41.
518 "Using Other Health Insurance" U.S. Department of Defense, January 16, 2015, http://www.tricare.mil/Plans/OHI.aspx (Accessed 3/2/215).
519 "Double Coverage" 32 C.F.R. § 199.8(d)(ix)(3) (2015).
520 "Understanding Health Insurance: A Guide to Billing and Reimbursement" By Michelle A. Green and JoAnn C. Rowell, Twelfth Edition, Stamford, CT: Cengage Learning, 2013, p. 573.
521 Ibid.

Billing and Reimbursement

The CHAMPVA program reimburses providers for services rendered on a FFS basis up to the CHAMPVA allowable amount, which is equal to Medicare and TRICARE's allowable amount for similar services.[522] All claims for reimbursement must be accompanied by the proper claim form and submitted to CHAMPVA Claims within one year from the date of service.[523] Claims submitted by providers should use the CMS 1500 or the UB-04 (institutional providers, i.e. hospitals, skilled nursing facilities, end stage renal disease providers, home health agencies, hospices, outpatient rehabilitation clinics, comprehensive outpatient rehabilitation facilities, community mental health centers, critical access hospitals, federally qualified health centers, histocompatibility laboratories, Indian Health Service facilities, organ procurement organizations, religious non-medical health care institutions, and rural health clinics) forms, and an itemized list of charges for each service must accompany every claim.[524]

CHAMPVA typically does not sign contracts with providers. Instead, providers elect to participate in the program by either submitting a claim or agreeing to treat a beneficiary.[525] Providers choosing to treat CHAMPVA beneficiaries must accept the allowable rate as payment in full; they cannot bill the patient for the difference between their usual fee for the service and the VA allowable amount.[526] A provider is free to refuse to accept the CHAMPVA allowable rate if he or she makes this fact clear to the patient before treatment is rendered, in which case the patient is responsible for paying the entire bill and submitting a claim to CHAMPVA for reimbursement up to the allowable amount.[527] CHAMPVA typically reimburses 95 percent of their claims within thirty days.[528]

It is important for providers to understand the relationship among payors, because CHAMPVA assumes the role of both primary and secondary payer.[529] If a beneficiary is eligible for Medicaid, has a Medicaid or CHAMPVA supplemental insurance policy, or is eligible for a state's Victims of Crime Compensation Program, CHAMPVA assumes the role of primary payer and all claims should be filed with CHAMPVA first.[530] However, some CHAMPVA members may be enrolled in Medicare, covered by a workers' compensation policy, or have other health insurance. In these instances, Medicare, the relevant workers' compensation program, or the other health insurance plan should be billed first and CHAMPVA will assume the role of secondary payor.[531]

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522 "Fact Sheet 01-11, Payment Methodology" Department of Veterans Affairs Health Administration Center, VA.gov, July 2008, http://www.va.gov/PURCHASEDCARE/docs/pubfiles/factsheets/FactSheet_01-11.pdf (Accessed 2/27/15), p. 1.
523 "How to File a CHAMPVA Claim" U.S. Department of Veterans Affairs, http://www.va.gov/PURCHASEDCARE/docs/pubfiles/brochures/HowToFileACHAMPVAClaim.pdf (Accessed 3/2/15), p. 3.
524 Ibid, p. 2.
525 "Fact Sheet 01-15, Participating Providers" Department of Veterans Affairs Health Administration Center, VA.gov, July 2009, http://www.va.gov/PURCHASEDCARE/docs/pubfiles/factsheets/FactSheet_01-15.pdf (Accessed 2/27/15), p. 1.
526 Ibid.
527 Ibid.
528 "Fact Sheet 01-16, For Outpatient Providers and Office Managers" Department of Veterans Affairs Health Administration Center, October 2010, http://www.va.gov/PURCHASEDCARE/docs/pubfiles/factsheets/FactSheet_01-16.pdf (Accessed 2/5/15).
529 "A Guide for the CHAMPVA Program" U.S. Department of Veterans Affairs, 2014, http://www.va.gov/PURCHASEDCARE/docs/pubfiles/programguides/champva_guide.pdf (Accessed 2/27/15), p. 64-65.
530 Ibid, p. 64.
531 Ibid, p. 65.

Other Public Payors

Workers' Compensation

Federal and state laws mandate that employers provide workers' compensation coverage for their employees.[532] *Workers' compensation* provides healthcare coverage and monetary payments to employees injured at work or suffering from an occupational disease. They also provide monetary benefits for the dependents of employees killed on the job.[533] In addition, the *Workers' Compensation Laws* limit the financial liability of employers, and they nearly eliminate the financial liability of co-workers for most accidents.[534]

The Department of Labor's Office of Workers' Compensation Programs (OWCP) oversees four workers' compensation programs covering federal employees: The Energy Employees Occupational Illness Compensation Program, the Federal Employees' Compensation Program, the Longshore and Harbor Workers' Compensation Program, and the Black Lung Benefits Program.[535]

In addition, each state establishes a workers' compensation board or commission, tasked with administering workers' compensation programs that cover employees of private companies and state and local governments.[536] Depending on the state, employers can comply with workers' compensation laws by obtaining coverage through:[537]

(1) **State insurance (or compensation) funds.** Agencies that provide workers' compensation insurance coverage to both public and private employers.
(2) **Self-insurance plans** - Plans under which employers set aside a percentage of capital funds to cover expenses that may arise.
(3) **Commercial workers' compensation insurance**. Policies purchased from commercial insurance companies.
(4) **Combination programs.** Programs under which employers cover their workers through a combination of any of the aforementioned methods.

Billing and Reimbursement

Providers treating ill or injured employees covered under one of the four federal workers' compensation acts are reimbursed according to the Department of Labor's OWCP fee schedule for the *Federal Employees' Compensation Program Act*, the *Longshore and Harbor Workers' Compensation Program Act*, and the *Energy Employees Occupational Illness Compensation*

532 "Workers' Compensation: Benefits, Coverage, and Costs, 2010" By Ishita Sengupta, et al., Washington, DC: National Academy of Social Insurance, August 2012, p. 2.
533 "Workers Compensation" Cornell University Law School, https://www.law.cornell.edu/wex/workers_compensation (Accessed 3/2/15).
534 Ibid.
535 "Workers' Compensation" United States Department of Labor, DOL.gov, http://www.dol.gov/dol/topic/workcomp/ (Accessed 8/10/09).
536 "Understanding Health Insurance: A Guide to Billing and Reimbursement" By Michelle A. Green and JoAnn C. Rowell, Twelfth Edition, Stamford, CT: Cengage Learning, 2013, p. 602; "Workers' Compensation" United States Department of Labor, DOL.gov, http://www.dol.gov/dol/topic/workcomp/ (Accessed 8/10/09).
537 "Understanding Health Insurance: A Guide to Billing and Reimbursement" By Michelle A. Green and JoAnn C. Rowell, Twelfth Edition, Stamford, CT: Cengage Learning, 2013, p. 602-603.

Program Act.[538] A modified version of the fee schedule is used to reimburse providers treating patients covered under the *Federal Black Lung Benefits Act*.[539] The OWCP's schedule is based in part on the fee schedule developed by CMS with some program specific adjustments.[540] Claims for reimbursement should be submitted to the Department of Labor using the UB-04 form for inpatient hospital charges and the CMS-1500 form for physician services.[541] In addition, various forms, progress reports, and supplemental reports may be required as well.[542] Bills must be submitted to OWCP by December 31 of the year following the year in which services were provided, or by December 31 of the year following the year when the condition was first accepted as covered by the workers' compensation program, whichever is later.[543]

> Medicare claims for physician services must be submitted using the CMS-1500 claim form, whereas institutional providers (i.e. hospitals, skilled nursing facilities, end stage renal disease providers, home health agencies, hospices, outpatient rehabilitation clinics, comprehensive outpatient rehabilitation facilities, community mental health centers, critical access hospitals, federally qualified health centers, histocompatibility laboratories, Indian Health Service facilities, organ procurement organizations, religious non-medical health care institutions, and rural health clinics) must submit the UB-04 claim form. Medicare claims must be filed within one calendar year of the date of service.
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> ***U.S. Department of Veterans Affairs; United States Department of Labor, 2009.***

Although some state workers' compensation programs reimburse providers using a fee schedule based on RVUs established by the state compensation board or commission, many states have developed managed care plans, in an effort to improve quality of care and control costs.[544] The claims forms, progress reports, and supplemental reports used, as well as the filing deadlines for them, vary from state to state.[545]

Providers treating patients eligible for coverage under workers' compensation programs must accept assignment, meaning they must accept the compensation as payment in full.[546] Patients covered by workers' compensation programs are charged no fees at the time of treatment; they pay no deductible and no co-payment.[547] In addition, the patient's employer pays all premiums.[548]

538 "Workers' Compensation: Benefits, Coverage, and Costs, 2010" By Ishita Sengupta, et al., Washington, DC: National Academy of Social Insurance, August 2012, p. 80, 83.
539 "Office of Workers' Compensation Program Medical Fee Schedule 2009" United States Department of Labor, May 12, 2009, http://www.dol.gov/esa/owcp/regs/feeschedule/fee/fee09/fs09instructions.htm (Accessed 8/19/09).
540 Ibid.
541 Ibid.
542 "Understanding Health Insurance: A Guide to Billing and Reimbursement" By Michelle A. Green and JoAnn C. Rowell, Twelfth Edition, Stamford, CT: Cengage Learning, 2013, p. 612.
543 "From Patient to Payment: Insurance Procedures for the Medical Office, Third Edition" By Cynthia Newby, Columbus, OH: Glencoe/McGraw-Hill, 2002, p. 132.
544 "Understanding Health Insurance: A Guide to Billing and Reimbursement" By Michelle A. Green and JoAnn C. Rowell, Twelfth Edition, Stamford, CT: Cengage Learning, 2013, p. 621.
545 "From Patient to Payment: Insurance Procedures for the Medical Office, Third Edition" By Cynthia Newby, Columbus, OH: Glencoe/McGraw-Hill, 2002, p. 132.
546 "Understanding Health Insurance: A Guide to Billing and Reimbursement" By Michelle A. Green and JoAnn C. Rowell, Twelfth Edition, Stamford, CT: Cengage Learning, 2013, p. 621.
547 "Understanding Health Insurance: A Guide to Billing and Reimbursement" By Michelle A. Green and JoAnn C. Rowell, Ninth Edition, Clifton Park, NY: Delmar Cengage Learning, 2008, p. 543-544.
548 Ibid, p. 544.

Indian Health Services (IHS)

The *Indian Health Services* (*IHS*) *Agency* is located within HHS.[549] The agency provides healthcare services to approximately 2.2 million American Indians and Alaskan Natives through IHS direct healthcare services, tribally operated healthcare services, and Urban Indian healthcare services and resource centers.[550] Most of the agency's resources fund the care of American Indians or Native Alaskans living on or near reservations or Alaskan villages.[551] However, Congress has provided some funding for programs for eligible individuals in urban areas as well.[552]

Billing and Reimbursement

On occasion, IHS needs to purchase healthcare services from private providers.[553] In these instances, IHS contracts with non-IHS facilities and providers to deliver healthcare services when:

(1) No IHS facility exists;
(2) The direct care element is incapable of providing the required emergency or specialty care;
(3) The direct care element has an overflow of medical care workload; or
(4) Supplementary alternate resources are needed.[554]

Typically, IHS pays providers for these services in accordance with the terms of the negotiated contract.[555] When these services are purchased from hospitals participating in the Medicare program, the MMA provides IHS with the authority to limit the reimbursement amount to rates similar to those paid by the Medicare program.[556] Providers should submit their claims to the IHS *fiscal intermediary*, Blue Cross Blue Shield (BCBS) of New Mexico, using the appropriate claim form.[557]

IHS is considered a payor of last resort, so if a patient has other insurance, providers should submit claims to the patient's insurance provider first "notwithstanding any state or local law or regulation to the contrary."[558] The contract standards between IHS and BCBS of New Mexico

549 "Indian Health Service Introduction" By Indian Health Services, IHS.gov, June 2009, http://www.ihs.gov/PublicInfo/PublicAffairs/Welcome_Info/IHSintro.asp (Accessed 8/10/09).
550 "Indian Health Service Year 2015 Profile" Indian Health Service, January 2015, http://www.ihs.gov/newsroom/factsheets/ihsyear2015profile/ (Accessed 2/5/15), p. 1.
551 "Indian Health Service: A Quick Look" Indian Health Service, June 2009, http://info.ihs.gov/QuickLook09.asp (Accessed 8/10/09).
552 Ibid.
553 Ibid.
554 "CHS 101" Contract Health Services Data Quality Work Group, http://www.ihs.gov/NonMedicalPrograms/dqwg/dqwg-section1-home.asp (Accessed 08/27/09).
555 "Contract Health Services" Indian Health Services, IHS.gov, June 2009, http://info.ihs.gov/CHS.asp (Accessed 08/26/09).
556 "Section 506 of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003—Limitation on Charges for Services Furnished by Medicare Participating Inpatient Hospitals to Individuals Eligible for Care Purchased by Indian Health Programs" Federal Register Vol. 72 No. 106 (June 4, 2007), p. 30706.
557 "About the Fiscal Intermediary (FI)" BlueCross BlueShield of New Mexico, 2015, http://www.bcbsnm.com/ihsfi/about_fi.html (Accessed 2/5/15), p. 1.
558 "CHS 101" Contract Health Services Data Quality Work Group, http://www.ihs.gov/NonMedicalPrograms/dqwg/dqwg-section1-home.asp (Accessed 08/27/09).

call for 97 percent of *clean claims* submitted to the IHS *fiscal intermediary* to be completed within 30 days of receiving the claim from the provider.[559]

PRIVATE PAYORS

Private health insurance consists of commercial insurers, BCBS plans, MCOs, and *self-funded* plans. In 2012, private health insurance financed 34 percent of the amount spent on personal healthcare.[560]

For Profit Commercial Insurers

Commercial health insurers entered the health insurance market in the 1940s.[561] *Commercial health insurance* refers to plans that are offered by life insurance companies, casualty insurance companies, and companies that were formed for the sole purpose of offering health insurance.[562] *Commercial insurers* are taxable entities organized as either mutual or stock insurers.[563] Mutual insurance companies are owned by their policyholders, whereas stock insurance companies are owned by their stockholders.[564] Commercial insurers typically offer a variety of health insurance plans, which offer varying trade-offs between cost, the variety of the services covered, and the flexibility to select providers.

To compete in today's health insurance market, many commercial insurers offer a variety of plan options. As such, it can be hard to generalize patient and insurance billing requirements for commercial insurers, because co-pay and deductible amounts, reimbursement methods, claim form requirements, claims submission deadlines, remittance schedules, policies, and the claim submittal process will vary by plan. Further complicating matters, it is uncommon for commercial insurers to publish their billing manuals or inform providers of changes to their claims process.[565] Accordingly, to avoid claim denials and to ensure maximum reimbursement, it may be important for providers to routinely contact commercial insurers with whom they frequently work in order to stay informed of any changes to the claims process.

559 "Indian Health Service: Opportunities May Exist to Improve the Contract Health Services Program" U.S. Government Accountability Office, December 2013, http://www.gao.gov/assets/660/659602.pdf (Accessed 2/5/15), p. 18.
560 "Table 5: Personal Health Care Expenditures; Aggregate and per Capita Amounts, Percent Distribution and Annual Percent Change by Source of Funds: Calendar Years 2007-2023" in "National Health Expenditure Projections 2013-2023" Centers for Medicare & Medicaid Services, September 17, 2014, http://www.cms.gov/Research-Statistics-Data-and-Systems/Statistics-Trends-and-Reports/NationalHealthExpendData/NationalHealthAccountsProjected.html (Accessed 1/27/15).
561 "Health Care Economics, Sixth Edition" By Paul J. Feldstein, Clifton Park, NY: Thomson Delmar Learning, 2005, p. 184.
562 "Healthcare Finance: An Introduction to Accounting and Financial Management" By Louis C. Gapenski, Third Edition, Chicago, IL: Health Administration Press, 2004, p. 35.
563 Ibid.
564 "Introduction to Health Services" By Stephen J. Williams and Paul R. Torrens, Seventh Edition, Clifton Park, NY: Thomson Delmar Learning, 2008, p. 114.
565 "Understanding Health Insurance: A Guide to Billing and Reimbursement" By Michelle A. Green and JoAnn C. Rowell, Twelfth Edition, Stamford, CT: Cengage Learning, 2013, p. 438.

Managed Care

Overview

Managed care plans integrate the financing (that is, insurance) and provision of health services under the administration of one managed care organization (MCO) in an effort to contain costs.[566] Because managed care plans assume risk, they focus on managing care as well as managing costs. Under managed care, costs are contained by holding providers accountable to offer quality services at predetermined levels of reimbursement. Managed care plans hold providers accountable for providing care to a population through:

(1) Clinical practice standardization;
(2) Selective contracting;
(3) Low-cost settings;
(4) Reduced discretionary hospital admissions; and
(5) Effective staff use.[567]

These mechanisms ensure that financial risk is shared by the managed care plan and the providers, forcing them both to be accountable for the delivery, cost, and quality of services.

Typically, managed care plans are created by an insurer that owns its own provider network or by an insurer that creates a network by way of contracts with independent providers.[568] Managed care plans are structured in a variety of ways, each with their own unique characteristics. However, three of the more popular forms of managed care plans are health maintenance organizations (HMO), preferred provider organizations (PPO), and point-of-service plans (POS).

Health Maintenance Organizations (HMOs)

Health maintenance organizations (HMOs) are healthcare financing and delivery systems that provide comprehensive healthcare services for enrollees in a particular geographic area through its network of providers.[569] The HMO structure benefits health plans, enrollees, and providers.[570] Health plans benefit because they are able to limit their financial risk by contracting with providers to care for the enrolled population for a fixed amount per member per month, regardless of the amount of services provided to any given beneficiary (this system of reimbursement is known as *capitation*).[571] Enrollees receive the benefit of little or no deductibles

566 "Healthcare Finance: An Introduction to Accounting and Financial Management" By Louis C. Gapenski, Third Edition, Chicago, IL: Health Administration Press, 2004, p. 37.
567 "A Guide to Consulting Services for Emerging Healthcare Organizations" By Robert J. Cimasi, New York, NY: John Wiley & Sons, Inc., 1999, p. 24-25.
568 "Healthcare Finance: An Introduction to Accounting and Financial Management" By Louis C. Gapenski, Third Edition, Chicago, IL: Health Administration Press, 2004, p. 37.
569 "Managed Care Health Plans in Wisconsin" State of Wisconsin: Office of the Commissioner of Insurance, July 2013, http://oci.wi.gov/pub_list/pi-044.pdf (Accessed 4/18/14), p. 6; "Medicare Advantage in Wisconsin," State of Wisconsin, Office of the Commissioner of Insurance, March 2012, http://oci.wi.gov/pub_list/pi-099.pdf (Accessed 4/27/14), p. 6.
570 "Introduction to Health Services" By Stephen J. Williams and Paul R. Torrens, Seventh Edition, Clifton Park, NY: Thomson Delmar Learning, 2008, p. 126.
571 "Paying Physicians by Capitation: Is the Past Now Prologue?" By Samuel Zuvekas and Joel Cohen, Health Affairs, Vol. 29, No. 9, http://content.healthaffairs.org/content/29/9/1661.full (Accessed 4/28/14), p. 1661.

and nominal or no co-payments for the care they receive; providers benefit from a steady stream of income regardless of how often enrollees seek care.[572]

> The HMO came into existence in Los Angeles in 1923 with the founding of the Ross-Loos Clinic. The clinic, founded by two physicians, Donald E. Ross and H. Clifford Loos, provided medical and hospital care to Los Angeles Department of Water and Power employees and their families in exchange for monthly payments. [573]

HMOs are more restrictive than other health plans, as they generally operate on a closed panel basis, i.e., enrollees must receive all of their care from the plan's provider network.[574] In serious emergencies, however, HMOs will generally allow their enrollees to receive care from providers outside of the HMO's network.[575] Under some HMO models, enrollees must select a primary care physician to oversee and coordinate their healthcare. This physician also helps to control costs by limiting which providers the enrollee has access to; by acting as a *gatekeeper*, the physician's authorization is required before the plan will pay for specialized or referral services.[576] In addition, because enrollees are typically limited to seeking care from the plan's network of providers, HMOs do assume responsibility for quality assurance and are able to transfer some of the financial risk to their preferred providers.[577]

HMOs may be classified by the methods by which they contract with their physicians and other providers. The following are common forms of HMOs:

(1) **Staff model HMOs.** The HMO employs its physicians and care is usually provided in a facility owned by the HMO. There is a high degree of control over the care that is delivered. Costs are often lower in this type of structure due to the HMO's ownership of the treatment facility.[578]
(2) **Group model HMOs.** The HMO plan is structured around a multi-specialty medical group that may include internists; obstetricians; gynecologists; cardiac and oncology specialists; and surgeons, contracting exclusively with the HMO to provide services. Care may be delivered in facilities owned by the physician group, e.g., clinics, or in facilities owned by the HMO, e.g., hospitals.[579]
(3) **Network model HMOs.** The HMO plan contracts with many different independent practice associations (IPA) or other provider groups to form a physician network. Care can be provided in a larger geographic service area than would be possible with only one physician group. This model offers the patient choice of physicians and managed costs.[580]

572 "Introduction to Health Services" By Stephen J. Williams and Paul R. Torrens, Seventh Edition, Clifton Park, NY: Thomson Delmar Learning, 2008, p. 126.
573 "Private Health Insurance and Managed Care" in "Introduction to Health Services, Seventh Edition" by Alma Koch., Thomson Delmar Learning, 2008, p. 115; www.economicexpert.com/a/Ross:Loos:Medical:Group.htm.
574 "Health Maintenance Organization (HMO) Plan" Centers for Medicare & Medicaid Services, http://www.medicare.gov/sign-up-change-plans/medicare-health-plans/medicare-advantage-plans/hmo-plans.html (Accessed 3/3/2015).
575 Ibid.
576 "Healthcare Finance: An Introduction to Accounting and Financial Management" By Louis C. Gapenski, Third Edition, Chicago, IL: Health Administration Press, 2004, p. 38.
577 "Fundamentals of Health Law" By Daniel J. Schwartz, Fourth Edition, Washington, DC: American Health Lawyers Association, 2008, p. 248-250.
578 "HMO Organizational Models," Patient Advocate Foundation, 2012, http://www.patientadvocate.org/index.php?p=383 (Accessed 4/18/14).
579 Ibid.
580 Ibid.

(4) **Independent Practice Association (IPA) HMOs.** The HMO plan contracts with an association of physicians who are members of a separate legal entity, i.e. an IPA, but who practice as solo practitioners or in a group practice. Most physicians in an IPA model are in solo practice and typically have a significant number of patients who are not members of the HMO plan.[581]
(5) **Direct Contract Model HMOs.** The HMO plan delivers healthcare services to beneficiaries using individual physicians in the community.[582]

Preferred Provider Organizations (PPOs)

A *preferred provider organization (PPO),* a hybrid of an HMO and traditional health insurance plan, is a managed care plan that allows members to choose from an array of healthcare providers that have contracted with the plan to provide services on a discounted basis.[583] The health plan, the members, and the providers all benefit when the member chooses to receive services from a provider on the preferred provider list.[584] Health plans benefit through increased purchasing power, which allows them to negotiate lower prices; members benefit because they are charged lower co-insurance and deductibles when they see in-network providers; and providers benefit because being a preferred provider status may make plan members more likely to choose them when seeking medical treatment.[585]

> The PPO evolved in California in 1982 in response to the legislature's desire to have a system that "*would allow selective contracting for Medicaid through private insurers*."[586]

PPO members are not required to have a *gatekeeper* physician authorize the care they receive, nor are PPO members required to use the preferred providers on their plan's list, although going outside the network will result in higher co-insurance rates and deductibles.[587] However, because members are not limited to seeking care from the list of preferred providers, PPOs do not usually cover preventative care because they do not undertake the same responsibility for quality assurance as HMOs.[588] Also different from HMOs, PPOs do not transfer financial risk to their preferred providers.[589]

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581 "What is the Difference Between Health maintenance Organization (HMO) and a Preferred Provider Organization (PPO)?" City of Pomona, California, http://www.ci.pomona.ca.us/mm/humres/pdf/BENEFIT/Pg2_Diff_HMO_PPO.doc (Accessed 4/18/14); "Are there different types of HMOs?" Archdiocese of Cincinnati, https://pcms.plansource.com/entities/18315/pub_nodes/16066 (Accessed 4/18/2014); "Managed Care Glossary," Patient-Physician Network, 2001, http://www.drppg.com/managed_care.asp (Accessed 4/18/14).
582 "Understanding Health Insurance: A Guide to Billing and Reimbursement" By Michelle A. Green and JoAnn C. Rowell, Twelfth Edition, Stamford, CT: Cengage Learning, 2013, p. 55.
583 "Healthcare Finance: An Introduction to Accounting and Financial Management" By Louis C. Gapenski, Third Edition, Chicago, IL: Health Administration Press, 2004, p. 37; "Introduction to Health Services" By Stephen J. Williams and Paul R. Torrens, Seventh Edition, Clifton Park, NY: Thomson Delmar Learning, 2008, p. 124.
584 "Introduction to Health Services" By Stephen J. Williams and Paul R. Torrens, Seventh Edition, Clifton Park, NY: Thomson Delmar Learning, 2008, p. 124.
585 Ibid, p. 124-125.
586 "Understanding Health Insurance and the PPO" Sheila Guilloton, Examiner, June 15, 2009, www.examiner.com/x-11804-Health-Care-Examiner~y2009m6d15-Understanding-health-insurance-and-the-PPO, (accessed July 10, 2009).
587 "Healthcare Finance: An Introduction to Accounting and Financial Management" By Louis C. Gapenski, Third Edition, Chicago, IL: Health Administration Press, 2004, p. 37; "Introduction to Health Services" By Stephen J. Williams and Paul R. Torrens, Seventh Edition, Clifton Park, NY: Thomson Delmar Learning, 2008, p. 125.
588 "Healthcare Finance: An Introduction to Accounting and Financial Management" By Louis C. Gapenski, Third Edition, Chicago, IL: Health Administration Press, 2004, p. 37.
589 "Fundamentals of Health Law" By Daniel J. Schwartz, Fourth Edition, Washington, DC: American Health Lawyers Association, 2008, p. 245.

Exclusive Provider Organizations (EPOs)

A subset of the PPO model, the *exclusive provider organization* (EPO) utilizes the PPO preferred provider list, but does not allow the insured to obtain services from an out-of-network physician except in the case of an emergency. Although EPOs have a small market footprint, they have become increasingly popular as a means to control costs for *self-funded* employer plans.[590]

Point-of-Service (POS) Plans

Point-of-service (POS) plans combine many of the elements of HMOs and PPOs.[591] POS plans are usually an addition to an HMO product that allows members the benefit of seeking care from non-PARs.[592] As with an HMO, when members seek care from in-network providers they typically pay no deductible or coinsurance.[593] However, similar to a PPO, members are free to seek services outside the network subject to higher cost sharing in the form of deductibles and coinsurance.[594] Although the cost is higher, this freedom of choice is why many consider POS plans to be the least restrictive form of managed care.[595]

Like members of an HMO, POS enrollees must choose a primary care physician from the list of in-network providers to oversee the provision of healthcare services.[596] This primary care physician is also responsible for referrals to specialists and hospitals.[597] Should a POS member choose not to seek a referral from his or her primary care physician before undergoing treatment, his or her expenses associated with this treatment typically will be higher.[598]

Billing Managed Care Organizations

To ensure timely payment and maximum reimbursement, it is important that a provider's staff be aware of the managed care contracts in effect in their practice, the rules of the various plans, and how these contracts affect the claims process.[599] Providers should be aware of the co-pay and deductible amounts, plan requirements, policies, and if applicable, the length of time it takes a plan to remit payment for the practice's various contracts, as they will usually vary by plan.

HMO Billing

Patients in HMOs typically pay a fixed premium to enroll in the plan and co-payments at the time of treatment ranging from $1 to $35, unless the co-pay is waived because a *co-insurance*

590 "Essentials of Managed Health Care" By Peter R. Kongstvedt, 6th Edition, Burlington, MA: Jones and Bartlett Learning, LLC, 2013, p. 29.
591 "Introduction to Health Services" By Stephen J. Williams and Paul R. Torrens, Seventh Edition, Clifton Park, NY: Thomson Delmar Learning, 2008, p. 127.
592 "Fundamentals of Health Law" By Daniel J. Schwartz, Fourth Edition, Washington, DC: American Health Lawyers Association, 2008, p. 258.
593 "Understanding Health Insurance: A Guide to Billing and Reimbursement" By Michelle A. Green and JoAnn C. Rowell, Twelfth Edition, Stamford, CT: Cengage Learning, 2013, p. 55.
594 Ibid.
595 "Point of Service (POS)" All Insurance Info, AllInsuranceInfo.org, 2007, http://allinsuranceinfo.org/health/pos.html (Accessed 7/13/09).
596 "Understanding Health Insurance: A Guide to Billing and Reimbursement" By Michelle A. Green and JoAnn C. Rowell, Twelfth Edition, Stamford, CT: Cengage Learning, 2013, p. 55.
597 "Point of Service (POS)" All Insurance Info, AllInsuranceInfo.org, 2007, http://allinsuranceinfo.org/health/pos.html (Accessed 7/13/09).
598 Ibid.
599 "From Patient to Payment: Insurance Procedures for the Medical Office, Third Edition" By Cynthia Newby, Columbus, OH: Glencoe/McGraw-Hill, 2002, p. 112.

payment, a fixed percentage of the bill the patient is required to pay after meeting their deductible, is required instead.[600] It should be noted that providers are often required to file claims with procedure codes for all services rendered, even those directly employed by the HMO and those compensated on a capitated basis.[601] In turn, HMOs use these claims to adjust rates and track the quality of care.[602]

PPO Billing

PPOs contract with providers to render services to the plan's enrollees on a reduced fee basis.[603] Patients in most PPOs have the freedom to receive care from providers outside the plan, with the trade-off being higher out-of-pocket expenses.[604] Members of a PPO usually pay higher premiums, deductibles, and co-payments than those paid by members of HMOs, but these payments are generally lower than FFS plans.[605]

POS Plan Billing

Providers in POS plans generally are reimbursed according to the terms of the contract, except that specialty services typically are paid on a FFS basis.[606] Patients in a POS plan pay only small co-pays or charges, no co-insurance, and no deductibles for care received from network providers and out-of-network providers to whom they have a referral to see.[607] However, when a patient sees a non-network specialist without first obtaining a referral from his or her primary care physician, the patient usually will be subject to higher out-of-pocket expenses in the form of a larger deductible and 20 - 25 percent coinsurance charges.[608]

Not For Profit Insurers

Not for profit health plans include many of the largest health insurance providers in the United States. In 2012, approximately 45% of enrollees in the 154 largest health plans in the United States belonged to nonprofit health plans.[609] Similar to for profit insurers, nonprofit health insurers plans offer a variety of types of health plans, including HMOs, PPOs, and POS plans.

600 "Health Maintenance Organizations" Texas Department of Insurance, November 2014, http://www.tdi.texas.gov/pubs/consumer/cb069.html (Accessed 2/17/15), p. 2; "Understanding Health Insurance: A Guide to Billing and Reimbursement" By Michelle A. Green and JoAnn C. Rowell, Twelfth Edition, Stamford, CT: Cengage Learning, 2013, p. 54; "Definitions of Health Insurance Terms," Bureau of Labor Statistics, http://webcache.googleusercontent.com/search?q=cache:orHxVTPXSEwJ:www.bls.gov/ncs/ebs/sp/healthterms.pdf+&cd=1&hl=en&ct=clnk&gl=us (Accessed 4/29/14).

601 "From Patient to Payment: Insurance Procedures for the Medical Office, Third Edition" By Cynthia Newby, Columbus, OH: Glencoe/McGraw-Hill, 2002, p. 113.

602 Ibid.

603 "Essentials of Managed Health Care" By Peter Kongstvedt, Sixth Edition, Burlington, MA: Jones & Bartlett Learning, 2013, p. 9.

604 Ibid.

605 "Understanding Health Insurance: A Guide to Billing and Reimbursement" By Michelle A. Green and JoAnn C. Rowell, Twelfth Edition, Stamford, CT: Cengage Learning, 2013, p. 56.

606 "From Patient to Payment: Insurance Procedures for the Medical Office, Third Edition" By Cynthia Newby, Columbus, OH: Glencoe/McGraw-Hill, 2002, p. 112.

607 "Point of Service (POS)" All Insurance Info, AllInsuranceInfo.org, 2007, http://allinsuranceinfo.org/health/pos.html (Accessed 7/13/09).

608 "Understanding Health Insurance: A Guide to Billing and Reimbursement" By Michelle A. Green and JoAnn C. Rowell, Twelfth Edition, Stamford, CT: Cengage Learning, 2013, p. 55.

609 "Basic Facts & Figures: Nonprofit Health Plans" Alliance for Advancing Nonprofit Health Care, http://www.nonprofithealthcare.org/resources/BasicFacts-NonprofitHealthPlans.pdf (Accessed 2/24/15), p. 1.

Blue Cross Blue Shield

Overview

Blue Cross began providing private health insurance in 1929 by offering coverage for hospital expenses.[610] Blue Shield began providing insurance to cover expenses associated with physicians' services in 1939.[611] In 1986, the independent boards of directors of the national *Blue Cross and Blue Shield (BCBS)* accrediting associations merged to form a single nonprofit BCBS Association (BCBSA).[612] Today, the BCBSA consists of thirty-seven independent BCBS companies, in addition to a Federal Employee Program and an Association that serves the collective needs of the BCBS plans.[613] The BCBSA works to coordinate the nationwide plans by establishing standards for new plans and programs; assisting local plans with enrollment activities, national advertising, public education, professional relations, and statistical and research activities; and serving as the primary contractor for processing Medicare hospital, hospice, and home health claims.[614]

During the 1990s, many nonprofit BCBS plans were in need of additional capital in order to compete with for-profit insurers and requested permission from their respective state governments to convert to for-profit corporations. In the instances in which the plans were allowed to convert to for-profit status, the transitions were closely watched to ensure that the plans' charitable assets were preserved.[615]

BCBS plans offer a variety of health insurance options, including FFS coverage, indemnity plans, managed care plans, a federal employee program, Medicare supplemental plans, and Healthcare Anywhere, an option that allows enrollees of independently owned and operated plans to receive the benefits of their plan from other BCBS plans worldwide.[616] As of 2013, BCBS plans provide healthcare coverage to over 80 million Americans.[617]

Billing and Reimbursement

BCBS plans include a variety of managed care plans (e.g. health maintenance organization [HMO] programs, preferred provider organization [PPO] programs, and point-of-service [POS] plans and traditional FFS coverage, among others).[618] BCBS FFS plans are typically divided into two types of coverage: (1) basic coverage, which covers a variety of minimum benefits and (2) major medical (MM) coverage, which is usually subject to patient deductible and copayment

610 "Introduction to Health Services" By Stephen J. Williams and Paul R. Torrens, Seventh Edition, Clifton Park, NY: Thomson Delmar Learning, 2008, p. 114.
611 Ibid.
612 "Understanding Health Insurance: A Guide to Billing and Reimbursement" By Michelle A. Green and JoAnn C. Rowell, Twelfth Edition, Stamford, CT: Cengage Learning, 2013, p. 459.
613 "BlueCross BlueShield" BlueCross BlueShield Association, 2015, http://www.bcbs.com/ (Accessed 2/16/15), p. 2.
614 "Understanding Health Insurance: A Guide to Billing and Reimbursement" By Michelle A. Green and JoAnn C. Rowell, Twelfth Edition, Stamford, CT: Cengage Learning, 2013, p. 459.
615 Ibid, p. 460.
616 Ibid, p. 462-466.
617 "About Blue Cross blue Shield Association" BlueCross BlueShield, http://www.bcbs.com/about-the-association/ (Accessed 3/2/15).
618 "Understanding Health Insurance: A Guide to Billing and Reimbursement" By Michelle A. Green and JoAnn C. Rowell, Twelfth Edition, Stamford, CT: Cengage Learning, 2013, p. 462; For more information on managed care plans, see the Managed Care section above.

requirements.[619] Similar to the Medicare participating provider program, providers can enter into contracts with BCBS in order to become PARs. BCBS PARs agree to: (1) write off the difference between the amount charged by the provider to the patient and the approved fee established by the insurer and (2) only bill patients for the deductible and copay amounts that are based on BCBS allowed fees for covered services.[620] In return, BCBS corporations make direct payments to PARs and publish the name, location, and specialty of all PARs in a directory that is distributed to all BCBS subscribers.[621] Providers that do not sign such agreements (i.e., non-PARs) can bill patients for the full charge for any given service, who in turn may be reimbursed by BCBS for the allowed fee for the service, minus deductible and copay obligations, assuming that the service is covered by the patient's BCBS plan.[622]

Depending on the enrollee's coverage and the services sought, patients usually are subject to deductible, coinsurance, and co-pay requirements, with coinsurance amounts commonly ranging from 20 percent to 25 percent.[623] The CMS-1500 claim form is accepted by most BCBS plans, and it typically must be filed within one year from the date of service unless the provider's contract states otherwise.[624]

Health System Plans (HSPs)

A *health system plan* (HSP) is a type of health plan that acts as a payor and also manages the delivery of medical services. These plans serve as the primary payor for services offered at the health system's own facilities, enabling the health plan to streamline billing, and limit the complexity of their payment systems. Although most HSPs have a modest national footprint,[625] their ability to attract and retain individuals and small groups in their geographic regions make PHSPs highly competitive.[626] Examples of HSPs include Kaiser Permanente and Geisinger Health Plan, among others. As of 2011, approximately 13% of U.S. hospitals reported having an equity position in an HMO.[627]

With the advent of the ACA and its focus on ACOs, health systems are showing renewed interest in operating their own insurance plans.[628] Health systems with internal health plans may be able to better align financial incentives and clinical operations in an ACO arrangement by having one entity represent both the provider and the payor. Further, entities where the ACO and payor are under the same overall organizational structure may be more apt to implement pay-for-

619 "Understanding Health Insurance: A Guide to Billing and Reimbursement" By Michelle A. Green and JoAnn C. Rowell, Twelfth Edition, Stamford, CT: Cengage Learning, 2013, p. 462-463.
620 "Anthem Blue Cross and Blue Shield Provider Agreement" Blue Cross Blue Shield, http://www.anthem.com/provider/va/f4/s0/t0/pw_e188276.pdf (Accessed 3/2/15), p. 6.
621 "Understanding Health Insurance: A Guide to Billing and Reimbursement" By Michelle A. Green and JoAnn C. Rowell, Twelfth Edition, Stamford, CT: Cengage Learning, 2013, p. 461.
622 Ibid, p. 461-462.
623 Ibid, p. 467.
624 Ibid, p. 467.
625 "Provider Sponsored health Plans: Past, Present and Future" By Chris Myers, http://www.navigant.com/insights/library/healthcare/2013/pulse-providers-sponsored-healthplans/?page=2 (Accessed 4/29/14).
626 "Provider Sponsored Health Plans" By James Smith et al., First Illinois Speaks, January 2014, http://firstillinoishfma.org/january-2014-newsletter/ (Accessed 4/29/2014); "Deciding Whether to Enter Provider-Sponsored Health Plans Requires Careful Up-Front Analysis" By Michael Finnerty, HFMA, May 29, 2013, https://www.hfma.org/Content.aspx?id=17327 (Accessed 4/29/2014); "Provider Sponsored Health Plans as a new Accountable Care Entity" By Phil Kamp, Accountable Care News, Vol. 4, No. 5, May 2013, http://valencehealth.com/uploads/files/Accountable_Care_News_Reprint_Phil_Kamp_byline_May_2013.pdf. (Accessed 4/29/14), p. 1.
627 "Provider Sponsored health Plans: Past, Present and Future" By Chris Myers, http://www.navigant.com/insights/library/healthcare/2013/pulse-providers-sponsored-healthplans/?page=2 (Accessed 4/29/14).
628 Ibid.

performance (*P4P*) initiatives to improve cost and quality outcomes, since they are more able to monitor and influence the performance of individual providers by incorporating physician compensation into incentive programs.

Consumer Driven Health Plans—The Shift From Defined Benefits to Defined Contributions

To combat the problem of ever increasing premiums for employee health insurance, many employers have implemented *defined contribution* health insurance plans instead of the traditional *defined benefit* plans.[629] The goal is to model health insurance programs after *defined contribution* pension programs, such as 401(k)s.[630] Unlike a *defined benefit* system, in which an employer has the obligation to contribute the necessary premium for a certain health insurance benefit package, a *defined contribution* system allows an employer to contribute a designated amount of money and give the employee the freedom to do with it what he or she chooses.[631]

The shift toward *defined contribution* health insurance plans has directed the focus from the employer to the employee when it comes to making healthcare decisions.[632] Many forms of *defined contribution* leave substantial decisions to employee (that is, the consumer of the healthcare services), putting the employee in the driver's seat when it comes to deciding which services are worth purchasing and from whom to purchase them.[633] To accomplish this, employers occasionally will present employees with what amounts to a voucher to purchase insurance on their own, but more often, employers will create an account for each employee into which the employer, the employee, or both will contribute funds, and from which the employee will be able to draw to purchase health services.[634]

Health Savings Accounts (HSAs)

One of the most common models of *defined contribution* health insurance is the establishment of a *health savings account (HSA),* coupled with enrollment in a high-deductible health plan (HDHP), whereby employers and employees both contribute to a special account from which the employee can draw funds to pay for health services.[635] HSAs were first introduced in the MMA. An individual, an employee, or his or her employer may make contributions to an HSA. If the employer contributes, the value of those contributions is not taxable to the employee. Similarly, if the employee makes contributions, they count as *above-the-line* deductions.[636]

Individuals excluded from HSA eligibility are those not covered by a HDHP, those with health coverage other than a HDHP, those who can be claimed as a dependent on someone else's tax

629 "Defined Contribution Health Insurance" By Greg Scandlen, National Center for Policy Analysis, October 26, 2000, http://www.ncpa.org/pdfs/bg154.pdf (Accessed 09/10/09).
630 Ibid.
631 "Defined Contribution: From Managed Care to Patient-Managed Care" By E. Haavi Morreim, Cato Journal, Vol. 22, No. 1 (Spring/Summer 2002), p. 110-111.
632 "Defined-Contribution Health Insurance Products: Development and Prospects" By Jon B. Christianson, Stephen T. Parente, and Ruth Taylor, Health Affairs, Vol. 21, No. 1 (January/February 2002), p. 51.
633 "Defined Contribution: From Managed Care to Patient-Managed Care" By E. Haavi Morreim, Cato Journal, Vol. 22, No. 1 (Spring/Summer 2002), p. 112.
634 Ibid, p. 111.
635 "All About HSAs" U.S. Treasury Department, July 22, 2007, http://www.treas.gov/offices/public-affairs/hsa/pdf/all-about-HSAs_072208.pdf (Accessed 07/01/09), p. 2.
636 Ibid, p. 14.

return, and Medicare recipients.[637] However, enrollees are allowed to have non HDHP insurance coverage for the following reasons: (1) a specific disease or illness; (2) a fixed amount per period of hospitalization; and (3) liabilities incurred under workers' compensation laws, tort liabilities, or liabilities related to the ownership or use of property.[638] Furthermore, coverage for (1) accidents; (2) disability; (3) dental care; (4) vision care; or (5) long-term care does not preclude an individual from HSA eligibility.[639] No requirement exists that an individual have earned income, nor are there any upper-end limits on income, that would restrict an individual's ability to contribute to an HSA.[640]

Legislative Impacts

In 2006, President George W. Bush signed into law the *Health Opportunity Patient Empowerment Act of 2006*, which provided new opportunities for HSA participants to build their funds. Included among the provisions of the act was an allowance for employers to transfer funds from flexible spending arrangements (FSAs) or health reimbursement arrangements (HRAs) to an HSA plan for those employees wishing to switch. The new act also increased the maximum HSA contribution amount to a statutorily defined amount (indexed for inflation), eliminated the system of prorating HSA contributions based on the number of months that an individual was eligible and replaced it with a system allowing individuals who enrolled in a month other than January to make a contribution equal to a full year's enrollment. Additionally, the act allowed for a one-time transfer from an individual retirement arrangement (IRA) to an HSA, which avoided early withdrawal and income taxes, eliminated FSA coverage previously deemed as disregarded coverage which reduced HSA contribution for a given year, set an earlier date for cost-of-living index adjustments, and allowed greater employer contributions for lower-paid employees.[641]

More recently, the ACA may pose a threat to HSAs for three reasons: (1) the law contains a provision that prohibits the use of HSA funds to pay for over-the-counter pharmaceuticals, unless they are obtained with a prescription or doctor's orders;[642] (2) the law contains a provision that increases the penalty for early withdrawal of HSA funds from 10% to 20%;[643] and (3) the ACA requires that health insurance plans pay at least 60% of the actuarial value of covered benefits.[644] Due to the fact that HDHPs generally have lower actuarial values than traditional health insurance plans, supporters of HSAs feared that HDHPs may have difficulty reaching this threshold, thus reducing access to HSAs.[645] However, a 2014 analysis found that HSA-eligible

637 "Publication 969 – Main Content" Internal Revenue Service, 2013, http://www.irs.gov/publications/p969/ar02.html (Accessed 2/17/15), p. 1.
638 Ibid.
639 Ibid, p. 3.
640 "All About HSAs" U.S. Treasury Department, July 22, 2007, http://www.treas.gov/offices/public-affairs/hsa/pdf/all-about-HSAs_072208.pdf (Accessed 07/01/09), p. 4.
641 "President Bush Signs Bill to Make Health Care More Affordable, Accessible" U.S. Treasury Department, Press Release, Dec. 20, 2006, http://www.treas.gov/press/releases/hp209.htm (Accessed 7/1/09).
642 "Patient Protection and Affordable Care Act" Pub. L. 111-148, § 9003, 124 STAT 119, 854 (March 23, 2010); "State Legislation and Actions on Health Savings Accounts (HSAs) and Consumer-Directed Health Plans, 2004-2015" National Conference of State Legislatures, January 2015, http://www.ncsl.org/research/health/hsas-health-savings-accounts.aspx (Accessed 2/17/15), p. 2.
643 "Patient Protection and Affordable Care Act" Pub. L. 111-148, § 9003, 124 STAT 119, 854 (March 23, 2010) ; "State Legislation and Actions on Health Savings Accounts (HSAs) and Consumer-Directed Health Plans, 2004-2015" National Conference of State Legislatures, January 2015, http://www.ncsl.org/research/health/hsas-health-savings-accounts.aspx (Accessed 2/17/15), p. 2.
644 "Patient Protection and Affordable Care Act" Pub. L. 111-148, § 1302, 124 STAT 119, 167 (March 23, 2010); "State Legislation and Actions on Health Savings Accounts (HSAs) and Consumer-Directed Health Plans, 2004-2015" National Conference of State Legislatures, January 2015, http://www.ncsl.org/research/health/hsas-health-savings-accounts.aspx (Accessed 2/17/15), p. 2.
645 "State Legislation and Actions on Health Savings Accounts (HSAs) and Consumer-Directed Health Plans, 2004-2015" National Conference of State Legislatures, January 2015, http://www.ncsl.org/research/health/hsas-health-savings-accounts.aspx (Accessed 2/17/15), p. 2.

plans made up about 25% of the plans offered on the ACA's exchanges.[646] Accordingly, although the ACA may inhibit the access to and use of HSAs in some ways, they are still available.

Prevalence and Growth of HSAs

According to a 2014 census conducted by America's Health Insurance Plans (AHIP), the number of individuals covered by HSAs and HDHPs has increased by an annual average of 15% since 2011, with over than 17 million individuals covered as of January 2014.[647]

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>
> ***America's Health Insurance Plans, July 2014.***

Reimbursement with HSAs and HDHPs

Providers may receive reimbursement from an individual with an HSA in a variety of forms, including debit card, checks, and *automatic claims forwarding*.[648] The fact that an individual has an HSA does not mean that a provider will be paid the day the services are provided, because some HSAs encourage their patients not to pay for the provider's services until the plan informs the patient of the amount.[649] To combat this issue, providers should insist on payment at the time of service, always check their patient's insurance eligibility to determine how much of the deductible has been met, and, if the entire deductible has been met, whether the service is covered by their HDHP and whether the patient has co-insurance requirements.[650] Performing these tasks at the time of service can ensure the provider receives the appropriate payment in a timely manner, without having to go through the costly and time consuming process of seeking payment from the patient at a later date or reimbursing the patient due to an overpayment.[651]

Self Insurance

Self-insurance plans, often referred to as *self-funded* plans, have been one of the leading trends in the health insurance industry since the late 1970s.[652] Self-insuring employers make a conscious choice to undertake the risks associated with the cost of healthcare and set aside money to pay

646 "Health Savings Accounts Under the Affordable Care Act: Challenges and Opportunities for Consumer-Directed Health Plans" By Paul Howard and Yevgeniy Feyman, Center for Medical Progress, Manhattan Institute for Policy Research, October 2014, http://www.manhattan-institute.org/pdf/mpr_18.pdf (Accessed 2/17/15), p. 5.

647 "January 2014 Census Shows 17.4 Million Enrollees in Health Savings Account-Eligible High Deductible Health Plans (HSA/HDHPs)" America's Health Insurance Plans, July 2014, http://www.ahip.org/News/Press-Room/2014/New-Census-Survey-Shows-Continued-Growth-in-HSA-Enrollment.aspx (Accessed 2/17/15), p. 1.

648 "CIGNA Choice Fund Health Savings Account: Frequently Asked Questions About a Health Savings Account" CIGNA, CIGNA.com, 2009, http://www.cigna.com/our_plans/medical/hsa/for_you.html#3a (Accessed 08/28/09).

649 "Healthonomics: How to Handle Health Savings Accounts" By Suz Redfearn, physicianspractice.com, February 2008, http://www.physicianspractice.com/index/fuseaction/articles.details/articleID/1115/page/1.htm (Accessed 08/28/09).

650 Ibid.

651 Ibid.

652 "Introduction to Health Services" By Stephen J. Williams and Paul R. Torrens, Seventh Edition, Clifton Park, NY: Thomson Delmar Learning, 2008, p. 113; "Self Insurance In Times Of Growing And Retreating Managed Care" By Jon R. Gabel et al., Health Affairs, Vol. 22, No. 3 (March/April 2003), p. 203.

these costs as they arise.[653] Often, a self-insurer will hire a commercial insurer or third-party administrator to run its medical benefits program and adjudicate claims.[654]

Self-insurance plans vary by the amount of risk an employer is willing to assume.[655] In a fully *self-funded* plan, the employer undertakes the responsibility for 100 percent of the healthcare expenses submitted for reimbursement.[656] Typically, this type of funding is limited to employers or groups of 5,000 or more, as medical expenses for large groups can be reasonably predicted.[657] However, employers with fewer than 5,000 employees often are unwilling to assume the risk of funding their entire health insurance program.[658] Accordingly, these employers may opt for a partially *self-funded* plan.[659] The most common type of partially *self-funded* plans is the *minimum premium plan*.[660] Under a *minimum premium plan*, the employer covers claims up to a predetermined amount, and an insurance policy assumes liability for claims thereafter.[661] Another popular form of partially *self-funded* plans involves combining self-funding with stop-loss insurance. Under these plans, the employer covers employee claims up to a predetermined amount per employee, at which time stop-loss insurance covers any employee who exceeds his or her out-of-pocket maximum.[662]

Employers choose to self-insure as an alternative to purchasing health insurance policies for several reasons. First, self-insurers avoid the charges, fees, and profits that insurance companies build into the price of insurance premiums.[663] In addition, because self-insurance is not technically insurance, state taxes assessed on premium revenue can be avoided.[664] Perhaps the most important benefit of self-insurance is the fact that the *Employee Retirement Income Security Act of 1974* exempts self-insured plans from state regulation.[665] This exemption provides the self-insured considerable flexibility to design benefit programs as they see fit, and it provides them with the opportunity to save considerable money by avoiding state mandates requiring the coverage of particular services.[666]

Self-insured employers contract directly with providers and reimburse them according to the terms of the contract. Employers have designed self-insurance programs to provide coverage for their employees using a variety of plans, including indemnity, HMOs, PPOs, and POSs.[667] However, some states may prohibit a self-insured employer from signing capitated contracts with

653 "Healthcare Finance: An Introduction to Accounting and Financial Management" By Louis C. Gapenski, Third Edition, Chicago, IL: Health Administration Press, 2004, p. 36.
654 "Introduction to Health Services" By Stephen J. Williams and Paul R. Torrens, Seventh Edition, Clifton Park, NY: Thomson Delmar Learning, 2008, p. 113.
655 "Self-Insured Group Health Plans" Self-Insurance Institute of America, Inc., http://www.siia.org/i4a/pages/Index.cfm?pageID=4546 (Accessed 3/2/15).
656 "Introduction to Health Services" By Stephen J. Williams and Paul R. Torrens, Seventh Edition, Clifton Park, NY: Thomson Delmar Learning, 2008, p. 113.
657 Ibid.
658 Ibid.
659 Ibid.
660 Ibid.
661 Ibid.
662 "When You're Considering Self-Funding" The Alliance, August 2014, p. 7, http://www.the-alliance.org/uploadedFiles/Downloads/WhenYoureConsideringSelfFunding.pdf (Accessed 3/2/15).
663 "Introduction to Health Services" By Stephen J. Williams and Paul R. Torrens, Seventh Edition, Clifton Park, NY: Thomson Delmar Learning, 2008, p. 113.
664 Ibid.
665 Ibid.
666 Ibid.
667 "Self Insurance In Times Of Growing And Retreating Managed Care" By Jon R. Gabel et al., Health Affairs, Vol. 22, No. 3 (March/April 2003), p. 203.

physicians.[668] The forms used and the claims process likely will vary by employer, as will the coverage, co-insurance amount, and length of time for remittance, as the employer will design its plan in accordance with its particular needs.

It should be noted that, although the ACA makes significant changes to the small-group insurance market, self-insured group plans are exempted from these reforms, regardless of the size of the employer.[669] As a result, beginning in 2014, firms with relatively low-cost workers may be able to save money by self-insuring.[670]

Self-Pay

Individuals may pay out-of-pocket for their own healthcare costs for a number of reasons, including a lack of health insurance, a desire to keep a medical condition from their health insurer, or due to the conscious decision not to purchase health insurance.

Having decided to treat a self-pay patient, a provider must determine what form of payment to accept for these medical services, what to charge for these services, and how to collect the payment due.

Most public insurers, like Medicare, set their reimbursement rates independently of a provider's actual charges.[671] In addition, most private insurers have the bargaining power to negotiate discounts.[672] However, most self-pay patients will lack the ability to set their payment amount or negotiate lower charges, and, as a result, they may pay more than the amount an insurer would pay for the same service. Charges for services vary widely, but the 2010 average full-charge hospital bill was 3.6 times the hospital's costs.[673] This billing practice has led to multiple class action lawsuits against providers, and it has resulted in settlements by which the providers offer both prospective and retrospective discounts to their self-pay patients.[674] Thus, to avoid costly litigation at a later date, a provider may choose to offer all self-pay patients discounts similar to those negotiated by other payors.

Once a provider has determined what form of payment to accept and what to charge self-pay patients, he or she must face the question of how to collect payment. Staff training and a requirement that the bill be paid in full before the patient leaves can help reduce the chance that

668 Ibid.
669 "Small Firm Self-Insurance Under the Affordable Care Act" By Matthew Buettgens and Linda J. Blumberg, The Commonwealth Fund, November 2012, http://www.commonwealthfund.org/~/media/files/publications/issue-brief/2012/nov/1647_buettgens_small_firm_self_insurance_under_aca_ib.pdf (Accessed 2/17/15), p. 2.
670 Ibid, p. 5.
671 "From 'Soak The Rich' To 'Soak The Poor': Recent Trends In Hospital Pricing" By Gerard F. Anderson, Health Affairs, Vol. 26, No. 3 (May/June 2007), p. 784.
672 "From 'Soak The Rich' To 'Soak The Poor': Recent Trends In Hospital Pricing" By Gerard F. Anderson, Health Affairs, Vol. 26, No. 3 (May/June 2007), p. 784.
673 "Uninsured Americans Get Hit With Biggest Hospital Bills: Markups Vary" By Charles Babcock, Bloomberg Business, March 10, 2013, http://www.bloomberg.com/news/articles/2013-03-11/uninsured-americans-get-hit-with-biggest-hospital-bills (Accessed 2/18/15).
674 "Settlement in Uninsured Billing Lawsuit" BJC HealthCare, BJC.org, http://www.bjc.org/?id=5557&sid=1, March 03, 2008 (Accessed 7/31/09); Healthcare system and uninsured patients reached a settlement in a class action suit that called for a "Self-Pay Discount Policy" to be implemented at the system's hospitals. The discount is to apply prospectively for at least four years for all self-pay patients regardless of income level. In addition, upon request, the discount is to be available retroactively to all uninsured patients with bills dating back to January 1, 1999.

the provider will have to write off the visit as bad debt.[675] In addition, some providers require self-pay patients to give both their driver's license and Social Security numbers to ensure they are more readily pursuable should collection become an issue.[676]

Commercial ACOs

Since the advent of the MSSP, commercial insurers have been experimenting with commercial ACOs. In contrast to federal ACOs, which contract with CMS through the MSSP, commercial ACOs assume risk and realize financial incentives by means of contractual ACO arrangements made with private payors. Similar to the Federal market, Commercial ACOs accept the accountability and responsibility for the health outcomes and cost containment of an established patient population by offering coordinated, high quality care.[677] In the absence of the type of regulatory guidelines imposed on Federal ACOs, Commercial ACOs may develop any number of operational and governance structures depending on the nature and terms of the contract negotiated with the chosen private payor, as well as the resources available to the ACO based on its scale. Although Commercial ACOs and Federal ACOs share a common policy goal, i.e., higher quality of care at lower costs, these commercial ACOs generally contract with private payors utilizing one of three payment arrangements:

(1) *Shared Savings Arrangements*, in which the ACO is reimbursed under a fee-for-service model, and, at the end of the year, any savings generated by the ACO are shared between the payor and ACO, based upon the ACO's quality performance;
(2) *Global Budget Arrangements*, in which the ACO has a predetermined global budget for their assigned patient population, which is reconciled at the end of the year, and where the ACO is awarded bonuses above their global budget for achieving quality benchmarks; or
(3) *Capitated Arrangements*, in which the ACO are paid a set amount per assigned ACO patient, and where a portion of this capitated payment is withheld until the end of the year and then returned to the ACO if the ACO meets certain quality benchmarks.[678]

The most common form of commercial ACO arrangement is the *shared savings* model, and the majority of commercial ACOs have some form of downside risk associated with their commercial contracts, unlike the *one-sided risk model* of the MSSP described above.[679]

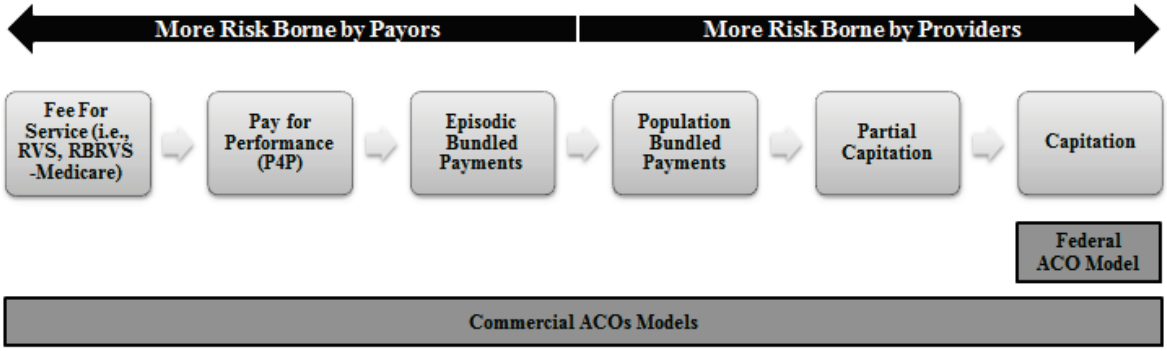
METHODS OF REIMBURSEMENT

Insurers use a variety of methodologies to negotiate and calculate reimbursement for their contracted healthcare providers. The most commonly utilized reimbursement methods for both primary and specialty care physicians are risk-based reimbursement methods like *capitation* or

675 "Pay Up, Self-Payor: Getting the Most From Patients Who Pay Out-of-Pocket" By Suz Redfearn, PhysicianPractice.com, March/April 2002, http://www.physicianspractice.com/index/fuseaction/articles.details/articleID/293.htm (Accessed 7/31/09).
676 "Pay Up, Self-Payor: Getting the Most From Patients Who Pay Out-of-Pocket" By Suz Redfearn, PhysicianPractice.com, March/April 2002, http://www.physicianspractice.com/index/fuseaction/articles.details/articleID/293.htm (Accessed 7/31/09).
677 "ACO Results: What We Know So Far" by Matthew Petersen and David Muhlestein, Health Affairs, May 30, 2014, http://healthaffairs.org/blog/2014/05/30/aco-results-what-we-know-so-far/ (Accessed 3/3/2015).
678 "ACO Contracting with Private and Public Payers: A Baseline Comparative Analysis" By Valerie A. Lewis, et al., American Journal of Managed Care, Vol. 20, No. 12 (December 2014), p. 1009.
679 Ibid, p. 1010.

FFS.[680] Figure 2-4: Methods of Reimbursement, below, displays the various options for reimbursement in the U.S. Healthcare system.

Figure 2-4: Methods of Reimbursement



Capitation

In order to reduce healthcare service utilization, insurers have passed some of their risk to providers in the form of *capitation*.[681] *Capitation* is a pre-paid reimbursement method that pays a provider a set price for providing medical services to a defined population for a defined set of services, regardless of service utilization.[682] Providers must manage the financial risk of providing adequate care by calculating the expected volume of referrals, the average cost, and their ability to control utilization.[683] Capitated payments are often based on actuarial or historical data that may help to determine an appropriate and acceptable amount of risk to the organization.[684]

Capitated contracts allow providers to budget for expected medical costs while accepting both the financial risk and potential rewards, and they provide providers with financial incentives that encourage them to become more active participants in controlling (and accepting responsibility for) utilization.[685]

Full Risk Capitation

Full risk *capitation* occurs when a healthcare plan, facility, or provider accepts the entire financial risk for a plan's members.[686] However, due to the significant risk involved, any medical

680 "The Managed Health Care Handbook" By Peter R. Kongstvedt, Third Edition, Gaithersburg, MD: Aspen Publishers, Inc., 1996, p. 120.
681 "A Guide to Consulting Services for Emerging Healthcare Organizations" By Robert J. Cimasi, New York, NY: John Wiley & Sons, Inc., 1999, p. 11, 16.
682 "Overview of Alternative Payment Models" Massachusetts Medical Society, Department of Health Policy and Health Systems, March 2009, http://www.massmed.org/advocacy/key-issues/health-care-reform/mms-overview-of-alternative-payment-models-(pdf)/ (Accessed 2/13/15) p. 1.
683 "The Complete Capitation Handbook: How to Design and Implement At-Risk Contracts for Behavioral Healthcare" By Gayle L. Zieman, Tiburon, CA: CentraLink Publications, 1995, p. 30, 294.
684 "Capitation Models" Health Care Incentives Improvement Institute, 2012, http://www.hci3.org/content/capitation-models (Accessed 2/17/15).
685 "Overview of Alternative Payment Models" Massachusetts Medical Society, Department of Health Policy and Health Systems, March 2009, http://www.massmed.org/advocacy/key-issues/health-care-reform/mms-overview-of-alternative-payment-models-(pdf)/ (Accessed 2/13/15), p. 2.
686 Ibid.

group undertaking full risk *capitation* must have strong financial management skills and management information systems.[687] In absence of such safeguards, many insurers will refuse such arrangements in order to avoid the risk of failure.[688] Usually, large groups or an organized system of providers are best suited to support full risk *capitation*.[689]

Blended Capitation

Blended capitation is a payment method that combines per-member-per-month rates and FFS remuneration to pay for physician services as a way to counterbalance the faults identified with a purely capitated or a purely FFS payment system. In the healthcare context, the FFS payment method encourages providers to see many patients and perform difficult and unpleasant procedures.[690] However, a purely FFS system does not provide the physician with an incentive to reduce costs associated with his or her practice style, nor does it encourage cooperation among physicians.[691] Similarly, *capitation* rewards provider activities that strive for high clinical quality and customer service.[692] However, without adjustments, a purely capitated form of remuneration may lead a physician to withhold preventative services, narrow his or her scope of practice, and refuse to treat patients that are in need of a greater amount of care due to the fear of financial burden.[693] Therefore, organizations may utilize a blended system that combines elements of both *capitation* and FFS payments, in order to address the weaknesses of a given payment method.[694] Furthermore, a blended system can be organized such that the payments incentivize providers to achieve specific policy targets, such as promoting preventative services while controlling overall healthcare costs.[695]

Fee-for-Service (FFS)

Fee-for-service (FFS) health coverage occurs when healthcare providers receive separate compensation for each service they provide (for example, an office visit, procedure, etc.).[696] Critics condemn FFS systems, stating that physicians tend to over-treat patients, up-code, and unbundle services in order to receive higher reimbursement.[697] Nonetheless, FFS systems are often used as an incentive for healthcare providers in markets where managed care penetration is low.[698]

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687 "The Capitation Sourcebook: A Practical Guide to Managing At-Risk Arrangements" By Peter Boland, Berkeley, CA: Boland Healthcare, Inc., 1996, p. 107.
688 "The Capitation Sourcebook: A Practical Guide to Managing At-Risk Arrangements" By Peter Boland, Berkeley, CA: Boland Healthcare, Inc., 1996, p. 107.
689 Ibid.
690 "Amid Tough Times With Capitation, Doctors Struggle To Balance Risk" By Phyllis Maguire, American College of Physicians-American Society of Internal Medicine, May 2000, http://www.acpinternist.org/archives/2000/05/capitation.htm (Accessed 7/31/09); "Blended Payment Methods in Physician Organizations Under Managed Care" By James C. Robinson, The Journal of the American Medical Association, Vol. 282, No. 13 (October 6, 1999), p. 1259.
691 "Blended Payment Methods in Physician Organizations Under Managed Care" By James C. Robinson, The Journal of the American Medical Association, Vol. 282, No. 13 (October 6, 1999), p. 1262.
692 Ibid, p. 1259.
693 Ibid, p. 1262.
694 "Overview of Alternative Payment Models" Massachusetts Medical Society, Department of Health Policy and Health Systems, March 2009, http://www.massmed.org/advocacy/key-issues/health-care-reform/mms-overview-of-alternative-payment-models-(pdf)/ (Accessed 2/14/15), p. 1.
695 Ibid.
696 "Insurance Programs: Glossary" U.S. Office of Personnel Management, http://www.opm.gov/insure/glossary/index.asp (Accessed 10/05/09).
697 "The Managed Health Care Handbook" By Peter R. Kongstvedt, Third Edition, Gaithersburg, MD: Aspens Publishers, Inc., 1996, p. 139, 143.
698 Ibid.

Insurers can sometimes negotiate discounts with providers, based either directly on charges or based on volume:

(1) **Straight discount on charges**. Discounting a specific amount off the reimbursement rate for every procedure code.
(2) **Discount based on volume or a sliding scale**. The degree of discount is based upon a pre-agreed set of procedural volume ranges. For example, if the provider performs five or less of a specific procedure per month, he or she earns a 10 percent discount. However, should the provider perform six to ten procedures per month, he or she earns a 15 percent discount. Many plans combine a discount arrangement with a fee maximum. The fee maximum is a fee schedule; the plan pays the lesser of the discounted charges or the fee maximum.[699]

Pay for Performance (P4P)

Pay for performance (*P4P*) is a method of reimbursement in which part of the payment is dependent upon the quality of services delivered.[700] Common elements of all *P4P* systems include a set of targets or objectives that define what will be evaluated, measures and performance standards for establishing specific physician target criteria, and rewards for meeting those criteria.[701] Generally, these payment systems also include a portion of the payment that is independent of any quality metrics.[702] Examples of *P4P* programs include Medicare's Value Based Purchasing Programs,[703] as set forth in the Value Based Purchasing Programs section above.

Specialty Care Reimbursement

The most commonly utilized reimbursement methods for specialty care physicians (SCPs) are risk-based models: FFS and *capitation*.[704] However, SCPs are reimbursed by way of additional methods including: (1) relative value scales or fee allowance schedules, (2) performance-based FFS, (3) retainers, (4) hourly and salary wages, (5) single fees, (6) bundled case rates or package pricing plans, (7) DRGs, and (8) periodic interim payments and cash advances.[705]

Payment Bundling

Bundling is a method of reimbursement that combines institutional and professional charges into a single payment.[706] A bundled payment or episode-based payment occurs when payments for multiple related procedures or diagnoses are combined to reimburse for the entirety of one

699 "The Managed Health Care Handbook" By Peter R. Kongstvedt, Third Edition, Gaithersburg, MD: Aspens Publishers, Inc., 1996, p. 207-208.
700 "Pay-for-Performance in Health Care" By Jim Hahn, CRS Report for Congress, December 12, 2006, http://www.allhealth.org/briefingmaterials/crsreportingforcongress-pay-for-performanceinhealthcare-501.pdf (Accessed 2/23/15), p. i.
701 Ibid.
702 Ibid.
703 "Linking Quality to Payment" Centers for Medicare & Medicaid Services, http://www.medicare.gov/hospitalcompare/linking-quality-to-payment.html (Accessed 2/23/15).
704 "The Managed Health Care Handbook" By Peter R. Kongstvedt, Third Edition, Gaithersburg, MD: Aspens Publishers, Inc., 1996, p. 181.
705 Ibid, p. 179-187.
706 "The Managed Health Care Handbook" By Peter R. Kongstvedt, Third Edition, Gaithersburg, MD: Aspens Publishers, Inc., 1996, p. 187.

episode of care.[707] During the healthcare reform debate, several proposals were advanced by legislators to reduce Medicare costs by various methods of bundling payments to hospitals and physicians for services provided over the course of a patient's treatment plan. The trend was validated by the United States Senate Finance Committee's *Proposals to Improve Patient Care and Reduce Health Care Costs*, whereby it released a plan to use the bundling of payments for inpatient and post-discharge care to save $16 billion.[708] Further, CMS has also created a pilot program to examine the benefits of bundling Part A and Part B Medicare payments.[709]

The Senate Finance Committee proposed to bundle payments for acute inpatient care and post-acute care occurring or initiating up to thirty days following a patient's discharge, including home health, skilled nursing, rehabilitation, and long-term hospital services. This bundled payment included the inpatient Medicare Severity Diagnosis-Related Group (MS-DRG) amount plus post-acute care costs for the treatment of patients in that MS-DRG, including any expected or planned readmissions within the thirty-day window. Although the hospital would receive the bundled payment even if no post-discharge care was given, the bundled amount will have already been adjusted to "capture savings from the expected efficiencies gained from improving patient care and provider coordination within the bundled payment system."[710] Further, Medicare is establishing DRG bundling for certain services, whereby if two or more procedures are inextricably linked, then reimbursement cannot be claimed for each procedure separately, but rather for one episode of care.[711]

Proponents of bundled payments assert that the move toward bundled payments could provide higher coordination between providers and more efficient levels of care.[712] However, critics articulate concern regarding the level of savings and patient care improvement that a blanket bundling of payments will actually generate. For example, the AMA expressed concern that such bundling proposals could result in the withholding or limiting of appropriate post-discharge or inpatient services.[713] The AMA also called for the appropriate distribution of the payments to individual providers, risk-adjustment for patients whose care exceeds the amount accounted for in the bundled payment, and safeguards to ensure that patient care decisions remain in the hands of the individual providers.[714] Similarly, in a letter to the Senate Finance Committee, the American Hospital Association stated that the administration's approach to bundling payments was "problematic" and would require a "paradigm shift in health service delivery" resulting in the revision or withdrawal of numerous regulations promulgated to manage the current

707 "Accountable Care Organizations: Value Metrics and Capital Formation" By Robert James Cimasi, Taylor & Francis Group, Boca Raton: FL, 2013, p. 90.

708 "President Obama's Budget Request Includes $828B for HHS" Kaisernetwork.org., May 8, 2009. http://www.kaisernetwork.org/daily_reports/print_report.cfm?DR_ID=58379&dr_cat=3 (Accessed 5/14/09).

709 "Acute Care Episode Demonstration Fact Sheet" Centers for Medicare & Medicaid Services, March 20, 2009, http://www.cms.hhs.gov/DemoProjectsEvalRpts/downloads/ACEFactSheet.pdf (Accessed 06/01/09).

710 "Transforming the Health Care Delivery System: Proposals to Improve Patient Care and Reduce Health Care Costs" By the Senate Finance Committee, April 29, 2009, http://www.abanet.org/health/04_government_sub/media/Transforming_the_Health_Care_Delivery_System.pdf (Accessed 05/24/10), p. 15.

711 "End Stage Renal Disease Drugs: Facility Acquisition Costs and Future Medicare Payment Concerns," Statement by Daniel R. Levinson, the HHS Office of Inspector General, September 2010, p. i-iv.

712 "Effects of Bundled Payment Policy Options" RAND, 2009, http://www.randcompare.org/analysis/mechanism/bundled_payment (Accessed 11/12/09).

713 "Reforming Medicare's Physician Payment System" By Nancy H. Nielsen, Statement of the American Medical Association to the Committee on Ways and Means, September 11, 2008, p. 6.

714 "Reforming Medicare's Physician Payment System" By Nancy H. Nielsen, Statement of the American Medical Association to the Committee on Ways and Means, September 11, 2008, p. 6.

healthcare delivery and payment system.[715] Finally, the Association of American Medical Colleges, which supports the concept of care coordination provided through bundling, criticized Medicare's ACE program for not ensuring that payments are made directly to all parties (that is, physicians) who provide the services.[716]

While many expressed their concerns, on August 23, 2011, pursuant to the ACA mandate, CMS announced the *Bundled Payments for Care Improvement Initiative* (*Bundled Payments Initiative*); which included four approaches to the payment model consisting of three retrospective payment system models that set a target cost for an established episode of care and one single prospective payment model for all services during a patient's single inpatient stay.[717] The table below compares the specific features of the 4 models to each other.

Table *2*-10: Key Features of Bundled Payment Models Compared[718]

Model Feature	Model 1	Model 2	Model 3	Model 4
	Inpatient Stay Only	Inpatient Stay plus Post-Discharge Services	Post-Discharge Services Only	Inpatient Stay Only
Eligible Awardees	Physician group practices; Acute care hospitals paid under the IPPS; Health systems	Physician group practices; Acute care hospitals paid under the IPPS; Health systems	Physician group practices; Acute care hospitals paid under the IPPS; Health systems	Physician group practices; Acute care hospitals paid under the IPPS; Health systems; Physician-hospital organizations; and Conveners of participating health care providers
	Physician-hospital organizations; and Conveners of participating health care providers	Physician-hospital organizations; Post-acute providers; and Conveners of participating health care providers	Long-term care hospitals	
			Inpatient rehabilitation facilities; Skilled nursing facilities	
			Home health agency; Physician-owned hospital organizations; and Conveners of participating healthcare providers	
Payment of Bundle and Target Price	Discounted IPPS payment; no separate target price	Retrospective comparison of target price and actual FFS payment	Retrospective comparison of target price and actual FFS payment	Prospectively set payment
Clinical Conditions Targeted	All MS-DRGs	Applicants to propose based on MS-DRG for inpatient hospital stay	Applicants to propose based on MS-DRG for inpatient hospital stay	Applicants to propose based on MS-DRG for inpatient hospital stay

715 "Statement of the American Hospital Association to the Senate Finance Committee" American Hospital Association, Roundtable on Health Care Delivery System Reform: Washington, DC, April 21, 2009.

716 "Transforming the Health Care Delivery System: Proposals to Improve Patient Care and Reduce Health Care Costs" By the Senate Finance Committee, April 29, 2009, http://www.abanet.org/health/04_government_sub/media/Transforming_the_Health_Care_Delivery_System.pdf (Accessed 5/24/10), p. 5.

717 "Bundled Payments for Care Improvement Initiative" Centers for Medicare & Medicaid Services, August 23, 2011, http://www.innovations.cms.gov/areas-of-focus/patient-care-models/bundled-payments-for-care-improvement.html (Accessed 2/20/2015).

718 Ibid, p. 5-6.

Model Feature	Model 1	Model 2	Model 3	Model 4
	Inpatient Stay Only	Inpatient Stay plus Post-Discharge Services	Post-Discharge Services Only	Inpatient Stay Only
Types of Services Included in Bundle	Inpatient hospital services	Inpatient hospital and physician services; Related post-acute care services; Related readmissions; and Other services defined in the bundle	Post-acute care services; Related readmissions; and Other services defined in the bundle	Inpatient hospital and physician services; and Related admissions
Expected Discount Provided to Medicare	To be proposed by applicant CMS requires minimum discounts increasing from 0% in first 6 mos. to 2% in Year 3	To be proposed by applicant; CMS requires minimum discount of 3% for 30-89 days post-discharge episode; 2% for 90 days or longer episode	To be proposed by applicant	To be proposed by applicant; subject to minimum discount of 3%; larger discount for MS-DRGs in ACE Demonstration
Payment from CMS to Providers	Acute care hospital: IPPS payment less pre-determined discount; and, Physician: Traditional fee schedule payment (not included in episode or subject to discount)	Traditional fee-for-service payment to all providers and suppliers, subject to reconciliation with predetermined target price	Traditional fee-for-service payment to all providers and suppliers, subject to reconciliation with predetermined target price	Prospectively established and bundled payment to admitting hospital; hospitals distribute payments from bundled payment
Quality Measures	All Hospital IQR measures and additional measures to be proposed by applicants	To be proposed by applicants, but CMS will ultimately establish a standardized set of measures that will be aligned to the greatest extent possible with measures in other CMS programs		

All four of these models were designed to incentivize care coordination and the reduction of costs while, at the same time, using a patient centered approach to provide the patient with high quality care.

PAYOR MIX AND THE EFFECT ON THE REVENUE CYCLE

It is important to realize that a healthcare provider's payor mix can have a profound impact on their practice's financial performance. Today, many providers are reimbursed for treating patients through an array of payment sources using a variety of payment methods, FFS, *capitation*, and self-pay, all of which can affect financial performance.[719]

When determining the appropriate payor mix to ensure financial viability, providers must be aware that it is not uncommon for Medicare, Medicaid, and major health plans to reimburse at levels that are less than the full or average cost of providing the services.[720] In addition, providers must take into account the discounts they offer on billed charges to health plans and the uninsured, and they should consider the likelihood that they may not collect a large portion of the charges billed to the uninsured patients they treat.[721] Thus, to remain viable, a provider may need to offset the losses incurred on these patients by increasing the prices charged to other patients, specifically marketing their services to attract payors that traditionally reimburse at a more

719 "Basics of Financial Management for the Medical Practice" By Marcel Frenkel, Phoenix, MD: Greenbranch Publishing, 2003, p. 24.
720 "Essentials of Heath Care Finance" By William O. Cleverley and Andrew E. Cameron, 6th Edition, Sudbury, MA: Jones and Bartlett Publishers, Inc., 2007, p. 106.
721 "Essentials of Heath Care Finance" By William O. Cleverley and Andrew E. Cameron, 6th Edition, Sudbury, MA: Jones and Bartlett Publishers, Inc., 2007, p. 106.

favorable level, or limiting the number of patients they will accept from lower reimbursing payors.

In addition to having an appropriate payor mix, financial viability also may depend on a provider's mix of payment methods; having too many or too few of one type of method may negatively affect a practice's revenue. When providers are reimbursed on an FFS basis, practice revenues increase as patient visits and the intensity of the services provided increase.[722] However, under a *capitation* payment method a provider's profits are higher if its patients require minimal medical services and have few, if any, chronic conditions.[723] The provider's mix of self-pay and uninsured patients and their effect on a provider's practice is dependent on the patients' abilities to pay their bills and the effort expended by the practice to collect the payments. If a majority of the self-pay and uninsured patients are affluent and have no trouble paying their bills at the time of service, a provider's revenue may increase, as they can avoid the billing and collection process altogether. However, if these patients are not affluent or have trouble paying their bills, it is likely that the practice's revenue will decrease because it may now have to make multiple attempts to receive payment through the billing and collection process or write off the debt altogether. A provider's awareness of his or her practice's reimbursement mix and its effect on financial performance may help ensure financial viability by providing useful insight when considering new contracts, renegotiating existing contracts, or dropping less lucrative contracts.[724]

EMERGING REIMBURSEMENT TRENDS

The ACA includes many provisions that aim to utilize financial incentives and policies to address the *triple aim* of healthcare.[725] Federal policy debates, e.g., disallowing tax rebates for health plans bought on the federal health insurance exchange and the repeal of the SGR, also have the potential to change the way reimbursement is provided and impacts provider compensation. Many of these reimbursement initiatives share the common trend of shifting away from traditional FFS models.

HEALTHCARE REFORM EFFORTS

Although healthcare reform has been a recurring policy theme throughout the past few decades, reform efforts took center stage with the 2008 presidential election, the subsequent leadership under the Obama administration, and the passage of the Affordable Care Act in 2010. Twenty-first century reform efforts share many common themes, all aimed at combating the problems of uninsured individuals and the rising cost of services.[726]

722 "Basics of Financial Management for the Medical Practice" By Marcel Frenkel, Phoenix, MD: Greenbranch Publishing, 2003, p. 24.
723 Ibid.
724 Ibid.
725 "The IHI Triple Aim" Institute for Healthcare Improvement, 2015, http://www.ihi.org/Engage/Initiatives/TripleAim/pages/default.aspx (Accessed 2/25/15).
726 "Comparing the Three Main Health Reform Bills" By John Commins and Janice Simmons, Health Leaders Media, August 4, 2009, http://www.healthleadersmedia.com/content/236931/topic/WS_HLM2_LED/Comparing-the-Three-Main-Health-Reform-Bills.html (Accessed 8/06/09).

Many common elements to the reform proposals exist. Among these elements are:

(1) The creation of standardized health insurance benefits packages;
(2) Reforms of state insurance markets for small and nongroup health insurance;
(3) Limits on an insurer's ability to charge higher premiums based on health status, gender, and other factors;
(4) The elimination of insurance coverage denials due to pre-existing conditions;
(5) Prohibitions on cost sharing for preventative treatments;
(6) Credits to make premiums affordable;
(7) Limits on out-of-pocket expenses;
(8) Coverage of preventative services;
(9) The promotion of quality healthcare by the use of provider incentives;
(10) The elimination of lifetime and annual limits on dollar value for individual and group policies; and
(11) Requirements that employers must either provide health insurance for their employees or contribute to a fund on their behalf.[727]

A significant amount of reform rhetoric was defined by proposals of a public insurance option and a healthcare exchange that would provide consumers with a choice between private insurance and the government-run plan.[728] Another plan proposed to include the possibility of creating a nonprofit consumer owned and operated health insurance plan instead of a public option.[729] While both the public option and the nonprofit consumer owned health insurance organization did not make the final draft of the legislation in 2010, the Affordable Care Act did include provisions to penalize individuals who fail to obtain health insurance coverage and to provide subsidies for the purchase of health insurance with tax credits.[730] Additionally, the Affordable Care Act also utilized cost controlling mechanisms including ACOs, bundling provider payments for acute and post-acute care, and establishing mechanisms to simplify paperwork.[731]

MOVE FROM FEE FOR SERVICE

The current trend toward value based reimbursement, discussed in the Value Based Purchasing Programs section above, and pay for performance measures, discussed in the Increased Emphasis on Quality: Pay-for-Performance (P4P) section below, are not new developments. Originally viewed as a cost saving alternative to FFS arrangements, many *capitation* contracts actually have been replaced by FFS arrangements because the risk can be difficult for physicians to manage

727 Ibid.
728 Ibid.
729 "Side-by-Side Analysis of Key Provisions of the Senate HELP Bill, H.R. 3200, and the Senate Finance Draft Proposal" Rand Corporation, randcompare.org, July 17, 2009, http://www.randcompare.org/downloads/hot/07/SidebySide_071709.pdf (Accessed 8/6/09).
730 "America's Affordable Health Choices Act: Quality Affordable Health Care" House Committees on Ways and Means, Energy and Commerce, and Education and Labor, July 14, 2009, http://edlabor.house.gov/documents/111/pdf/publications/AAHCA-BILLSUMMARY-071409.pdf (Accessed 8/06/09); "Comparing the Three Main Health Reform Bills" By John Commins and Janice Simmons, Health Leaders Media, August 04, 2009, http://www.healthleadersmedia.com/content/236931/topic/WS_HLM2_LED/Comparing-the-Three-Main-Health-Reform-Bills.html (Accessed 8/06/09); "Side-by-Side Analysis of Key Provisions of the Senate HELP Bill, H.R. 3200, and the Senate Finance Draft Proposal" By Rand Corporation, randcompare.org, July 17, 2009, http://www.randcompare.org/downloads/hot/07/SidebySide_071709.pdf (Accessed 8/6/09).
731 "Patient Protection and Affordable Care Act: Pub. L. No 111-148, §§ 1561, 3022, 3023, 124 Stat. 119, 262, 395, 399 (March 23, 2010).

without the requisite economic and actuarial skills.[732] A study released by the Center for Studying Health System Change, shows that the shift from FFS remuneration toward *capitation* as a method of physician reimbursement has waned from the mid-1990s.[733] According to the data, the number of physicians accepting capitated payments fell 9.5 percent, from 54.2 percent in 1996-97, to 44.7 percent in 2004-05.[734]

However, in 2008, the pendulum began to swing back to greater utilization of *capitation*. The resurgence was led, at least in part, by BCBS of Massachusetts and its *Alternative Quality Contract* (AQC).[735] Unlike previous generation *capitation* plans designed by insurance companies to place the risk on providers while offering little or no rewards for improved quality of care, the AQC offered providers the opportunity to earn substantial rewards for quality.[736] The new contract reimbursed providers on a per-member-per-month basis, with increases yearly for inflation, combined with incentive payments for meeting national standards in quality, effectiveness, and patient experience.[737]

In addition, in 2008 the Massachusetts state legislature established the Special Commission on the Health Care Payment System to recommend improvements to the state's current payment system that would "motivate and reward effective, efficient, and patient centered care."[738] The commission concluded that the state should transition to a global payment model used by all payors, including the state and federal government, within five years.[739] The commission recommended that the payment model include, in addition to other features, accountable care organizations (ACOs),[740] consisting of hospitals, physicians or other clinicians, and non-clinicians, to manage and coordinate care to meet patient needs, patient-centered care, pay-for-performance (*P4P*) incentives, and financial risk sharing among ACOs and *carriers*.[741]

As a result of the ACA, many of the reimbursement models that shift risk to the providers in exchange for potential financial gains may be gaining traction, such as accountable care organizations (ACOs);[742] bundled payments;[743] and, value based reimbursement agreements.[744] Some commentators have suggested that the most recent trend toward reimbursement contracts

732 "Can the Massachusetts Blues Revive Capitation? New Twist Includes Quality Bonus" By Emily Berry, American Medical News, February 11, 2008, http://www.ama-assn.org/amednews/2008/02/11/bil10211.htm (Accessed 08/04/09).
733 "CTSonline Physician Survey Results" Center for Studying Health System Change, 2009, http://ctsonline.s-3.com/displaytable.asp?xtopic=18!4&xrow=4&xYrSel=&xpcp=&xother= (Accessed 08/09/09).
734 Ibid.
735 "Can the Massachusetts Blues Revive Capitation? New Twist Includes Quality Bonus" By Emily Berry, American Medical News, February 11, 2008, http://www.ama-assn.org/amednews/2008/02/11/bil10211.htm (Accessed 08/04/09).
736 Ibid.
737 "Alternative Quality Contract" BlueCross BlueShield Massachusetts, 2009, http://www.qualityaffordability.com/solutions/alternative-quality-contract.html (Accessed 08/04/09).
738 "Recommendations of the Special Commission on the Health Care Payment System" By Leslie A. Kirwan and Sarah Iselin, Division of Health Care Finance and Policy, July 16, 2009, http://www.mass.gov/Eeohhs2/docs/dhcfp/pc/Final_Report/Final_Report.pdf (Accessed 8/4/09), p. 5.
739 Ibid, p. 10.
740 "Can Accountable Care Organizations Improve the Value of Health Care by Solving the Cost and Quality Quandaries?" by Kelly Devers and Robert Berenson, Robert Wood Johnson Foundation, Urban Institute, October 2009, http://www.rwjf.org/files/research/acosummaryfinal.pdf (Accessed 1/19/2012), p. 1.
741 "Can Accountable Care Organizations Improve the Value of Health Care by Solving the Cost and Quality Quandaries?" by Kelly Devers and Robert Berenson, Robert Wood Johnson Foundation, Urban Institute, October 2009, http://www.rwjf.org/files/research/acosummaryfinal.pdf (Accessed 1/19/12), p. 1.
742 Discussed in the Medicare Shared Savings Program section and the Commercial ACOs section above.
743 Discussed in the Payment Bundling section above.
744 Discussed in the Value Based Purchasing Programs section above.

which more appropriately shift risk to providers, may persist, in contrast to the failures of many *capitation* plans in the past.[745]

INCREASED EMPHASIS ON QUALITY: PAY-FOR-PERFORMANCE (P4P)

In the wake of an ongoing national controversy with several recent studies finding that medical errors are a leading cause of death in the United States, demands have been waged by both private and public payors regarding the accountability of providers. After a 1999 study from the Institute of Medicine reported that as many as 44,000 – 98,000 deaths annually may be linked directly to medical errors, increased focus has been placed on paying physicians based on the quality of their services, as a way of improving quality and lowering costs.[746] However, since there has never been an actual count of how many patients experience preventable harm, there is no way to know for sure whether or not the 98,000 number is accurate or not. More recent studies have claimed that the deaths linked to medical errors ranges between 210,000 and 440,000 patients annually.[747]

> A 1999 study from the Institute of Medicine (IOM) reported that as many as 44,000–98,000 deaths annually may be linked directly to medical errors. More recent studies suggest this number is much closer to 210,000 and 440,000 patients annually.
>
> ***Linda T. Kohn, Janet M. Corrigan and Molla S. Donaldson, 2000; John T. James, September 2013.***

Pay-for-performance (*P4P*) is a remuneration system in which part of the payment is dependent on performance as measured against a defined set of criteria.[748] Although a *P4P* system can be structured in several ways, the common elements to all systems are (1) a set of targets or objectives that define what will be evaluated; (2) measures and performance standards for establishing the target criteria; and (3) rewards, typically financial incentives, that are at risk, including the amount and the method for allocating the payments among those who meet or exceed the reward threshold.[749] Proponents of *P4P* remuneration systems argue that they have the potential to improve the quality of care and slow the growth in healthcare costs through improvements in quality and provider efficiency.[750]

745 "The Return of Capitation: Preparing for Population-Based Health Care" By Jonathan W. Pearce, Healthcare Financial Management Association, July 2, 2012, http://www.hfma.org/Content.aspx?id=3234 (Accessed 3/3/2015).
746 "Pay-for-Performance in Health Care" By Jim Hahn, CRS Report for Congress, Washington, DC: Congressional Research Service, November 2, 2006, p. CRS-1; "To Err is Human: Building a Safer Health System" By Linda T. Kohn, Janet M. Corrigan and Molla S. Donaldson, Washington, DC: National Academy Press, 2003, p. 26.
747 "A New, Evidence-Based Estimate of Patient Harms Associated with Hospital Care" By John T. James, Journal of Patient Safety, Vol. 9, No. 3 (September 2013) p. 122-128.
748 "Pay-for-Performance: New payment systems reward doctors and hospitals for improving the quality of care, but studies to date show mixed results" Robert Wood Johnson Foundation, Health Affairs, Health Policy Brief, October 11, 2012, http://healthaffairs.org/healthpolicybriefs/brief_pdfs/healthpolicybrief_78.pdf (Accessed 3/3/2015), p. 1.
749 "Pay-for-Performance in Health Care" By Jim Hahn, CRS Report for Congress, Washington, DC: Congressional Research Service, November 2, 2006, p. CRS-4.
750 Ibid., p. CRS-1, 13.

P4P's Impact on Provider Revenue

The impact of *P4P* on quality outcomes has been measured in multiple studies but has had varying results. While some studies have demonstrated that *P4P* reduced costs and improved quality, other studies have had different results and conclusions.

Some studies have indicated that *P4P* has had a significant impact on controlling hospital costs. A 2008 report of a study conducted by CMS and Premier, Inc., measured cost and quality improvements among *P4P* providers for five different patient populations and determined that the median hospital cost per patient declined over $1,000.[751] The study concluded that "if all hospitals nationally were to achieve the three-year cost and mortality improvements found among the [study] project participants for [the five different patient populations], they could save an estimated 70,000 lives per year and reduce hospital costs by more than $4.5 billion annually."[752] However, this study did not compare any findings to a control group of hospitals not utilizing the *P4P* guidelines, which limited its ability to assess any trends for casual conclusions.[753] A review of the literature on *P4P* programs determined that "…P4P has the potential to be cost-effective, but that convincing evidence is lacking."[754]

Contrary to the CMS and Premier study above, multiple other studies have found that *P4P* has no significant or very minimal impact on improving revenue. Specifically, a 2009 report documented a study that reviewed CMS records in a hospital demonstration project to assess whether *P4P* had a significant impact on cost changes from the Medicare perspective. While it found that there was no evidence to show that *P4P* had a significant effect, the study did not include all payments associated with hospitalization, but instead only examined inpatient costs on a few conditions for the first 60 days after hospitalization.[755] Notably, in a more recent study published in 2012, investigators were able to demonstrate that *P4P* had only a minimal impact on hospital financials and payments to providers.[756] Additionally, another 2012 study released through the Harvard School of Public Health found that there was little evidence to show that participation in *P4P* has meaningfully improved patient outcomes and could not demonstrate any significant difference in the mortality trends of those conditions with outcomes linked to payment incentives and those conditions without outcomes linked to payment incentives.[757]

Efficacy and revenue are not the only concern providers have when it comes to transitioning between a FFS and *P4P* payment system. Specifically, providers are worried that the transition could have a profound impact on their practice's incurred costs. Providers may have to undertake the time consuming process of hand collecting and reviewing the data needed to satisfy reporting

751 "Hospital Quality Improving, Cost, Mortality Rate Trends Declining for Participants in Medicare Pay-For-Performance Project" Premier Inc., Press Release (January 31, 2008), http://premierinc.com/about/news/08-jan/performance-pays-2.jsp (Accessed 04/25/08).
752 Ibid.
753 "The Impact of Hospital pay-for-Performance on Hospital and Medicare Costs" By Gregory B. Kruse, Daniel Polsky, et al., HSR: Health Services Research, Vol. 47, No. 6 (December 2012), p. 2120.
754 "Effects of pay for performance in health care: A systematic review of systematic reviews" by Frank Eijkenaar et al., Health Policy, Vol. 110 (January 2013), p. 115-130.
755 "Effects of the Premier Hospital Quality Incentive Demonstration on Medicare Patient Mortality Cost" By A. M. Ryan, HSR: Health Services Research, Vol. 44, No. 3 (2009), p. 821-42.
756 "The Impact of Hospital pay-for-Performance on Hospital and Medicare Costs" By Gregory B. Kruse, Daniel Polsky, Elizabeth A. Stuart, and Rachel M. Werner,, HSR: Health Services Research, Vol. 47, No. 6 (December 2012), p. 2120.
757 "The Long-Term Effect of Premier Pay for Performance on Patient Outcomes" By K. Jha Ashish, et al., New England Journal of Medicine (March 28, 2012), p. 9.

requirements or make a significant capital investment in an electronic health records system.[758] Regardless of the collection method used, the bonuses for achieving the requisite reporting standards may not be sufficient to offset the costs associated with the data collection process.[759] In addition, providers who practice in low-income minority communities may see their revenue fall, as it is likely that these providers will miss out on incentive pay because of lower quality scores due to their treating patients who may be less likely to obtain preventative care, follow treatment recommendations, and return for further investigation into abnormal test results than their wealthier counterparts.[760]

While some have used these studies and the rapid rise of healthcare costs to conclude that no impact on hospital financials suggests hospital quality-improvement investment decisions are paying off and that they are not negatively impacting costs and margins,[761] other providers are worried that the transition from a FFS payment system to a *P4P* model could have a profound impact on practice revenue. While these varying study results have not helped the efficacy concerns with *P4P* initiatives, the final assessment and widespread acceptance of the *P4P* model are still unknown.

INCREASED REIMBURSEMENT TO ENCOURAGE IMPLEMENTATION OF ELECTRONIC HEALTH RECORDS (EHR) THROUGH MEANINGFUL USE

With the passage of the *American Recovery and Reinvestment Act of 2009* (ARRA), the government adopted, as part of the overarching economic stimulus package, a stimulus plan to promote the universal implementation of electronic health records (EHR).[762] Through the *Health Information Technology for Economic and Clinical Health* (HITECH) *Act*, incorporated into the ARRA, providers are incentivized with increased reimbursement rates to implement EHR systems.[763] As part of this process, the HITECH Act officially established the Office of the National Coordinator for Health Information Technology (ONCHIT) and Health Information Technology (HIT) Policy and Standards Committees to recommend, develop, and promote a national HIT infrastructure.[764]

In particular, the HITECH Act permitted the secretary of HHS to appropriate funds each year, beginning 2009 through 2013, to promote the implementation of EHR.[765] Under the act, nonhospital-based physicians will receive financial incentives or penalties through Medicare and Medicaid for use or nonuse of EHRs. Originally, if a provider began the program in 2011, the

758 "Paying for Performance-Risks and Recommendations" By Elliot S. Fisher, The New England Journal of Medicine, Vol. 355, No. 18 (November 2, 2006), p. 1846.
759 Ibid.
760 "Will Pay-For-Performance And Quality Reporting Affect Health Care Disparities?" By Lawrence P. Casalino and Arthur Elster, Health Affairs 26, No. 3 (April 2007), http://content.healthaffairs.org/cgi/content/abstract/hlthaff.26.3.w405 (Accessed 5/25/10), p. 406-407.
761 "The Impact of Hospital pay-for-Performance on Hospital and Medicare Costs" By Gregory B. Kruse, Daniel Polsky, et al., HSR: Health Services Research, Vol. 47, No. 6 (December 2012), p. 2132.
762 "American Recovery and Reinvestment Act of 2009" Pub. L. No. 111-5, § 4101, 123 Stat. 115, 467 (February 17, 2009).
763 "American Recovery and Reinvestment Act of 2009" Pub. L. No. 111-5, § 13001, 123 Stat. 115, 226 (February 17, 2009).
764 "Health Information Technology for Economic and Clinical Health Act or HITECH Act" Committee on Ways and Means, January 16, 2009, http://waysandmeans.house.gov/media/pdf/110/hit2.pdf (Accessed 6/17/09); "Health Information Technology for Economic and Clinical Health Act or HITECH Act" Committee on Ways and Means, January 16, 2009, http://waysandmeans.house.gov/media/pdf /110/hit2.pdf (Accessed 6/17/09).
765 "American Recovery and Reinvestment Act of 2009" Pub. L. No. 111-5, § 3018, 123 Stat. 115, 258 (February 17, 2009).

provider would be eligible to receive incentive payments up to a maximum of $44,000 under Medicare over a five-year period, if *meaningful use* of an EHR system begins by 2012.[766] However, the Medicare amounts were adjusted by 2% in 2013 due to the sequestration order.[767] As a result, total payments under Medicare equaled $43,720 for having begun in 2011, $43,480 for having begun in 2012, $38,220 for having begun in 2013, and $23,520 for having begun in 2014.[768] In 2015, if practitioners do not adopt meaningful EHR use, they will receive a percentage reduction in their MPFS payment that increases yearly until 2019.[769] The table below displays the possible penalties and incentives for a provider under Medicare's *meaningful use* EHR program.

Table 2-11: Meaningful Use EHR Incentive Payments and Payment Reductions Under Medicare[770]

Year	Maximum Incentive Payment for Provider Using Meaningful Use EHR if Program Began in 2011	Maximum Incentive Payment for Provider Using Meaningful Use EHR if Program Began in 2012	Maximum Incentive Payment for Provider Using Meaningful Use EHR if Program Began in 2013	Maximum Incentive Payment for Provider Using Meaningful Use EHR if Program Began in 2014	Total MPFS Payment Reduction for Not Using Meaningful Use EHR
2011	$18,000	$0	$0	$0	0%
2012	$12,000	$18,000	$0	$0	0%
2013	$7,840	$11,760	$14,700	$0	0%
2014	$3,920	$7,840	$11,760	$11,760	0%
2015	$1,960	$3,920	$7,840	$7,840	1%
2016	$0	$1,960	$3,920	$3,920	2%
2017	$0	$0	$0	$0	3%
Beyond 2017	$0	$0	$0	$0	3% - 5%

Those who qualify for Medicaid payments are eligible for up to 6 years of payments, totaling $63,750, and may begin participation as late as 2016.[771] Additionally, those who are only eligible for the Medicaid program are not subject to payment adjustments resulting from the sequester order. If a provider qualifies for *meaningful use* reimbursement under both EHR incentive programs, the provider must choose to participate in one or the other, as they are not allowed to participate in both.[772] Additionally, hospitals will receive millions of dollars in increased reimbursement under Medicare and Medicaid for successfully implementing HIT and certified EHR systems.[773] Rural health clinics, federally qualified health centers, and other providers other

766 "Incentives and Beyond: Maximizing the Opportunities from Moving to Meaningful Use of HER" PNC, PNC Healthcare Whitepapers, https://content.pncmc.com/live/pnc/microsite/CFO/pdf/pnc_healthcare_whitepaper.pdf (Accessed 2/15/15); "American Recovery and Reinvestment Act of 2009" Pub. L. No. 111-5, § 4101(a), 123 Stat. 115, 467 (February 17, 2009).

767 "Medicare & Medicaid EHR Incentive Program Basics" by Centers for Medicare & Medicaid Services, 2015, http://www.cms.gov/Regulations-and- Guidance/Legislation/EHRIncentivePrograms/Basics.html (Accessed 2/15/15).

768 Ibid.

769 "Incentives and Beyond: Maximizing the Opportunities from Moving to Meaningful Use of HER" PNC, PNC Healthcare Whitepapers, https://content.pncmc.com/live/pnc/microsite/CFO/pdf/pnc_healthcare_whitepaper.pdf (Accessed 2/15/15).

770 "Medicare & Medicaid EHR Incentive Program Basics" Centers for Medicare & Medicaid Services, 2015, http://www.cms.gov/Regulations-and- Guidance/Legislation/EHRIncentivePrograms/Basics.html (Accessed 2/25/2015), p.1; "Incentives and Beyond: Maximizing the Opportunities from Moving to Meaningful Use of EHR" PNC Healthcare Whitepapers, https://content.pncmc.com/live/pnc/microsite/CFO/pdf/pnc_healthcare_whitepaper.pdf (Accessed 2/25/2015), p. 3.

771 "Medicare & Medicaid EHR Incentive Program Basics" Centers for Medicare & Medicaid Services, 2015, http://www.cms.gov/Regulations-and- Guidance/Legislation/EHRIncentivePrograms/Basics.html (Accessed 2/25/15).

772 "Medicare & Medicaid EHR Incentive Program Basics" Centers for Medicare & Medicaid Services, 2015, http://www.cms.gov/Regulations-and- Guidance/Legislation/EHRIncentivePrograms/Basics.html (Accessed 2/25/15).

773 "Health Information Technology for Economic and Clinical Health Act or HITECH Act" Committee on Ways and Means, January 16, 2009, http://waysandmeans.house.gov/media/pdf/110/hit2.pdf (Accessed 6/17/09).

than physicians and hospitals will be eligible for increased incentive funding under Medicaid or through grants offered for the implementation of EHR systems.[774]

Although the term "*meaningful use*" has yet to be defined, the ARRA specified three specific components that make up the context of *meaningful use*, including the use of a certified EHR in a meaningful manner, the electronic exchange of health information to improve quality of care, and the use of certified EHR technology to submit clinical quality and other measure.[775] HITECH's incentive program, which aims to gain meaningful and effective use from EHR systems, focuses on five specific goals including:

(1) Improving the quality, safety, and efficiency of care while reducing disparities;
(2) Engaging patients and families in their care;
(3) Promoting public and population health;
(4) Improving care coordination; and
(5) Promoting the privacy and security of patient information.[776]

In order to demonstrate *meaningful use*, a system must include a function for electronic prescribing, information exchanges between systems, qualitative reporting methods, and additional coding of the use of and the ability to complete survey responses in the system.[777]

Initially, CMS and the Office of the National Coordinator of Health Information Technology (ONC) published Stage 1 of the *meaningful use* requirement, consisting of two complimentary rules that enumerated: (1) the criteria for eligible hospitals and providers to meaningfully use health information technology[778] and (2) the certification criteria and standards for EHR technology.[779] In order to meet Stage 1 *meaningful use* standards, providers must meet at least 18 of 22 objectives, which include: (1) using e-prescriptions; (2) demographics record keeping; and (3) providing patients with an electronic copy of their health information.[780] On September 4, 2012, CMS released the Final Rule for Stage 2 of the *meaningful use* requirement of the Medicare and Medicaid EHR Incentive Program,[781] which stated that in order to continue receiving EMR incentive payments, providers who have met Stage 1 standards for two years must meet new Stage 2 standards in their third year.[782] These providers must meet a total of 20 Stage 2 objectives, which include similar objectives as Stage 1, but at increasingly difficult levels of compliance.[783] Preliminary requirements for Stage 3 *meaningful use* objectives were

774 Ibid.
775 "What is Meaningful Use?" Health Resources and Services Administration, U.S. Department of Health and Human Services, 2015, http://www.hrsa.gov/healthit/meaningfuluse/stage1clinicalquality/whatis.html (Accessed 2/25/15).
776 Ibid.
777 "American Recovery and Reinvestment Act of 2009" Pub. L. No. 111-5 (February 17, 2009), Section 4101(a)(2).
778 "Fact Sheets: CMS and ONC Final Regulations Define Meaningful Use and Set Standards for Electronic Health Record Incentive Program" Centers for Medicare & Medicaid Services, July 13, 2010, http://www.cms.gov/Newsroom/MediaReleaseDatabase/Fact-Sheets/2010-Fact-Sheets-Items/2010-07-13.html (Accessed 2/26/15).
779 "Establishment of the Temporary Certification Program for Health Information Technology" Federal Register Vol. 75, No. 121 (July 24, 2010), p. 36158.
780 "Eligible Professional Meaningful Use Table of Contents Core and Menu Set Objectives" EHR Incentive Program, http://www.cms.gov/Regulations-and-Guidance/Legislation/EHRIncentivePrograms/Downloads/EP-MU-TOC.pdf (Accessed 4/25/14); "Meaningful Use" Centers for Medicare & Medicaid Services, 4/15/2014, http://www.cms.gov/Regulations-and-Guidance/Legislation/EHRIncentivePrograms/Meaningful_Use.html (Accessed 4/25/14).
781 "Medicare and Medicaid Programs; Electronic Health Record Incentive Program-Stage 2" Federal Register, Vol. 77, No. 171 (September 4, 2012), p. 53968.
782 "Stage 2," Centers for Medicare & Medicaid Services, 4/11/2014, http://www.cms.gov/Regulations-and-Guidance/Legislation/EHRIncentivePrograms/Stage_2.html (Accessed 4/25/14).
783 "Stage 1 vs. Stage 2 Comparison Table for Eligible Professionals," EHR Incentive Program, August 2012, https://www.cms.gov/Regulations-and-Guidance/Legislation/EHRIncentivePrograms/Downloads/stage1vsStage2CompTablesforEP.pdf (Accessed 4/25/14).

later issued on March 11, 2014, the majority of which consisted of updates to the Stage 2 objectives.[784]

While HIT may enhance patient care and make the healthcare delivery system more efficient, there is a high cost associated with the technology necessary to meet these goals. As a result, reimbursement programs are considered necessary to help offset the expense of transitioning to new technology. Overall, a total of roughly $1.5 billion will go toward federal grants for the implementation of EHR systems and capital improvements of EHR systems.[785]

REIMBURSEMENT OF AESTHETIC AND RECONSTRUCTIVE PROCEDURES

As technological advances in recent years have increased the accessibility of plastic surgery, the number of many procedures has increased despite downswings in the economy. In 2013, there were 20.8 million plastic surgery procedures performed in the United States, up roughly 3 percent from the previous year.[786] Of these, 15.1 million were *cosmetic* procedures, divided between surgical (1.6 million) and minimally-invasive (13.4 million), while 5.7 million were *reconstructive* procedures.[787]

Despite this increased prevalence, however, reimbursement for elective *cosmetic* procedures has remained minimal. In the field of plastic surgery, the two types of procedures are treated differently by payors. *Aesthetic*, or *cosmetic*, procedures typically are performed at the election of the patient to reshape a normal part of the body to the patient's satisfaction and, since they normally are elective surgeries, they are not generally covered by health insurance plans.[788] By contrast, *reconstructive* procedures are necessary for the correction of physical disfigurement or function or to restore a normal appearance following trauma or disease.[789] Examples include skin grafts and the rebuilding of bones for burn and accident victims.[790] These procedures generally are covered by most health insurance policies, though specific coverage may vary by procedure, as well as the degree to which the procedures are covered.[791]

When procedures that typically are classified as *cosmetic* are medically necessary to correct a problem or relieve symptoms, insurance *carriers* may treat that procedure as *reconstructive* and

784 "Preliminary Stage 3 Meaningful Use Recommendations Released" By Chris Dimick, Journal of American Health Information Management Association, March 11, 2014, http://journal.ahima.org/2014/03/11/preliminary-stage-3-meaningful-use-recommendations-released/ (Accessed 12/8/14).
785 "Health Information Technology for Economic and Clinical Health Act or HITECH Act" Committee on Ways and Means, January 16, 2009, http://waysandmeans.house.gov/media/pdf/110/hit2.pdf (Accessed 6/17/09).
786 "2013 Plastic Surgery Statistics Report" The American Society of Plastic Surgeons, 2014, http://www.plasticsurgery.org/Documents/news-resources/statistics/2013-statistics/plastic-surgery-statistics-full-report-2013.pdf (Accessed 2/20/15), p. 5.
787 Ibid.
788 "Insurance Coverage: A Patient's Guide: Staying Informed About Your Healthcare Costs" American Society of Plastic Surgeons, 2009, http://www.plasticsurgery.org/Patients_and_Consumers/Planning_Your_Surgery/Insurance_Coverage_A_Patients_Guide.html (Accessed 9/28/09).
789 Ibid.
790 "Cosmetic and Reconstructive Surgery Procedures" Priority Health, September 1, 2007, http://www.priorityhealth.com/provider/manual/policies/91535.pdf (Accessed 10/05/09).
791 "Insurance Coverage: A Patient's Guide: Staying Informed About Your Healthcare Costs" American Society of Plastic Surgeons, 2009, http://www.plasticsurgery.org/Patients_and_Consumers/Planning_Your_Surgery/Insurance_Coverage_A_Patients_Guide.html (Accessed 9/28/09).

cover part or all of the cost of the surgery.[792]An example of this is a nasal surgery called rhinoplasty. Typically, nasal surgeries are *cosmetic* however, a rhinoplasty can be a *reconstructive* surgical procedure that changes the shape of the nose to correct a broad range of nasal defects and return an abnormal or damaged nasal structure to a more normal state.[793] In such cases, the payor will generally require verification of the true reason for the surgery (that is, whether it was truly *reconstructive* or merely *cosmetic*), as well as require that the physician obtain prior approval and then supply post-procedure documentation from which the payor can determine how much it will reimburse.[794]

Like most private payors, Medicare and Medicaid do not cover *cosmetic* procedures that are not medically necessary.[795]

CONCIERGE MEDICINE

Recent years have seen the emergence of the practice of concierge, or boutique, medicine. In terms of reimbursement, it is important to understand that boutique medicine is not a substitution for traditional insurance. Patients will typically keep their traditional health insurance to pay for any tests or scans ordered by their physician. Medicare beneficiaries cannot be charged more than 115 percent of the rate for services, and many politicians have said that the annual fees patients pay is a lot more than the Medicare rate and, thus, is illegal billing.[796]

MEDICAL HOME MODEL

The term "medical home" was coined in 1967 and originally was used by the American Academy of Pediatrics "to describe a single source of medical information about a patient."[797] The term evolved overtime and is now used to describe a patient centered model of healthcare delivery and payment reform, which focuses on improving the quality of care and reducing costs through its emphasis on the role of primary care.[798]

792 Ibid.

793 "ASPS Recommended Insurance Coverage Criteria for Third Party Payers: Nasal Surgery" American Society of Plastic Surgeons, http://www.plasticsurgery.org/Documents/medical-professionals/health-policy/insurance/Nasal-Surgery-Insurance-Coverage.pdf (Accessed 2/20/2015), p. 1.

794 "Insurance Coverage: A Patient's Guide" American Society of Plastic Surgeons, http://www.plasticsurgery.org/Patients_and_Consumers/Planning_Your_Surgery/Insurance_Coverage_A_Patients_Guide.html (Accessed 10/05/09).

795 "Medicare and You 2009" Centers for Medicare & Medicaid Services, 2009, http://www.medicare.gov/Publications/Pubs/pdf/10050.pdf (Accessed 10/05/09).; "Reconstructive and Cosmetic Surgery Clinical Coverage Policy No.: 1-O-1," Division of Medical Assistance, North Carolina Department of Health and Human Services, January. 1, 1985, http://www.ncdhhs.gov/dma/mp/1-O-1.pdf (Accessed 10/5/09).

796 "Paying a Visit to the Doctor: Current Financial Protections for Medicare Patients When Receiving Physician Services" By Cristina Boccuti, The Henry J. Kaiser Family Foundation, Issue Brief, April 2014, https://kaiserfamilyfoundation.files.wordpress.com/2014/04/8573-paying-to-see-your-doctor.pdf (Accessed 2/6/15).

797 "The Patient Centered Medical Home: History, Seven Core Features, Evidence and Transformational Change" By Robert Graham Center, Center for Policy Studies in Family Medicine and Primary Care, adfammed.org, November 2007, http://www.adfammed.org/documents/grahamcentermedicalhome.pdf (Accessed 8/10/09).

798 "Measuring The Medical Home Infrastructure In Large Medical Groups" By Diane R. Rittenhouse et al., Health Affairs, Vol. 27, No. 5 (September/October 2008), p. 1246-1247; "Medical Home Models: Improving Care and Reducing Costs in Healthcare" By Laura M. Greene, Healthcare Intelligence Network, May 2009, www.hin.com/cgi-local/link/news/pl.cgi?pcmh09 (Accessed 5/24/10).

The *medical home* is comprised of seven components:

(1) **A personal physician** who provides a patient with ongoing, comprehensive care;
(2) **Physician-directed medical practices** in which the physician and his or her team members assume responsibility for the ongoing care of their patients;
(3) **Whole person orientation** which tasks the physician with the responsibility to ensure that the patient receives all necessary care, including care provided by other qualified healthcare professionals;
(4) **Coordinated or integrated care** calls for the use of information technology, registries, and health information exchanges to coordinate and integrate patient care within the community;
(5) **Quality and safety** improvements through the use of a variety of quality improvement activities, feedback, and evidence based decision support systems;
(6) **Improved access** is sought through the timely access to care and improved communication with patients; and
(7) **Payment methods** that reimburse physicians for direct patient interaction, coordinating patient care, adopting information technology for quality improvement, and achieving quality improvement goals, which allows physicians to share in the savings attributed to reduced hospitalizations.[799]

In addition to being endorsed by various medical associations, the *medical home* model has gained the attention of the federal government. Notably, the *Tax Relief and Health Care Act of 2006* mandated a Medicare *medical home* demonstration project to measure the effectiveness of the model.[800] The two-year project was designed to examine the efficacy of "targeted, accessible, continuous, and coordinated care to Medicare beneficiaries with chronic or prolonged illnesses," which requires "regular medical monitoring, advising, or treatment."[801] While this demonstration was planned to run between 2010 and 2012, it never came to life after being delayed by the *Medicare Improvements for Patients and Providers Act of 2008,*[802] and eventually replaced by the Centers for Medicare and Medicaid Innovation Center that was established by the ACA.[803]

The Center for Medicare and Medicaid Innovation (CMMI) tests payment and service delivery models to determine their effect on program expenditures and the quality of care received. The CMMI is currently running two studies, the Federally Qualified Health Center Advanced Primary Care Practice Demonstration and the Multi-Payer Advanced Primary Care Practice

799 "Measuring The Medical Home Infrastructure In Large Medical Groups" By Diane R. Rittenhouse et al., Health Affairs, Vol. 27, No. 5 (September/October 2008), p. 1247.

800 "Medicare Demonstrations: Details for Medicare Medical Home Demonstration" Centers For Medicare & Medicaid Services, March 31, 2009, http://www.cms.hhs.gov/demoprojectsevalrpts/md/itemdetail.asp?filterType=none&filterByDID=0&sortByDID=2&sortOrder=ascending&itemID=CMS1199247&intNumPerPage=10 (Accessed 8/10/09); "The Patient Centered Medical Home: History, Seven Core Features, Evidence and Transformational Change" By Robert Graham Center, Center for Policy Studies in Family Medicine and Primary Care, adfammed.org, November 2007, http://www.adfammed.org/documents/grahamcentermedicalhome.pdf (Accessed 8/10/09).

801 "Fact Sheet: Medical Home Demonstration Fact Sheet" Centers For Medicare & Medicaid Services, January 09, 2009, http://www.cms.hhs.gov/DemoProjectsEvalRpts/downloads/MedHome_FactSheet.pdf (Accessed 8/10/09); "Medicare Demonstrations: Details for Medicare Medical Home Demonstration" Centers For Medicare & Medicaid Services, March 31, 2009, http://www.cms.hhs.gov/demoprojectsevalrpts/md/itemdetail.asp?filterType=none&filterByDID=0&sortByDID=2&sortOrder=ascending&itemID=CMS1199247&intNumPerPage=10 (Accessed 8/10/09).

802 "Medicare Improvements for Patients and Providers Act of 2008" Pub. L. 110-275, § 133(a)(2), 122 Stat. 2494, 2531 (July 15, 2008).

803 "Center for Medicare and Medicaid Innovation" 42 U.S.C. § 1315a (2010).

Demonstration, both of which encompass the main points of the original *medical home* model demonstration.[804]

Specifically, the Multi-Payer Advanced Primary Care Practice Demonstration is centered on the patient-centered *medical home* model developed in the 1967 as a means of achieving efficient management and delivery of quality healthcare services through prevention, health information technology, care coordination, and shared decision making among patients and providers.[805] The project pays a monthly care management fee for patients receiving care from advanced primary care practices, and the fee covers care coordination, patient education, and other services to support chronically ill patients.[806] The demonstration will allow CMS to evaluate whether advanced primary care practice will reduce medical expenditures, improve the safety of healthcare, and increase the availability of care in underserved areas.[807]

The Federally Qualified Health Center Advanced Primary Care Practice Demonstration was designed to operate for three years, from November 1, 2011 to October 31, 2014, to determine the impact of providing financial and technical resources to help federally qualified health centers make the transition to a patient-centered *medical home* or advanced primary care practice. It is hoped that through this demonstration, CMS will be able to determine what factors and resources are required for this transition across the country in order to meet its ultimate goal of providing better healthcare for the population at a lower cost.[808]

Regardless of the type of the organization formed, whether it is an ACO or *medical home* (as described above) all models will likely rely on a *clinically integrated network* to provide care. These *clinically integrated networks* consist of independent or employed physicians that share information and work together to provide increased value to patients through improved patient care and reduced costs.[809] These networks generally implement "…evidence-based medicine and align incentives between [their] providers and insurance payers."[810] On February 13, 2013, the FTC released its first approval of a *clinically integrated network*, with its advisory opinion regarding the Norman Physician Hospital Organization (Norman PHO), a network of 280 physicians and the Norman Regional Health System.[811]

804 "Details for Title Medicare Medical Home Demonstration" Centers for Medicare and Medicaid Services, April 14, 2011, http://www.cms.gov/Medicare/Demonstration-Projects/DemoProjectsEvalRpts/Medicare-Demonstrations-Items/CMS1199247.html (Accessed 2/12/15).

805 "Multi-Payer Advanced Primary Care Practice" Centers for Medicare and Medicaid Services, http://innovation.cms.gov/initiatives/Multi-Payer-Advanced-Primary-Care-Practice/ (Accessed 3/1/15).

806 Ibid.

807 Ibid.

808 "Federally Qualified Health Center Advanced Primary Care Practice Demonstration Details" Centers for Medicare and Medicaid Services, 2011, http://www.cms.gov/Medicare/Demonstration-Projects/DemoProjectsEvalRpts/Downloads/FQHC_DemoDetails.pdf (Accessed 2/12/15).

809 "Going Further: Value-Based Insights and Opportunities" Valence Health, 2013, http://valencehealth.com/uploads/files/Valence_Health_Further_2013_White_Paper.pdf (Accessed 3/2/2015), p. 2: "Creating a Clinically Integrated Network" McKesson, 2015, http://www.mckesson.com/population-health-management/solutions/create-a-clinically-integrated-network/ (Accessed 3/2/2015).

810 "Going Further: Value-Based Insights and Opportunities" Valence Health, 2013, http://valencehealth.com/uploads/files/Valence_Health_Further_2013_White_Paper.pdf (Accessed 3/2/2015), p. 2.

811 "RE: Norman PHO Advisory Opinion" By Markus H. Meier, Federal Trade Commission, February 13, 2013, http://www.ftc.gov/sites/default/files/documents/advisory-opinions/norman-physician-hospital-organization/130213normanphoadvltr_0.pdf (Accessed 3/2/2015), p. 1-5.

Under the Norman PHO advisory opinion, the FTC engaged in a rule of reason analysis, discussed more thoroughly in Chapter 3, Regulatory Environment, to evaluate whether the 186recompetitive effects of the Norman PHO outweighed any potential anticompetitive effects.[812] Among the potential benefits cited in the Norman PHO advisory opinion, the FTC identified benefits to:

(1) **Patients**—through reduced medical errors; earlier disease detection; more timely communication and scheduling; and elimination of unnecessary and duplicative paperwork and tests;
(2) **Payers**—through centralized administrative work; elimination of duplication of services; avoidance of preventable hospitalization; and, lower costs of care; and
(3) **Providers**—through more timely receipt of public health information (PHI) and scheduling of services; more streamlined referrals; and reduced paperwork, among others.[813]

Further, the Norman PHO stated that it would engage in efforts to reduce any potentially anticompetitive effects arising from the *clinically integrated network*, such as ensuring that information such as pricing and negotiating strategy would not be improperly shared among participants.[814] Accordingly, the FTC determined that these potential recompetitive benefits arising from the Norman PHO outweighed the associated, potential anticompetitive effects, i.e., the improper leveraging of market power associated with network participation in order to drive non-network contract reimbursement rates.[815] However, despite the tentative approval of the Norman PHO, the FTC explicitly reserved the right to revoke approval of future implementation if the program, "…results in substantial anticompetitive effects, if…used for improper purposes, if facts change significantly, or if it otherwise would be in the public interest to do so."[816] Accordingly, the Norman PHO Advisory Opinion requires, in essence, that the Norman PHO maintain a non-exclusive structure, and avoid vertical arrangements that may prevent collaboration between Norman PHO and non-network providers.[817] Despite the scrutiny to which *clinically integrated networks* may be subject, their ability efficiently coordinate the treatment of patients may make them a worthwhile investment.

CONCLUSION

As discussed above, there continues to be a major paradigm shift taking place in the *Healthcare reimbursement* environment. As healthcare reform efforts that focus on reducing costs have begun to gain traction, providers have felt even more presedbetween the cost of providing services and the value of the reimbursement/collections they receive for providing them. However, as more emphasis is placed on the shift from quantity to quality, providers who survive to be those which exhibit increased efficiency and reductions in the cost of service. While these trends will be most likely driven by federal and state government payors, their role

812 Ibid, p. 13-14.
813 Ibid, p. 11.
814 Ibid, p. 12.
815 Ibid, p. 20.
816 Ibid, p. 21.
817 Ibid, p. 19.

as the *gold standard* benchmarks for all *healthcare reimbursement*, will lead any future developments in the commercial reimbursement environment, as well.

Key Sources

Key Source	Description	Citation	Website
United States Department of Health and Human Services (HHS)	"The Department of Health and Human Services (HHS) is the United States government's principal agency for protecting the health of all Americans and providing essential human services." HHS has eleven agencies, among which are the Centers for Medicare and Medicaid Services (CMS), Indian Health Services (IHS), the Office of the Inspector General (OIG), and the National Institutes of Health (NIH).	"About HHS," Department of Health and Human Services, www.hhs.gov/about/ (Accessed 4/1/15).	www.hhs.gov
Centers for Medicare and Medicaid Services (CMS)	CMS administers the Medicare, Medicaid, and CHIP programs. CMS is responsible for setting reimbursement rates under Medicare and Medicaid. The CMS website contains important information for beneficiaries of these programs, as well as for guidelines for providers.	"Centers for Medicare and Medicaid Services" Centers for Medicare and Medicaid Services, U.S. Department of Health and Human Services, http://www.cms.gov/ (Accessed 4/1/15).	www.cms.hhs.gov
United States Department of Health And Human Services (HHS) Office of Inspector General (OIG)	The OIG of HHS oversees all of the department's programs in order to protect the integrity of the programs and the health and welfare of beneficiaries.	"Office of the Inspector General," U.S. Department of Health and Human Services, http://oig.hhs.gov/ (Accessed 4/1/15).	http://oig.hhs.gov
TRICARE	The TRICARE website provides useful information to program beneficiaries.	"TRICARE," http://www.tricare.mil/ (Accessed 4/1/15).	www.tricare.mil/
Civilian Health and Medical Program of the Department of Veteran Affairs (CHAMPVA)	The CHAMPVA page of the U.S. Department of Veterans Affairs website provides useful enrollment and benefit information for CHAMPVA enrollees.	"Department of Veterans Affairs Health Administration Center: CHAMPVA," United States Department of Veterans Affairs http://www.va.gov/purchasedcare/ (Accessed 4/1/15).	http://www.va.gov/purchasedcare/
Indian Health Services (IHS)	IHS is a division of HHS, and the website provides comprehensive information on the activities of IHS, as well as useful information on health programs for Native Americans and Alaska Natives.	"Indian Health Service," www.ihs.gov (Accessed 4/1/15).	www.ihs.gov
BlueCross BlueShield (BCBS)	The website of the BlueCross BlueShield Association contains information on regional BCBS carriers, as well as up-to-date news affecting the U.S. healthcare and health insurance industries.	"BlueCross BlueShield Association," www.bcbs.com (accessed February 20, 2015).	www.bcbs.com
Department of Labor (DOL)	The DOL website includes information regarding employer sponsored health insurance plans and the laws that govern them, such as the Employment Retirement Income Security Act.	"Health Plans and Benefits," United States Department of Labor, http://www.dol.gov/dol/topic/health-plans/index.htm (Accessed 4/1/15).	www.dol.gov

CHAPTER APPENDIX A

CHANGES IN MEDICARE PAYMENTS IN SELECT INDUSTRY SECTORS FROM 2005–PRESENT

Type of Practice	Specialty	2004-2005[818]	2005-2006[819]	2006-2007[820]	2007-2008[821]	2008-2009[822]	2009-2010[823]	2010-2011[824]	2011-2012[825]	2012-2013[826]	2013-2014[827]	2014-2015[828]
Primary Care	General Practice	2%	0.20%	3%	0%	0%	3%	1%	1%	1%	0%	0%
	Internal Medicine	2%	-0.10%	5%	0%	0%	3%	1%	1%	4%	1%	1%
Specialty Surgical	General Surgery	2%	0.20%	0%	-1%	0%	1%	1%	0%	0%	0%	0%
	Orthopedic Surgery	1%	-0.40%	-1%	-1%	0%	1%	3%	-1%	0%	-2%	-1%

818 "Medicare Program; Revisions to Payment Policies under the Physician Fee Schedule for Calendar Year 2005; Final Rule", Federal Register, Vol. 69, No. 219 (November 15, 2004), p. 66401

819 "Medicare Program; Revisions to Payment Policies under the Physician Fee Schedule for Calendar Year 2006; Proposed Rule" Federal Register, Vol. 70, No. 151 (August 8, 2005), p. 45860.

820 "Medicare Program; Revisions to Payment Policies, Five-Year Review of Work Relative Value Units, Changes to the Practice Expense Methodology Under the Physician Fee Schedule, and Other Changes to Payment Under Part B; Revisions to the Payment Policies of Ambulance Services Under the Fee Schedule for Ambulance Services; and Ambulance Inflation Factor Update for CY 2007," U.S. Department of Health and Human Services: Centers For Medicare & Medicaid Services, Federal Register, Vol. 71, No. 231, December 1, 2006, p. 69766.

821 "Medicare Program; Revisions to Payment Policies Under the Physician Fee Schedule, and Other Part B Payment Policies for CY 2008", Federal Register, Vol. 72, No. 227 (November 27, 2007), p. 66390.

822 "Medicare Program; Revisions to Payment Policies Under the Physician Fee Schedule, and Other Part B Payment Policies for CY 2009", Federal Register, Vol. 73, No. 130 (July 7, 2008), p. 38595

823 "Medicare Program; Payment Policies Under the Physician Fee Schedule and Other Revisions to Part B for CY 2010; Corrections; Final Rule" Federal Register, Vol. 75, No. 90 (May 11, 2010), p. 26358.

824 "Medicare Program; Payment Policies Under the Physician Fee Schedule and Other Revisions to Part B for CY 2011; Final Rule" Federal Register, Vol. 75, No. 228, (November 29, 2010), p. 73595.

825 "Medicare Program; Payment Policies under the Physician Fee Schedule, Five-year Review of Work Relative Value Units, Clinical Laboratory Fee Schedule: Signature on Requisition, and Other Revisions to Part B for CY 2012; Final Rule" Federal Register, Vol. 76, No. 228 (November 28, 2011), p. 73454.

826 "Medicare Program; Revisions to Payment Policies Under the Physician Fee Schedule, DME Face-to-Face Encounters, Elimination of the requirement for Termination of Non-Random Prepayment Complex Medical Review and Other Revisions to Part B for CY 2013; Final Rule" Federal Register, Vol. 77, No. 222, (November 16, 2012), p. 69344.

827 "Medicare Program; Revisions to Payment Policies under the Physician Fee Schedule, Clinical Laboratory Fee Schedule & Other Revisions to Part B for CY 2014; Final Rule" Federal Register, Vol. 78, No. 237, (December 10, 2013), p. 74800.

828 "Medicare Program; Revisions to Payment Policies Under the Physician Fee Schedule, Clinical Laboratory Fee Schedule, Access to Identifiable Data for the Center for Medicare and Medicaid Innovation Models & Other Revisions to Part B for CY 2015; Final Rule" Federal Register Vol. 79, No. 219, (November 13, 2014) p. 67988.

Type of Practice	Specialty	2004-2005[818]	2005-2006[819]	2006-2007[820]	2007-2008[821]	2008-2009[822]	2009-2010[823]	2010-2011[824]	2011-2012[825]	2012-2013[826]	2013-2014[827]	2014-2015[828]
Medical Specialties	Anesthesiology	2%	-0.70%	-7%	14%	-1%	0%	-1%	1%	1%	1%	0%
	Radiology	2%	0.40%	-5%	0%	0%	-2%	-10%	-3%	-3%	-2%	-1%
Allied Health Practitioners	Chiropractor	1%	-1.30%	-8%	-2%	-1%	2%	0%	2%	1%	12%	-1%
	Podiatrist	2%	1.30%	-1%	2%	2%	2%	4%	2%	2%	-1%	0%
Mid-level Providers	Nurse Anesthetist	2%	-0.40%	-8%	22%	0%	1%	-1%	2%	1%	3%	0%
	Physical or Occupational Therapist	-1%	1.50%	-5%	1%	1%	2%	-5%	4%	4%	0%	1%
Suppliers	Diagnostic Testing Facility	3%	-2.40%	-2%	0%	-1%	-4%	-15%	-3%	-7%	-11%	-2%

Chapter 3

Regulatory Environment

KEY TERMS

Accreditation
Ambulatory Surgery Center
Antitrust
Civil Monetary Penalty
Commercial Reasonableness
Cream Skimming
Designated Health Service
Electronic Health Record (EHR)
Fair Market Value (FMV)
Financial Relationship
Gainsharing
Kickback
Licensure
National Committee on Quality Assurance (NCQA)
Physician-Owned Facilities
Protected Health Information (PHI)
Qui Tam Action
Self-Referral
The Joint Commission
Treble Damages
Upcoding

Key Concept	Definition	Citation	Key Concept Mentioned on Page #
Corporate Practice of Medicine	The corporate practice of medicine doctrine was created by the American Medical Association (AMA) to protect the public as well as the profession of medical doctors. The doctrine essentially bans unlicensed individuals and entities from engaging in the practice of medicine by restricting them from employing licensed physicians. The intent of the doctrine was to ensure that only licensed professionals delivered medical care and that lay persons and entities not influence treatment decisions. The premise underlying the doctrine was that it would protect patients from potential abuses because commercialized medicine would ultimately divide a physician's loyalty between profits and the delivery of quality patient care.	"Corporate Medicine in 21st Century Health Care" By John W. Jones, Physician's News Digest, June 2007, http://www.physiciansnews.com/law/607jones.html (Accessed 7/09/09); "The People of the State of Illinois v. United Medical Service, Inc." 362 Ill. 442, 455 (1936).	198-200
Health Insurance Portability and Accountability Act of 1996 (HIPAA)	The HIPAA Privacy Rule provides standards for the use and disclosure of "protected health information" (PHI) to safeguard patient privacy. PHI is anything that relates to a patient's past, present, or future physical or mental health condition and the provision of healthcare services to the patient and the past, present, or future payment for the provision of healthcare to the individual. The Privacy Rule governs health plans, healthcare clearinghouses, and any healthcare provider that transmits health information in electronic form in connection with a transaction for which the secretary of Department of Health and Human Services (HHS) has adopted HIPPA standards ("covered entities"). The act was updated by the Health Information Technology for Economic Clinical Health (HITECH) Act, located within the Recovery and Reinvestment Act of 2009, and allows patients to request an audit trail that shows all disclosures of their PHI, prohibiting the sale of a patient's PHI without his or her authorization, and requiring individuals to be notified if there is an unauthorized disclosure or use of their PHI.	"Definitions" 45 C.F.R. § 160.103 (October 1, 2008); "Summary of the HIPAA Privacy Rule" Office of Civil Rights, Department of Health and Human Services, May 2003, http://www.hhs.gov/ocr/privacy/hipaa/understanding/summary/privacysummary.pdf (Accessed 3/6/15), p. 1.	211-214
False Claims Act (FCA)	Creates civil liability for knowingly presenting false or fraudulent claims for reimbursement to the federal government. Amended in 1986, it has become one of the primary weapons used to combat healthcare fraud. Under the statute's qui tam (whistleblower) provisions, any private citizen can enforce the FCA by filing a complaint alleging fraud against the federal government. The incentive is the potential to share in the recovery of any ill-gotten funds. In 1998, the Office of Inspector General (OIG) and the Department of Justice issued guidelines limiting enforcement actions.	"Civil Actions for False Claims" 31 U.S.C. § 3729(a) (1994); "Health Care Fraud Report: Fiscal Year 1998," Department of Justice, justice.gov, 1998, www.justice.gov/dag/pubdoc/health98.htm#national (Accessed 4/1/15); "Civil Actions for False Claims" 31 U.S.C. § 3730(d)(1) (1994).	217-220
Covered Entities Under HIPAA	"Health plans, healthcare clearinghouses, and any health care provider who transmits health information in electronic form in connection with a transaction for which the Secretary of HHS [Department of Health and Human Services] has adopted [HIPAA] standards."	"Summary of the HIPAA Privacy Rule," OCR Privacy Brief, United States Department of Health and Human Services, May 2003, p. 2, www.hhs.gov/ocr/privacy/hipaa/understanding/summary/privacysummary.pdf (Accessed 4/1/15).	213, 215

Key Concept	Definition	Citation	Key Concept Mentioned on Page #
Office of the Inspector General (OIG)	"Office of Inspector General's (OIG) mission is to protect the integrity of Department of Health & Human Services (HHS) programs as well as the health and welfare of program beneficiaries."	"Mission" U.S Department of Health Services, Office of the Inspector General, http://oig.hhs.gov/ (Accessed 4/1/15).	217, 219, 222-23, 225-26, 229, 235-38, 241, 246, 250-52, 256
The Department of Health and Human Services (HHS)	"The Department of Health and Human Services (HHS) is the United States government's principal agency for protecting the health of all Americans and providing essential human services, especially for those who are least able to help themselves."	"About HHS," U.S Department of Health and Human Services, www.hhs.gov/about/ (Accessed 4/1/15).	201, 206-7, 212-15, 220, 226-29, 232-33, 235, 240-41, 252, 257, 276, 281
Fraud Enforcement and Recovery Act of 2009 (FERA)	Expands government resources to combat fraud in the housing and mortgage arena and expands the scope of the FCA by clarifying the term knowingly to mean; a person who, "1) has actual knowledge of the information; 2) acts in deliberate ignorance of the truth or falsity of the information; or 3) acts in reckless disregard of the truth or falsity of the information." FERA also reduces the government's burden of proof, no longer requiring it to provide "proof of specific intent to defraud," and expanded the definition of claim.	"Fraud Enforcement and Recovery Act" Pub. L. No. 111-21, § 4, 123 Stat. 1617, 1622 (January 6, 2009); "Concerns with Proposed Amendments to the Fraud Enforcement and Recovery Act of 2009" By American Hospital Association et al., To the Members of the United States Senate, April 21, 2009, http://www.aha.org/aha/letter/2009/090421-FCA-Sen-ltr.pdf (Accessed 05/05/09), p. 1.	220
Health Care Quality Improvement Act of 1986	Among other things, established the National Practitioner Data Bank to improve the availability of information obtained during the peer review process.	"Health Care Quality Improvement Act of 1986," 42 U.S.C. § 11111 et seq. (2012).	201
Medicare and Medicaid Patient & Program Protection Act of 1987 (MMPPPA)	Amended the 1987 Anti-Kickback statute by including an alternative civil remedy to violation: exclusion from the Medicare Program.	"Medicare and Medicaid Patient & Program Protection Act of 1987" Pub. L. 100-93 § 2, 101 Stat. 680, 680-684 (August 18, 1987); "Medicare and State Health Care Programs: Fraud and Abuse OIG Safe Harbor Provisions" Federal Register Vol. 56 (July 29, 1991), p. 35952.	222
National Health Planning and Resources Development Act of 1974	Legislation that pushed Certificate of Need regulations to the forefront of government healthcare cost containment efforts. The act required that federal agencies pass health policy planning guidelines and establish "a statement of 'national health planning goals'".	"The National Health Planning and Resources Development Act of 1974" Pub. L. No. 93-641, 88 Stat. 2225 (January 4, 1975).	208
Balanced Budget Act of 1997	Added a civil monetary penalty of treble damages, or three times the illegal remuneration, plus $50,000 per violation of the Anti-Kickback statute.	"The Balanced Budget Act of 1997," Pub. L. No. 105-33, § 4304(b)(2)(A), 111 Stat. 251, 383-384 (August 5, 1997).	222
Patient Safety and Quality Act (PSQIA)	Legislation that established a voluntary reporting system for medical errors to increase the availability of such and more efficiently address issues related to patient care and quality.	"Patient Safety and Quality Improvement; Final Rule" Federal Register Vol. 73, No. 226 (November 21, 2008), p. 70732.	216-217
Health Information Technology for Economic Clinical Health (HITECH) Act	Legislation used to promote widespread adoption of health information technology, particularly electronic health records (EHRs). Also used to protect the privacy and security of PHI by allowing patients to request an audit trail that shows all disclosures of their PHI, prohibiting the sale of a patient's PHI without his or her authorization, and requiring individuals to be notified if there is an unauthorized disclosure or use of their PHI.	"Health Information Technology for Economic and Clinical Health," in "American Recovery and Reinvestment Act of 2009," Pub. L. No. 111-5, 123 Stat. 115 (February 17, 2009).	214-215

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Key Concept	Definition	Citation	Key Concept Mentioned on Page #
Stark Law	The federal physician self-referral law, or *Stark law*, prohibits physicians from referring Medicare or Medicaid patients to an entity for designated health services (defined by HHS) if the physician, or an immediate family member, has a financial relationship with that entity. It began in 1989 and has been revised many times. Stark I (1989)—The Ethics in Patient Referrals Act—physicians can't refer to family members. Stark II Phase I (2002) and Phase II (2004)—physicians can't refer if they have an ownership interest. Stark II Phase III (2007)—any financial arrangement is a direct compensation arrangement. Stark IV (2009)—physician with any ownership is considered part of the whole physician organization. There are many specified exceptions to Stark law.	"Limitation on Certain Physician Referrals" 42 U.S.C. 1395nn(a)(1)(A) (2012); "Medicare Program; Physician Financial Relationships With, and Referrals to, Health Care Entities That Furnish Clinical Laboratory Services and Financial Relationship Reporting Requirements," Federal Register Vol. 60, No. 156 (August 14, 1995), p. 41914; "Phase III Regulations Result in Dramatic Changes to Stark Law" By J. Kelly Barnes, et al., BNA Health Law Reporter, Vol. 16, No. 40, October 11, 2007, p. 1220-1221; "Medicare Program; Physicians' Referrals to Health Care Entities With Which They Have Financial Relationships (Phase III)" Federal Register Vol. 72, No. 171 (September 5, 2007), p. 51012, 51028.	228-35
Anti-Kickback Statute	Enacted in 1972, the federal Anti-Kickback statute makes it a felony for any person to "knowingly and willfully" solicit or receive or to offer or pay, any "remuneration" directly or indirectly in exchange for the referral of a patient for a healthcare service paid for by a federal healthcare program. Penalties were amended by Medicare and Medicaid Patient and Program Protection Act of 1987 and the Balanced Budget Act of 1997. Congress enacted "safe harbors," which detail specific regulatory criteria that must be met to shield an arrangement from liability and are meant to protect practices unlikely to result in fraud or abuse.	"Criminal Penalties for Acts Involving Federal Health Care Programs" 42 U.S.C. § 1320a-7b(b) (1997).	221-28
Centers for Medicare and Medicaid Services (CMS)	"…administers the Medicare program, providing health care security and choice for aged and disabled people in this country."	"Guidelines for Ensuring the Quality of Information Disseminated to the Public: E. Centers for Medicare & Medicaid Services," Department of Health and Human Services, http://aspe.hhs.gov/infoquality/Guidelines/CMS-9-20.shtml (Accessed 4/1/15).	202, 207, 213, 219, 227, 230-31, 233-41, 256, 278, 281-82
Osteopath	"Osteopathic medicine is dedicated to treating and healing the patient as a whole, rather than focusing on one system or body part. An osteopathic physician will often use a treatment method called osteopathic manipulative treatment (also called OMT or manipulation)—a hands-on approach to make sure that the body is moving freely. This free motion ensures that all of your body's natural healing systems are able to work unhindered. A doctor of osteopathic medicine (D.O.) is a physician licensed to practice medicine, perform surgery, and prescribe medication."	"Doctor of Osteopathy" Medical Encyclopedia, National Library of Medicine, www.nlm.nih.gov/medlineplus/ency/article/002020.htm (Accessed 4/1/15).	205-6

Key Concept	Definition	Citation	Key Concept Mentioned on Page #
Medicare Prescription Drug, Modernization, and Improvement Act of 2003 (MMA)	Implemented an eighteen-month moratorium on the development of new specialty hospitals, which represented a compromise between the idea that the "whole hospital" exception should be removed for all hospitals and the position of removing it only for specialty hospitals. The moratorium officially ended on June 8, 2005.	"The Medicare Prescription Drug, Modernization, and Improvement Act of 2003" Pub. L. No. 108-173, § 507, 117 Stat. 2066, 2295 (December 8, 2003); "Valuation of Healthcare Ancillary Service Providers," Robert James Cimasi ASA, CBA, AVA, FCBI, CM&A, CMP, President, Health Capital Consultants, National Association of Certified Valuation Analysts: Consultants' Training Institute 2007, September 13, 2007, p. 10.	234, 236
Emergency Medical Treatment and Active Labor Act (EMTALA)	Enacted by Congress in 1986 "to ensure public access to emergency services regardless of ability to pay. Section 1867 of the Social Security Act imposes specific obligations on Medicare-participating hospitals that offer emergency services to provide a medical screening examination (MSE) when a request is made for examination or treatment for an emergency medical condition (EMC), including active labor, regardless of an individual's ability to pay. Hospitals are then required to provide stabilizing treatment for patients with EMCs. If a hospital is unable to stabilize a patient within its capability, or if the patient requests, an appropriate transfer should be implemented."	"EMTALA Overview" Department of Health and Human Services, Centers for Medicare and Medicaid, www.cms.hhs.gov/emtala/ (Accessed 4/1/15).	279
Certificate of Need (CON)	Requires that healthcare providers obtain state approval before either developing new services, or expanding existing services.	"Certificate-of-Need Law in Illinois Slammed by Feds, AMA" By Amy Lynn Sorrel, American Medical News, October 6, 2008, www.ama-assn.org/amednews/2008/10/06/gvsb1006.htm (Accessed 4/1/15).	207-11
Sherman Antitrust Act	Prohibits any "contract, combination...or conspiracy, in restraint of trade or commerce to combat unfair competition and abuse of monopolistic power." Used by federal government to combat kickbacks and self-referral joint ventures.	"Sherman Antitrust Act" 15 U.S.C. § 1 (2013); "Health Care Fraud: Enforcement and Compliance" By Robert Fabrikant, et al., New York, NY: Law Journal Press, 2007, p. 2-60.	257-58
Racketeer Influenced and Corrupt Organizations Act	Federal laws which carry both criminal and civil penalties with the aim of protecting the public from, "parties who conduct organizations affecting interstate commerce through a pattern of criminal activity." Makes it illegal for any person to use or invest any income derived from a "pattern of racketeering activity" in an enterprise, to acquire or maintain control of any enterprise through a pattern of racketeering activity, and for any person employed by or associated with any enterprise to conduct the affairs of the enterprise through a pattern of racketeering activity.	"Health Care Fraud: Enforcement and Compliance," By Robert Fabrikant et al., New York, NY: Law Journal Press, 2007, p. 3-83-84, quoting 115 Cong. Rec. 9566, 9568 (April 18, 1969), statement of Sen. McClellan.	256
The Occupational Safety and Health Act of 1970	Established standards for occupational health and safety, and requires states to enact legislation implementing standards and procedures developed by the Department of Labor.	"Problems in Health Care Law" By Robert D. Miller, Ninth Edition, Sudbury, MA: Jones and Bartlett Publishers, 2006, p. 184–85.	277

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Key Concept	Definition	Citation	Key Concept Mentioned on Page #
Clinical Laboratory Improvement Act (CLIA)	Requires laboratories to regulate all laboratory testing performed on humans, except the testing performed for research purposes, in order to improve the accuracy, reliability, and timeliness of test results. Requires that healthcare providers that perform laboratory testing on specimens derived from humans to obtain a certificate and abide by established standards in order to operate these services. Overseen by CMS.	"Clinical Laboratory Improvement Amendments: Overview" Centers for Medicare & Medicaid Services, http://www.cms.hhs.gov/clia/ (Accessed 09/01/09).	278
The United States Nuclear Regulatory Commission (NRC)	An independent agency created by Congress in 1974 to ensure the safe use of radioactive material (including those used in medical facilities) for civilian purposes through a combination of regulatory requirements, licensing, safety oversight, operational evaluation, and support activities. Under section 274 of the Atomic Energy Act of 1954, the NRC is authorized to delegate its authority to oversee certain licensees to state regulatory commissions, or agreement states.	"Medical, Industrial, and Academic Uses of Nuclear Material" United States Nuclear Regulatory Commission, February 10, 2015, http://www.nrc.gov/materials/medical.html (Accessed 3/5/15); "Governing Legislation" United States Nuclear Regulatory Commission, September 30, 2014, http://www.nrc.gov/about-nrc/governing-laws.html#top (Accessed 3/5/15).	278
Medical Injury Compensation Reform Act	California legislation that caps pain and suffering and malpractice damages.	"Damages for Wrongs" Cal. Civ. Code § 3333.2 (1975).	280
Help Efficient, Accessible, Low-Cost, Timely Healthcare Act of 2009	Introduced before the U.S. House of Representatives in February 2009 as a new attempt to pass a federal cap on noneconomic damages in medical malpractice suits, which has been a continuing congressional goal since the same bill was first introduced in the House in 2002.	"Help Efficient, Accessible, Low-Cost, Timely Healthcare (HEALTH) Act of 2009" H.R. 1086 (February 13, 2009).	281
Federal Trade Commission (FTC) Act	Prohibits "unfair methods of competition in or affecting commerce..." One of the federal government's primary means of combating unfair competition and abuse of monopolistic power.	"Sherman Antitrust Act" 15 U.S.C. § 1 (2013).	257
Deficit Reduction Act (DRA)	Enacted February 8, 2006, and continued the suspension of CMS's enrollment of new specialty hospitals (from MMA) for about six months, until the release of the CMS's final report on specialty hospitals as required by the DRA.	"Deficit Reduction Act of 2005" Pub. L. 109-171, § 6031, 120 Stat. 4, 72-73 (February 8, 2006); "Health Law Update - The Deficit Reduction Act of 2005: New Medicaid Fraud and Abuse Provisions" Bass, Berry & Sims, May 31, 2006, www.bassberry.com/.../Health%20Law%20Update%20May%2031%202006.pdf (Accessed 05/10/10).	251

OVERVIEW

The U.S. healthcare industry is replete with overlapping state and federal regulations that shape the practice of medicine and delivery of healthcare services in the twenty-first century. A significant number of regulations apply to both physician and non-physician practitioners. While regulation has traditionally been directed at physicians and allied health professionals, regulation of mid-level providers has increased, resulting from the expanding scope of services provided under their own Medicare or Medicaid provider numbers. This chapter discusses the general provisions of federal and state regulations, noting whether they apply solely to medical professionals or to allied health professionals and mid-level providers as well. The regulatory environment surrounding these specific professions will be examined in further detail in the chapters dedicated to each profession.

HEALTHCARE LIABILITY

Generally speaking, *liability* is a measure of responsibility and accountability under the law.[1] Liability within healthcare is uniquely allocated, as practitioners and practices cannot completely shelter each other from all the various laws governing medicine. Historically, healthcare professionals were liable solely for their professional actions, i.e., the provision of medical care to patients. As healthcare grew in complexity, from the practice of medicine to the business of medicine, practitioners began to face liability as industry entrepreneurs as well. As such, liability in healthcare can be classified, as it affects both practice and practitioner, into three distinct categories: civil liability, financial liability, and tax liability.[2] Hospitals and practices, as business enterprises, are held liable for the way in which they file their taxes; depending on the affiliation, ownership, and arrangement structure, a practitioner can be held liable for tax purposes as well.[3] Practitioners with ownership interest may be financially liable for any violations related to business practices and, as a result, may suffer personal losses.[4] Lastly, each practitioner shoulders a certain amount of professional liability for services rendered based on their scope of practice and supervision or supervisory status.[5] As healthcare grows in complexity, both medically and entrepreneurially, the liability that practitioners and practices face likely will increase in complexity as well.

1 "Black's Law Dictionary: Liability" By Bryan A. Garner, 10th Edition, Thomson West, 2014, http://www.next.westlaw.com (Accessed 3/4/15).

2 "When Starting Your Own Practice, Be Savvy About Successful Business Structure Basics" Rehab Regs, April 8, 2004, http://www.hcpro.com/RHB-37280-882/When-starting-your-own-practice-be-savvy-about-successful-business-structure-basics.html (Accessed 2/9/10).

3 "S Corp, C Corp, LLC, LLP—Which is Best?" By Dennis Murray, Medical Economics, March 5, 2004, http://www.modernmedicine.com/modernmedicine/article/articleDetail.jsp?id=108814 (Accessed 7/30/09); see the IRS Tax Status section below.

4 "When Starting Your Own Practice, Be Savvy About Successful Business Structure Basics" Rehab Regs, April 8, 2004, http://www.hcpro.com/RHB-37280-882/When-starting-your-own-practice-be-savvy-about-successful-business-structure-basics.html (Accessed 2/9/10); see the Fraud and Abuse Laws section below.

5 "S Corp, C Corp, LLC, LLP—Which is Best?" By Dennis Murray, Medical Economics, March 5, 2004, http://www.modernmedicine.com/modernmedicine/article/articleDetail.jsp?id=108814 (Accessed 7/30/09); see the Tort Reform section below.

THE SHIFT FROM COTTAGE INDUSTRY TO CORPORATE PRACTICE OF MEDICINE

Historically, the practice of medicine has been a *cottage industry* with little crossover seen between specialties and practices.[6] The gradual corporatization of medicine necessitates the regulation of emerging entrepreneurial concerns, that is, business arrangements, fraud and abuse, tax compliance, and practitioner compensation. The Corporate Practice of Medicine doctrine is the most fundamental legislative manifestation of the healthcare transition from a *cottage industry* to, effectively, the corporate practice of medicine.

CORPORATE PRACTICE OF MEDICINE (CPOM)

The American Medical Association promulgated the *Corporate Practice of Medicine* (CPOM) to prohibit unlicensed individuals from engaging in the practice of medicine by employing licensed physicians.[7] CPOM was intended to ensure that licensed physicians could provide medical care without pressure from lay persons whose goals may not be in the best interest of the patient, as medicine should not be "subject to commercialization or exploitation."[8]

The CPOM is regulated by the states.[9] Although restrictions vary by jurisdiction, forty-eight states and the District of Columbia have some form of regulation that follows a CPOM standard.[10] However, the method by which states regulate COPM varies widely from state-to-state.[11] Some states, such as Colorado, expressly prohibit the corporate practice of medicine by statute.[12] Others have developed the prohibition based on applications of licensure statutes that prevent corporations from becoming licensed as physicians.[13] A separate group of states have developed CPOM doctrine by case law or attorney general actions.[14] Because the regulations vary significantly, it is important to understand restrictions regarding the CPOM on a state-by-state basis.

Certain healthcare organizations are generally exempt from the application of the CPOM doctrine. In all states, physicians are allowed to incorporate as professional corporations. In some states, the organization of *health maintenance organizations* (HMOs) and contracts between HMOs and professionals for the provision of services are exempted specifically from the

6 See Chapter 1, *The Rise and Fall of Managed Care.*
7 "Corporate Medicine in 21st Century Health Care" By John W. Jones, Physician's News Digest, June 2007, http://www.physiciansnews.com/law/607jones.html (Accessed 07/09/09); "Corporate Practice of Medicine: A Fifty State Survey" By Stuart Silverman et al., American Health Lawyers Association, Washington, D.C., 2014, p. v.
8 "The People of the State of Illinois v. United Medical Service, Inc." 362 Ill. 442, 455 (1936).
9 "Corporate Medicine in 21st Century Health Care" By John W. Jones, Physician's News Digest, June 2007, http://www.physiciansnews.com/law/607jones.html (Accessed 07/09/09).
10 See generally "Corporate Practice of Medicine: A Fifty State Survey" By Stuart Silverman et al., American Health Lawyers Association, Washington, D.C., 2014.
11 "Corporate Practice of Medicine: A Fifty State Survey" By Stuart Silverman et al., American Health Lawyers Association, Washington, D.C., 2014, p. v.
12 Ibid, p. 48.
13 Ibid, p. 21, 248 (citing Arkansas and North Carolina as examples).
14 Ibid, p. 190, 290 (citing Iowa as an example of CPOM doctrine developed through case law and Nevada as an example of CPOM doctrine developed by Attorney General opinions).

doctrine.[15] Further, some states exempt nonprofit healthcare entities under the rationale that the lack of profit incentive eliminates the dangers associated with the CPOM.[16]

As a result of CPOM, new practice areas have surfaced that may be prone to running afoul of current statutes. A growing practice area that may violate existing CPOM restrictions is the growth in *quick clinics,* or physician offices generally found in large retail stores or pharmacies.[17] Although retailers in states with CPOM restrictions typically cannot open in-store clinics and staff physicians, CPOM laws generally allow corporations to rent or lease space to providers.[18] With the growth of *accountable care organizations* (ACOs) and their increased emphasis on cost-saving measures through improved primary care, the fate of the *quick clinic* market may rest, in part, on the ability of ACOs to successfully navigate CPOM restrictions.[19]

Another growing trend in CPOM violation is the practice of non-physician-owned spas offering Botox injections and other medical procedures with physicians staffed as medical directors.[20] Under this arrangement, unlicensed spa owners may be involved in the unlicensed practice of medicine and the physician may be aiding and abetting.[21] Various states, such as California and Idaho, have taken affirmative steps to prohibit this practice.[22]

CPOM also has been influenced by the creation of new enforcement strategies and regulations that aid in the prevention of fraud. In 2005, the New York Court of Appeals held that no-fault insurance carriers could refuse payment for medical services provided by fraudulently incorporated medical businesses.[23] The court based its holding on two premises: (1) a business corporation law that prohibits individuals from owning a share in a professional service corporation if they are not licensed to practice in the same profession as the corporation and (2) an insurance regulation that excludes payments made to unlicensed or fraudulently licensed providers.[24] The defendant corporation argued that it should be reimbursed because all of its patients received care from licensed providers.[25] However, because the corporation was owned by non-physicians, the court found the organization to be in clear violation of state law.[26]

Despite these regulations, CPOM has found its way into the marketplace through new entities that utilize technology to address patient concerns while bypassing traditional methods of patient

15 Ibid, p. 84, 264 (citing Florida and North Dakota as examples).
16 Ibid, p.288 (citing Pennsylvania as an example).
17 "Demand Growing for Corporate Practice of Medicine" By Devon Herrick, National Center for Policy Analysis, January 1, 2006, http://healthcare.ncpa.org/commentaries/demand-growing-for-corporate-practice-of-medicine (Accessed 06/24/09).
18 "The Market for Medical Care: Why You Don't Know the Price; Why You Don't Know about Quality; And What Can Be Done About It" By Devon M. Herrick and John C. Goodman, The National Center for Policy Analysis, February 2007, http://www.ncpa.org/pub/st296 (Accessed 07/09/09), p. 25.
19 "Easy Access, Quality Care: The Role for Retail Health Clinics in New York" By Paul Howard, Center for Medical Progress, Manhattan Institute for Policy Research, February 2011, http://www.manhattan-institute.org/pdf/mpr_12.pdf (Accessed 1/30/15) p. 7, 16.
20 "Legal Issues Involving Medical Directors of Spas" By Michael H. Cohen, Complementary & Alternative Medicine Law Blog, 2009, http://www.camlawblog.com/spa-legal-issues-934-legal-issues-involving-medical-directors-of-spas.html (Accessed 07/09/09).
21 "Legal Issues Involving Medical Directors of Spas" By Michael H. Cohen, Complementary & Alternative Medicine Law Blog, 2009, http://www.camlawblog.com/spa-legal-issues-934-legal-issues-involving-medical-directors-of-spas.html (Accessed 07/09/09).
22 "Corporate Practice of Medicine" The Medical Board of California, Department of Consumer Affairs, 2007, http://www.mbc.ca.gov/Licensees/Corporate_Practice.aspx (Accessed 2/20/15); "Medispas and Licenses for Rent" By Jean Uranga, Idaho State Board of Medicine, The Report, Vol. 2011, No. 3, Fall 2011, http://bom.idaho.gov/BOMPortal/BOM/Newsletters/2011%20Volume%203.pdf (Accessed 1/30/15) p. 2.
23 "State Farm Mutual Automobile Insurance Co. v. Robert Mallela et al." 827 N.E.2d 758, 760 (N.Y. 2005).
24 "Measurement of No-Fault Benefits" 11 N.Y. Comp. Codes R. Regs. § 65.3.16(a)(12) (2009); "State Farm Mutual Automobile Insurance Co. v. Robert Mallela et al." 827 N.E.2d 758, 760-61 (N.Y. 2005).
25 "State Farm Mutual Automobile Insurance Co. v. Robert Mallela et al." 827 N.E.2d 758, 760 (N.Y. 2005).
26 Ibid.

consultation. Medical consultation services by phone or e-mail and *quick clinic* stores may promote efficiency and access for patients, but such acts may implicate state CPOM laws. These particular types of entities should be cognizant of the most recent CPOM in their states to avoid running afoul of restrictions.

HEALTHCARE REGULATION AT FEDERAL AND STATE LEVELS

For many actors, the regulatory environment surrounding healthcare takes place at both the state and federal levels. In fact, state legislative and regulatory enforcement measures may actually stem from federally elicited incentives or compliance standards, e.g., those federal regulations governing Medicaid eligibility and reimbursement. Conversely, there are matters that are federally regulated, which in turn constitutionally bind states to comply, i.e., federal edicts are preserved, but tailored through supplemental state laws to meet state-specific needs. Identifying the matters that are affected by a particular level of healthcare regulation as well as the interplay between different levels of healthcare regulation is essential to properly advise clients who face issues surrounding healthcare matters.

LICENSURE

State laws typically control the licensure of healthcare providers under the state's police powers. Through these laws states can regulate entry into the field, restrict professional scope of practice, and hold professionals accountable accordingly. State licensing laws specify the minimum level of qualification needed to practice in a field. It is argued that licensure is intended to ensure the public's safety by providing a standard for the evaluation of provider expertise and accurate assessment of the risks of substandard care.[27] However, the domination of professional licensure boards by the professionals themselves has also been criticized as serving the interests of the profession more than the interests of the public.[28] Licensure of the various provider types is discussed in the corresponding Chapters of *Consulting with Professional Practices* (Volume 2).

INDIVIDUAL PROFESSIONAL LICENSURE

Every state and the District of Columbia require licensure of all allopathic (M.D.) and osteopathic (D.O.) physicians.[29] Although the specific criteria for licensure vary by state, each state requires candidates to submit proof of completion of the requisite number of years of

27 "U.S. Health Law and Policy 2001: A Guide To The Current Literature" By Donald H. Caldwell Jr., San Francisco, CA: Jossey-Bass, 2001, p. 253; "50 State Regulatory Surveys: Health Care: Long Term Care: Licensure of Facilities" Thomson Reuters/West, June 2012, 0100 RegSurveys 20.

28 "Health Law: Cases Materials and Problems" By Barry R. Furrow, et al., Third Edition, St. Paul, MN: West Publishing, 1997, p. 92.

29 "State Medical Boards: Future Challenges for Regulation and Quality Enhancement of Medical Care" By James N. Thompson, Journal of Legal Medicine, Vol. 33, No. 9., January-March 2012, p. 94.

graduate medical education and passage of examinations verifying that "the physician is ready and able to practice competently and safely in an independent setting."[30]

A physician applying for licensure is typically found to be of "good moral character" absent his or her involvement in illegal activities.[31] Most physicians satisfy the exam requirement by submitting proof of their successful completion of the *United States Medical Licensing Examination* (USMLE) or the *Comprehensive Osteopathic Medical Licensing Examination* (COMLEX-USA) to the licensure board.[32] However, as some practicing physicians may have been licensed under a previously administered exam, certain state licensing boards may consider a combination of other examinations as sufficient to meet licensure requirements, so long as those exams were completed prior to 2000.[33]

As part of the *Health Care Quality Improvement Act of 1986*, Congress established the *National Practitioner Data Bank* to improve the availability of information obtained during the peer review process.[34] The Department of Health and Human Services (HHS) is responsible for overseeing the *National Practitioner Data Bank* system, and requires state medical and dental licensing boards to report disciplinary action taken against a licensed professional in regards to his or her professional competence and professional conduct.[35] Hospitals are also required to periodically check the status of the database for each member of their medical staff.[36] The general public does not currently have access to the data bank.[37]

In addition to physicians, all states require the licensure of dentists, registered nurses, practical nurses, dental hygienists, pharmacists, optometrists, physical therapists, podiatrists, chiropractors, and administrators of nursing homes.[38] Frequently, physician assistants, midwives, psychologists, social workers, opticians, physical therapy assistants, audiologists, and speech pathologists also are subject to state licensure laws.[39] As with physician licensing, state rules vary on licensure requirements for these professions.

PHYSICIAN VERSUS NON-PHYSICIAN SCOPES OF PRACTICE

Recent physician shortages coupled with declining reimbursement rates have led to increased calls for physician manpower relief.[40] To satisfy these calls, the healthcare workforce has diversified in ways beyond the traditional physician realms. Instead of healthcare workforce evolution limited to the *horizontal* expansion of medical specialty and subspecialty areas, current

30 Ibid, p. 102.
31 "Medical Practice: Education and Licensure," S. Sandy Sanbar, M.D., Ph.D., J.D., F.C.L.M., & Daniel J. Gamino, J.D., Legal Medicine, 6th Ed., Philadelphia, PA: Mosby, 2004, p. 81.
32 "Medical Licensure," American Medical Association, 2009, http://www.ama-assn.org/ama/pub/education-careers/becoming-physician/medical-licensure.shtml, (Accessed 7/9/09); See also "About NBOME," National Board of Osteopathic Medical Examination, 2008, http://www.nbome.org/about.asp, (Accessed 7/9/09).
33 "Medical Licensure," American Medical Association, 2009, http://www.ama-assn.org/ama/pub/education-careers/becoming-physician/medical-licensure.shtml, (Accessed 7/9/09).
34 "Hospital Peer Review and Clinical Privileges Actions: To Report or Not Report," By Troyen A. Brennan, Journal of the American Medical Association, July 28, 1999, p. 381; "Health Care Quality Improvement Act of 1986," 42 U.S.C. § 11111 et seq. (2012).
35 "Health Care Quality Improvement Act of 1986," 42 U.S.C. § 11132-33, 11151 (2012).
36 "Health Care Quality Improvement Act of 1986," 42 U.S.C. § 11134-35 (2012).
37 Ibid.
38 "Health Care Law: A Practical Guide" By Scott Becker et al., New York, NY: Matthew Bender and Co., 2008, p. 16-4, 16-4.1.
39 Ibid, p. 16-4.1.
40 See Chapter 6*: Healthcare Reform: Past as Prologue to the Future.*

trends demonstrate a *vertical* expansion in the role of the *non-physician workforce* to provide services that *support, supplement, and parallel physician services*, particularly for primary care.[41]

Traditionally, *non-physician providers* (NPPs) were referred to, collectively, as *"allied health professionals."*[42] However, NPPs have assumed multiple roles in the provision of healthcare services that may implicate their licensed scope of practice. Because the licenses issued to non-physician practitioners are limited in scope, so as not to run afoul of the prohibition against the unlicensed practice of medicine, these professionals must be careful to only practice within the limits set forth by relevant statutes. This has led nurses and allied health professionals to lobby legislatures and seek judicial rulings to expand the practice limits placed on their licenses.[43] Recent changes in technology, better education for nurses and allied health professionals, physician shortages, and the government's and third party payor's insistence on controlling healthcare costs have led to expanded roles for non-physician professionals.[44]

Practitioners are liable for violation of state laws that regulate the range of services they are permitted to provide. Additionally, Medicare fee schedules indirectly influence professionals by navigating the degree and magnitude of reimbursement rates from public and private payors, as well as which services are covered.[45] Overseen by the *Centers for Medicare and Medicaid Services* (CMS), Medicare reimbursement rates vary based on the level of specialization of each type of practitioner. For non-physician practitioners, reimbursement rates are dictated by policies related to incident-to billing, which state the percentage of a service cost that a non-practitioner may be reimbursed through Medicare.[46] These rates vary based on the level of supervision required (if at all) and the type of services provided.[47] CMS has periodically revised the supervision requirements for non-physician practitioners since the passage of the *Patient Protection and Affordable Care Act* (ACA)—particularly for hospital outpatient therapeutic services—with its most recent revision effective July 1, 2014.[48]

In some cases, Medicare rules and state laws overlap, which may be cause for controversy. For example, *Certified Registered Nurse Anesthetists* (CRNA) are authorized to administer anesthesia without supervision to Medicare patients if a state's governor petitions CMS on the

41 "Nurse Practitioners and Primary Care," Health Policy Brief, Health Affairs, October 25, 2012 http://www.healthaffairs.org/healthpolicybriefs/brief.php?brief_id=79 (Accessed 3/12/13).

42 "Interprofessional Healthcare: A Common Taxonomy to Assist with Understanding" By Alice B. Aiken and Mary Ann McColl, Journal of Allied Health, Vol. 38, No. 3 (Fall 2009), p. e-92.

43 "Nurse Practitioners Seek Right to Treat Patients on Their Own" By Melinda Beck, The Wall Street Journal, August 14, 2013, http://www.wsj.com/articles/SB10001424127887323455104579013193992224008 (Accessed 3/10/15).

44 "Health Care Law: A Practical Guide" By Scott Becker et al., New York, NY: Matthew Bender and Co., 2008, p. 16-22.1.

45 "In the Shadow of a Giant: Medicare's Influence on Private Physician Payments" By Jeffrey Clemens and Joshua D. Gottlieb, National Bureau of Economic Research, Working Paper No. 19503, http://www.nber.org/papers/w19503.pdf (Accessed 2/6/15) p. 6.

46 "'Incident to' Services" Centers for Medicare & Medicaid Services, MLN Matters No. SE0441 April 9, 2013, http://www.cms.gov/Outreach-and-Education/Medicare-Learning-Network-MLN/MLNMattersArticles/downloads/se0441.pdf (Accessed 2/6/15), p. 1.

47 "The Ins and Outs of 'Incident-To' Reimbursement" By Alice G. Gosfield, Family Practice Management, Vol. 8, No. 10 (November/December 2001), p. 25-26; "Chapter 12—Physicians/Nonphysician Practitioners" in "Medicare Claims Processing Manual" Centers for Medicare & Medicaid Services, October 17, 2014, http://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/downloads/clm104c12.pdf (Accessed 3/11/15), § 110, § 120(a); see *Mid-Level Providers Practices in Consulting with Professional Practices*.

48 "Hospital Outpatient Therapeutic Services That Have Been Evaluated for a Change in Supervision Level" Centers for Medicare & Medicaid Services, December 8, 2014, http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/HospitalOutpatientPPS/Downloads/Hospital-Outpatient-Therapeutic-Services-That-Have-Been-Evaluated.pdf (Accessed 2/6/15).

basis of state need.[49] As of September 2014, seventeen states have opted-out of CRNA physician supervision requirements.[50] Contention between physicians and mid-level providers has led to several lawsuits regarding this topic by physician groups interested in protecting physician provision of certain services.[51]

As the overlap between the scope of practice for physicians and non-physicians increases, malpractice liability, which jeopardizes the licenses of both the supervising physician and the non-physician professional, may increase as well.[52] For more information on mid-level provider competition with physicians.[53]

SPECIALTY LICENSURE AND CERTIFICATION

Technological advances during the past forty years have led to an increase in the specialization of healthcare personnel.[54] Physicians can seek specialty certification through the *American Board of Medical Specialties* (ABMS), an organization of 24 approved medical specialty boards.[55] As specialization took hold in the early and mid-1900s (ophthalmology being the first established specialty in 1917), medical professionals, began to self-regulate the profession by forming boards to establish *standards of practice*.[56] Established in 1933, the ABMS certifies physicians in over 150 general specialties and subspecialties, ensuring that they have completed the requisite training programs necessary for their areas of expertise and that they can demonstrate competence in their specialties or sub-specialties through a board-executed *evaluation*.[57] While board certification is not required of U.S. physicians in order to practice their chosen specialty, it has become the gold standard for demonstrating expertise and commitment in their field to patients, providers, insurance companies, and quality organizations across the nation.[58] Unlike a state licensure board, a professional association cannot bar a licensed physician from practicing in a particular specialty for failing to obtain board certification, although board certification is viewed favorably by hospitals and healthcare service providers as an indicator of competence.[59]

49 "Condition of Participation: Anesthesia Service" 42 CFR § 482.52(c) (October 1, 2011); see *Mid-Level Providers Practices in Consulting with Professional Practices*.
50 "Conditions for Coverage & Conditions of Participation Spotlight" Centers for Medicare & Medicaid Services, October 29, 2014, http://www.cms.gov/Regulations-and-Guidance/Legislation/CFCsAndCoPs/Spotlight.html (Accessed 2/6/15).
51 "California Anesthesiologists Buck Governor Over CRNA Role" By Ted Agres, Anesthesiology News, Vol. 36, No. 1 (January 2010), http://www.anesthesiologynews.com/index.asp?ses=ogst&section_id=3&show=dept&article_id=14427 (Accessed 02/10/10).
52 "Malpractice Risks with NPs and PAs in Your Practice" By Mark Crane, Medscape, January 3, 2013, http://www.medscape.com/viewarticle/775746 (Accessed 2/6/15).
53 See *Mid-Level Providers Practices in Consulting with Professional Practices.*
54 "Introduction to Health Services" By Stephen J. Williams and Paul R. Torrens, Seventh Edition, Clifton Park, NY: Thomson Delmar Learning, 2008, p. 268.
55 "American Board of Medical Specialties and ABMS Maintenance of Certification (ABMS MOC) Program" American Board of Medical Specialties, March 2013, http://www.abms.org/media/1209/abms_fact_sheet.pdf (Accessed 3/12/15).
56 "Board History" American Board of Ophthalmology, 2015, http://abop.org/about/board-history/ (Accessed 3/12/15).
57 "American Board of Medical Specialties and ABMS Maintenance of Certification (ABMS MOC) Program" American Board of Medical Specialties, March 2013, http://www.abms.org/media/1209/abms_fact_sheet.pdf (Accessed 3/12/15).
58 "What Board Certification Means" American Board of Medical Specialties, http://www.abms.org/About_Board_Certification/means.aspx (Accessed 4/22/10).
59 "U.S. Health Law and Policy 2001: A Guide to the Current Literature" By Donald H. Caldwell, Jr., San Francisco, CA: Jossey-Bass 2001, p. 253.

Advances in technology have also led to the development of new categories of healthcare providers, including radiological technologists and telemedicine provisions, as well as the state licensing programs and private certifying agencies governing these providers.[60]

HEALTHCARE FACILITY AND PRACTICE LICENSURE

Although the licensing of healthcare entities is typically handled by state governments, significant interplay exists between state and federal government regulations. Most states require entities to meet practice standards set forth by Medicare as a condition of licensure, and Medicare requires state licensure as a condition of reimbursement.[61] As with other types of professional licensure, the licensure of healthcare facilities is intended to ensure that patients receive quality healthcare.

State regulation designates the healthcare facilities that must be licensed. All states require hospitals and nursing homes to be licensed.[62] Many states require further licensure of specialized areas within an already-licensed facility, including clinical laboratories and hospital-based *ambulatory surgery centers* (ASCs).[63] In order to maintain licensure, facilities may need to meet certain building requirements, as well as comply with limits on the number of beds allowed in a given facility.

Physicians are not typically required to license their solo or group practices, because the state exercises control over these facilities through control of each physician's license.[64] However, as the provision of medical care continues to shift to the outpatient setting, more states have expanded the scope of their licensing regulations to require the licensure of facilities performing outpatient procedures similar to those performed in inpatient facilities for which a license is ordinarily required.[65]

ACCREDITATION

Accreditation is the process by which private organizations assess participating institutions and programs and issue accreditation certificates to institutions that meet their requirements. Ensuring the quality and safety of services is the focus of most accreditation standards; however, many also include documentation requirements, among others.[66] If a participating institution or program fails to maintain the requisite standards, they may not incur penalties other than the loss

60 "Introduction to Health Services" By Stephen J. Williams and Paul R. Torrens, Seventh Edition, Clifton Park, NY: Thomson Delmar Learning, 2008, p. 268; "Interstate Licensure of Telemedicine Practitioners" By Glenn W. Wachter, Telemedicine Information Exchange, March 10, 2000; "50 State Telemedicine Gaps Analysis: Physician Practice Standards & Licensure" By Latoya Thomas and Gary Capistrant, American Telemedicine Association, September 2014, http://www.americantelemed.org/docs/default-source/policy/50-state-telemedicine-gaps-analysis--physician-practice-standards-licensure.pdf (Accessed 3/11/15), p. 1.

61 "Health Care Law: A Practical Guide" By Scott Becker et al., New York, NY: Matthew Bender and Co., 2012, § 8.02[1].

62 "Health Care Law: A Practical Guide" By Scott Becker et al., New York, NY: Matthew Bender and Co., 2012, § 8.02[3]; "Health Care: Long Term Care: Licensure of Facilities" Thomson Reuters, June 2013.

63 "State Licensure of Clinical Laboratories" Thomson Reuters, 50 State Regulatory Surveys: Health Care: Health Care Facilities, May 2012; "Ambulatory Surgery Centers" Thomson Reuters, 50 State Regulatory Surveys: Health Care: Health Care Facilities, May 2012.

64 "Health Care Law: A Practical Guide" By Scott Becker et al., New York, NY: Matthew Bender and Co., 2012, § 8.01[3].

65 "ASC Legislative Guide" American Association for Accreditation of Ambulatory Surgery Facilities, 2015, http://www.aaaasf.org/pub/ASC_Legislative_Reference.pdf (Accessed 2/6/15).

66 "Problems in Health Care Law" By Robert D. Miller, Ninth Edition, Sudbury, MA: Jones and Bartlett Publishers, 2006, p. 73.

of their accreditation. In most states, there is no link between accreditation and institutional licensure, although, some states will forego further inspection and accept accreditation by organizations, such as *The Joint Commission*, as the basis for the state licensure of certain providers.[67]

Accreditation can be beneficial to organizations for purposes of federal compliance. Medicare grants deemed status to hospitals accredited by *The Joint Commission* (TJC)[68] or the *American Osteopathic Association* (AOA).[69] Deemed status allows providers to participate in the Medicare program unless a later Medicare validation survey finds noncompliance with the conditions of participation requirements set forth in federal regulations.[70] Accreditation is also important because some payors will only contract with accredited providers.[71]

Major accrediting bodies in the United States include the TJC, the AOA, and the *National Committee for Quality Assurance* (NCQA).

THE JOINT COMMISSION

TJC is a nongovernmental organization that strives to ensure the safety and quality of healthcare services provided to the public.[72] TJC pursues this goal by conducting on-site reviews and setting standards for institutional governance, support services, and patient care.[73] Facilities seek TJC accreditation because it helps to: (1) ensure the provision of quality services; (2) attract quality staff; (3) become qualified to receive Medicare reimbursement; and (4) in some states, TJC accreditation is a requirement for licensure.[74] TJC provides accreditation for ambulatory care centers, including group practices and office-based surgery practices, behavioral health centers, home health services, various types of hospitals—such as general, children's, psychiatric, critical access, and rehabilitation—laboratory services, long-term care facilities, and international healthcare providers.[75]

AMERICAN OSTEOPATHIC ASSOCIATION

The AOA is the main board certifying entity for osteopathic physicians (D.O.), and it is the accrediting body for every osteopathic healthcare facility and medical college.[76] The AOA strives to promote the practice of osteopathic medicine by ensuring quality in education,

67 Ibid.
68 Ibid.
69 "Effect of Accreditation" 42 U.S.C. § 1395bb(a)(1) (2012).
70 "Effect of Accreditation" 42 U.S.C. § 1395bb(c) (2012).
71 "Is Accreditation Really Worth It?" By Robert Kurtz, Outpatient Surgery Magazine, Vol. 9, No. 3 (March 2008), http://www.outpatientsurgery.net/issues/2008/03/is-accreditation-really-worth-it (Accessed 5/13/10).
72 "About The Joint Commission" The Joint Commission, 2015, http://www.jointcommission.org/about_us/about_the_joint_commission_main.aspx (Accessed 2/11/15).
73 "Facts about The Joint Commission" The Joint Commission, July 16, 2014, http://www.jointcommission.org/facts_about_the_joint_commission (Accessed 2/11/15).
74 "Benefits of Joint Commission Accreditation" The Joint Commission, August 21, 2014, http://www.jointcommission.org/accreditation/accreditation_main.aspx (Accessed 3/12/15).
75 "Facts about The Joint Commission" The Joint Commission, July 16, 2014, http://www.jointcommission.org/facts_about_the_joint_commission/ (Accessed 2/11/15).
76 "About the AOA" American Osteopathic Association, 2015, http://www.osteopathic.org/inside-aoa/about/Pages/default.aspx (Accessed 2/11/15).

research, and the delivery of healthcare services. Much like TJC, Medicare grants deemed status to those facilities accredited by the AOA.[77]

NATIONAL COMMITTEE ON QUALITY ASSURANCE

The NCQA is a not-for-profit organization that works with employers, physicians, policymakers, patients, and health plans to improve the quality of healthcare through the accreditation of managed care plans.[78] NCQA functions much like other accrediting bodies through the setting of standards and the collection of outcome and performance data.[79] In 1991, the NCQA accredited its first MCO, and focused its accreditation efforts throughout the 1990s primarily on the development of quality metrics for managed care organizations.[80] These efforts led to the development of the *Health Employer Data Information Set* (HEDIS), which measured essential elements of clinical care.[81] By 1998, 75 percent of all HMO enrollees were enrolled in plans that were subject to NCQA accreditation.[82] HEDIS was formally integrated into NCQA's accreditation procedures in 1999, with an emphasis on establishing preventive services (e.g., immunizations and screening tests) in the primary care setting. Since that time, HEDIS has grown to include additional programs related to disease management and protection of human research test subjects.[83]

MEDICARE AND MEDICAID CERTIFICATION

In order to receive reimbursement for services provided to patients that are Medicare or Medicaid beneficiaries, healthcare provider organizations must become a *certified participant* in the *Medicare and Medicaid programs*. *Certification* for participation in these federal programs is contingent upon the organization being "deemed*"* to have satisfied the health and safety standards components of the Medicare certification process.[84] Providers can achieve *"*deemed status*"* by earning a *certificate of compliance* with the *Conditions of Participation* established in federal regulations, which can be accomplished in one of two ways.[85] First, under *Section 1864(a) of the Social Security Act*, the Secretary of HHS is required to grant state health agencies the authority to approve, disapprove, or terminate the Medicare and Medicaid participation of certified providers[86] based on whether providers have met the *Conditions of Participation*.[87] In

77 "Effect of Accreditation" 42 U.S.C. § 1395bb(a)(1) (2012).
78 "About NCQA" National Committee for Quality Assurance, http://www.ncqa.org/tabid/675/Default.aspx, (Accessed 6/29/09).
79 "2009 Programs and Initiatives Case Statement" National Committee for Quality Assurance, April 2009, http://www.ncqa.org/Portals/0/Sponsor/2009_Case_Statement.pdf (Accessed 2/10/10).
80 "Insights for Improvement: Advancing COPD Care Through Quality Measurement" NCQA, 2009, http://www.ncqa.org/portals/0/publications/NCQA_Insights_Improvement_FINAL.pdf (Accessed 3/5/15) p. 10.
81 Ibid.
82 "Health Care Regulation in America: Complexity, Confrontation, and Compromise" By Robert I. Field, New York, NY: Oxford University Press, 2007, p. 84.
83 Ibid, p. 83-84.
84 "Accreditation and its Impact on Various Survey and Certification Scenarios" By Thomas E. Hamilton, Director, Survey and Certification Group, Centers for Medicare & Medicaid Services, To State Survey Agency Directors, October 17, 2008.
85 "Facts about federal deemed status and state recognition" The Joint Commission, June 19, 2012, http://www.jointcommission.org/assets/1/18/Facts_about_Federal_Deemed_Status.pdf (Accessed 9/14/12).
86 "Use of state agencies to determine compliance by providers of services with conditions of participation" 42 U.S.C. § 1395aa(a) (2012).
87 "Facts about federal deemed status and state recognition" The Joint Commission, June 19, 2012, http://www.jointcommission.org/assets/1/18/Facts_about_Federal_Deemed_Status.pdf (Accessed 9/14/12); "State Operations Manual" Centers for Medicare & Medicaid Services, May 21, 2004, http://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/Downloads/som107c01.pdf (Accessed 09/14/12), §§ 1008A, 1008B.

the alternative, a healthcare provider can achieve *Medicare certification* by obtaining accreditation through an HHS-approved national *accreditation organization* (AO), as specified in the Accreditation section above. As of March 2015, CMS utilizes nine AOs for the purpose of overseeing the health and safety compliance of accredited program participants.[88] An AO may obtain CMS "deeming" authority if it enforces standards that meet or exceed the *Conditions of Participation*.[89] Additional information on Medicare and Medicaid reimbursement can be found in *Reimbursement Environment.*

CERTIFICATE OF NEED (CON)

A *Certificate of Need* (CON) program is one in which government determines where, when, and how capital expenditures will be made for public healthcare facilities and major equipment.[90] CON is based on the theory that, in an unregulated market, healthcare providers will expand their services regardless of duplication or need.[91] However, the validity of CON programs is now contested by agencies such as the Antitrust Division of the *U.S. Department of Justice* (DOJ), which stated that "CON laws tend to create barriers to entry for health care providers…but they do not, on balance, tend to suppress health care spending."[92]

OVERVIEW: THE FEDERAL CERTIFICATE OF NEED PROGRAM

CON statutes and regulations specify those healthcare facilities, medical equipment, and services that require applications and approval to operate. The enactment of federal CON laws was the product of federally mandated health policy planning efforts that dated back to the post-World War II era.[93] However, program development and implementation generally takes place at the state or local level today.[94]

> The enactment of federally mandated CON laws was the product of government mandated health policy planning efforts that dated back to the post–World War II era.
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> ***Patrick John McGinley, 1995.***

88 "CMS-Approved Accreditation Organizations: Contact Information for Prospective Clients" Centers for Medicare & Medicaid Services, January 8, 2015, http://www.cms.gov/Medicare/Provider-Enrollment-and-Certification/SurveyCertificationGenInfo/Downloads/Accrediting-Organization-Contacts-for-Prospective-Clients-.pdf (Accessed 3/6/15).

89 "Facts about federal deemed status and state recognition" The Joint Commission, June 19, 2012, http://www.jointcommission.org/assets/1/18/Facts_about_Federal_Deemed_Status.pdf (Accessed 9/14/12).

90 "Certificate of Need: State Health Laws and Programs" National Conference of State Legislature, April 30, 2009, http://www.ncsl.org/IssuesResearch/Health/CONCertificateofNeedStateLaws/tabid/14373/Default.aspx (Accessed 1/13/10).

91 "Improving Health Care: A Dose of Competition" Report by the Federal Trade Commission and The Department of Justice, July 2004, Ch. 8, p. 2.

92 "Competition in Health Care and Certificates of Need: Joint Statement of the Antitrust Division of the U.S. Department of Justice and the Federal Trade Commission Before the Illinois Task Force on Health Planning Reform" U.S. Department of Justice, September 15, 2008, http://www.justice.gov/atr/public/comments/237351.htm (Accessed 2/21/15).

93 "Beyond Health Care Reform: Reconsidering Certificate of Need Laws in a 'Managed Competition' System" By Patrick John McGinley, |23 Fla. St. U. L. Rev. 141, 145 (1995).

94 "Beyond Health Care Reform: Reconsidering Certificate of Need Laws in a 'Managed Competition' System" By Patrick John McGinley, 23 Fla. St. U. L. Rev. 141, 145-148 (1995); "Certificate of Need: State Health Laws and Programs" National Conference of State Legislature, July 2014, http://www.ncsl.org/research/health/con-certificate-of-need-state-laws.aspx#Program (Accessed 2/21/15).

The *National Health Planning and Resources Development Act of 1974* pushed CON regulations to the forefront of government healthcare cost containment efforts.[95] The act required that federal agencies pass health policy planning guidelines and establish "a statement of national health planning goals."[96] It prompted states to enact CON programs by guaranteeing federal funding for state CON review programs and conditioning the receipt of certain healthcare funding on enacting CON programs.[97] It also specified that state CON programs must meet federal guidelines in order to receive federal funding.[98] In response to the act, all fifty states developed some form of CON review program.[99]

In 1987, Congress repealed the 1974 legislation, which caused fourteen states to discontinue their CON programs.[100] Despite the discontinuation of a formal CON program, all fourteen states retain certain regulatory mechanisms intended to prevent duplication of services.[101]

CON laws were modeled after federal legislation, but current CON regulation is based on various state statutes, rules, and regulations that designate an agency or board to administer the approval process.[102] State CON programs generally have two functions: (1) to develop a health plan promoting equitable access to healthcare services and (2) to review CON applications submitted by healthcare providers.[103] State CON programs are administered according to statutes and regulations controlling market entry for regulated facilities, services, and equipment. As of July 2014, at least 50% of U.S. states subject the following healthcare services and/or providers to CON laws:

(1) Acute Hospital Beds;
(2) ASCs;
(3) Cardiac Catheterization Services;
(4) Long-Term Acute Care Facilities;
(5) Nursing Home/ Long-Term Care Beds;
(6) Open Heart Surgery;
(7) Psychiatric Services; and
(8) Rehabilitation Services.[104]

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95 "The National Health Planning and Resources Development Act of 1974" Pub. L. No. 93-641,§ 1523(a)(4)(B), 88 Stat. 2225, 2246 (January 4, 1975).

96 "The National Health Planning and Resources Development Act of 1974" Pub. L. No. 93-641,§ 1501, 88 Stat. 2225, 2227 (January 4, 1975).

97 "Beyond Health Care Reform: Reconsidering Certificate of Need Laws in a 'Managed Competition' System" By Patrick John McGinley, 23 Fla. St. U. L. Rev. 141, 141, 147-148, (1995).

98 "Excess Capacity: Markets, Regulation, and Values" By Carolyn W. Madden, Health Services Research, Vol. 33, No. 6 (February 1999), p. 1658, 1662

99 "Certificate of Need: State Health Laws and Programs" National Conference of State Legislature, April 30, 2009, http://www.ncsl.org/IssuesResearch/Health/CONCertificateofNeedStateLaws/tabid/14373/Default.aspx (Accessed 1/13/10); "The Effect of Certificate-of-Need Laws on Hospital Beds and Healthcare Expenditures: An Empirical Analysis" By Fred Hellinger, American Journal of Medical Care, Vol. 15 No. 10, October 8, 2009, p. 738.

100 "Certificate of Need: State Health Laws and Programs" National Conference of State Legislature, April 30, 2009, http://www.ncsl.org/IssuesResearch/Health/CONCertificateofNeedStateLaws/tabid/14373/Default.aspx (Accessed 1/13/10)

101 "Certificate of Need: State Health Laws and Programs" National Conference of State Legislature, July 2014, http://www.ncsl.org/research/health/con-certificate-of-need-state-laws.aspx#Program (Accessed 2/21/15).

102 "The U.S. Healthcare Certificate of Need Sourcebook" By Robert James Cimasi, Washington, DC: BeardBooks, 2005, p. 30-33.

103 Ibid, p. 8.

104 "Certificate of Need: State Health Laws and Programs" National Conference of State Legislature, July 2014, http://www.ncsl.org/research/health/con-certificate-of-need-state-laws.aspx#Program (Accessed 2/21/15).

CON also often applies to the purchase of medical equipment and new technology, e.g., ultrasounds and *positron emission tomography* (PET) scanners.

CON regulatory policy has been highly contentious in the state legislative arenas since its widespread adoption four decades ago, and it has been the subject of significant administrative agency study and review. Beyond these activities, the grant or denial of a CON application frequently has resulted in complex and costly litigation.[105] During this period, CON also has been the subject of numerous academic and governmental scientific research studies, as well as the subject of thousands of news and journal articles.

Opponents of CON programs argue that its intervention into the healthcare industry disrupts natural market forces and limits competition.[106] Seeking to preserve competition in healthcare markets, the *Federal Trade Commission* (FTC) consistently has criticized CON as a failing, out-of-date regulatory policy that creates barriers to market entry for new players, preventing price competition.[107]

THE FEDERAL TRADE COMMISSION AND CON

The FTC has evaluated the impact of CON on competition for many years. A 1988 FTC study estimated that total hospital costs might decline by 1.4 percent, or $1.3 billion per year, if all states with CON laws doubled the dollar thresholds at which they require CON review of hospital expenditures.[108] Since this initial estimation, the FTC has embarked on a steady campaign against state CON programs and their anti-competitive nature.

A 1988 FTC study estimated that total hospital costs might decline by 1.4 percent, or $1.3 billion per year, if all states with CON laws doubled the dollar thresholds at which they require CON review of hospital expenditures.

Daniel Sherman, Jan. 1988.

105 Through 2005, state courts issued over 800 reported opinions regarding certificate of need programs and decisions. "The U.S. Healthcare Certificate of Need Sourcebook" By Robert James Cimasi, Washington, DC: BeardBooks, 2005, p. 1, 168. For examples of more current decisions, see, e.g., "Good Hope Health System, L.L.C. v. North Carolina Department of Health and Human Services" 659 S.E.2d 456 (2008); "Mainland Manor Nursing & Rehabilitation Center v. New Jersey Department of Health and Senior Services" 959 A.2d 885 (2008); "In re Certificate of Need Application of OPRS Communities" Case No. 13AP-46, (Ohio Ct. App. January 14, 2014) Decision.

106 "State Commission on the Efficacy of the Certificate of Need Program and its Effect on Cost, Quality, and Access in Georgia" Testimony of S. Houston Payne: Georgia Hand & Microsurgery, Before the Georgia Department of Community Health (August 8, 2005), http://dch.georgia.gov/sites/dch.georgia.gov/files/imported/vgn/images/portal/cit_1210/38/49/178516440-Testimony-Georgia-Society-of-Ambulatory-Surgery-Centers.pdf (Accessed 3/5/15).

107 "Improving Health Care: A Dose of Competition" Report by the Federal Trade Commission and The Department of Justice, July 2004, p. 23; "Federal Trade Commission, Department of Justice Issue Joint Statement on Certificate-of-Need Laws in Illinois" The Federal Trade Commission, September 12, 2008, https://www.ftc.gov/news-events/press-releases/2008/09/federal-trade-commission-department-justice-issue-joint-statement (Accessed 3/11/15).

108 "The Effect of State Certificate-of-Need Laws on Hospital Costs: An Economic Policy Analysis" By Daniel Sherman, Report for Bureau of Economics, Federal Trade Commission, Jan. 1988, http://www.ftc.gov/be/econrpt/232120.pdf (Accessed 10/29/09), p. vi.

In November 2002, FTC Chairman Timothy J. Muris announced that the FTC would hold joint hearings with the DOJ on competition in healthcare in the following year.[109] On July 23, 2004, following the conclusion of the hearings, the FTC and DOJ issued a joint report in which the agencies recommended that states decrease barriers to entry into provider markets.[110] Following the testimony, the agencies suggested that instead of reducing costs, there is evidence that CON programs actually drive up costs by "fostering anticompetitive barriers to entry."[111] In addition to raising prices, the FTC has stated that CON regulation may cause "lower quality… and reduced innovation in healthcare markets."[112]

The creation of ASCs has become a focal point surrounding CON regulation. In the opinion of the FTC and DOJ, ASCs are beneficial for consumers and state CON laws pose an anticompetitive barrier to entry. In response to ASC provider allegations that general hospitals attempted to use CON laws to prevent ASCs from entering the healthcare market, the FTC and DOJ have aggressively pursued activities of anticompetitive conduct against ASC facilities.[113] However, both agencies acknowledged that antitrust laws do not prevent individual hospitals from unilaterally approaching state governments in connection with CON proceedings, calling into question the effectiveness of their efforts encourage ASC creation in spite of CON programs.[114]

Currently, thirty-six states, the District of Columbia, and Puerto Rico retain some sort of CON program.[115] See Exhibit 3-1 for a complete list of states with CON legislation.

THE APPLICATION PROCESS

Every state has its own unique CON application process. However, general procedures tend to guide the application process in all states with CON programs. The typical application process involves submission of an application for review, agency review for consistency with planning criteria, and a public hearing and decision by the granting authority.[116] If an application is approved, the project must typically begin within a specified amount of time.[117] If a CON holder fails to fulfill the requirements of the CON, the state may retain the right to revoke it.[118] Additionally, each state has its own unique criteria and thresholds related to what type of CON

109 "FTC Chairman Announces Public Hearings on Health Care and Competition Law and Policy to Begin in February 2003" U.S. Federal Trade Commission, Press Release, November 7, 2002, http://www.ftc.gov/news-events/press-releases/2002/11/ftc-chairman-announces-public-hearings-health-care-and (Accessed 2/21/15).

110 "Improving Health Care: A Dose of Competition" Report by the Federal Trade Commission and The Department of Justice, July 2004, cover page.

111 Ibid, p. 22.

112 "Comment on Senate Bill 398" By Paul K. Davis: Federal Trade Commission, Letter To Senator Culver Kidd (March 4, 1988), http://www.ftc.gov/opp/advocacy/1988/V880021.PDF (Accessed 10/29/09). "Prepared Statement of the Federal Trade Commission Before the Florida State Senate" Federal Trade Commission, Statement to Florida Senate (April 2, 2008), https://www.ftc.gov/sites/default/files/documents/advocacy_documents/ftc-prepared-statement-florida-senate-concerning-florida-certificate-need-laws/v080009florida.pdf (Accessed 3/5/15), p. 2.

113 "Improving Health Care: A Dose of Competition" Report by the Federal Trade Commission and The Department of Justice, July 2004, Executive Summary p. 28, Chapter 3 p. 27, 28.

114 "Improving Health Care: A Dose of Competition" Report by the Federal Trade Commission and The Department of Justice, July 2004, Chapter 3 p. 2, 27, 28.

115 "Certificate of Need: State Health Laws and Programs" National Conference of State Legislature, July 2014, http://www.ncsl.org/research/health/con-certificate-of-need-state-laws.aspx#Program (Accessed 2/21/15).

116 "Corporate Law for the Healthcare Provider: Organization, Operation, Merger and Bankruptcy" By Ann Huckstep, James C. Wilson, Jr., and Richard P. Carmody, National Health Lawyers Association: Washington, D.C. 1993, p. 120-22.

117 Ibid, p. 122.

118 Ibid, p. 122.

review is required, particularly when it comes to examinations regarding utilization by a population. These standards include, for example, (1) *Full Review*: thresholds related to both utilization and population must be met; (2) *Expedited Review*: utilization threshold standards are not used, but rather "questions" related to "quality of care" and "technological advancements" must be answered; and (3) *Non-Substantive Review*: no formal application is required.[119] In some states, a CON may be transferable, but laws governing such rights differ from state to state.

Exhibit 3-1: States with Certificate of Need Legislation[120]

Alabama	Montana
Alaska	Nebraska
Arkansas	Nevada
Connecticut	New Hampshire
Delaware	New Jersey
District of Columbia	New York
Florida	North Carolina
Georgia	Ohio
Hawaii	Oklahoma
Illinois	Oregon
Iowa	Puerto Rico
Kentucky	Rhode Island
Louisiana	South Carolina
Maine	Tennessee
Maryland	Vermont
Massachusetts	Virginia
Michigan	Washington
Mississippi	West Virginia
Missouri	Wisconsin

THE APPEAL PROCESS

Because CON is an administrative process, an appeal of a negative application decision would first go through the proper administrative channels, which could then be appealed to the appropriate state court.[121]

PRIVACY LAWS

The handling of confidential healthcare information is regulated in order to protect patients and ensure that their privacy is secure, a concern of particular importance because practitioners, providers, and organizations have regular access to patient medical records. Specifically, the *Health Insurance Portability and Accountability Act of 1996* (HIPAA) regulates access to medical information, and the *Red Flags Rule* regulates access to financial information. With

119 "The US Healthcare Certificate of Need Sourcebook" By Robert James Cimasi, Washington, D.C.: Beard Books, 2005, p. 506-509.
120 "Certificate of Need: State Health Laws and Programs" National Conference of State Legislature, July 2014, http://www.ncsl.org/research/health/con-certificate-of-need-state-laws.aspx#Program (Accessed 2/21/15).
121 "Health Care Certificate-of-Need Laws: Policy or Politics?" By Tracy Yee, Lucy B. Stark, Amelia M. Bond , and Emily Carrier, National Institute for Health Care Reform, Research Brief No. 4, May 2011, http://www.nihcr.org/CON_Laws (Accessed 3/6/15), p. 2.

healthcare organizations typically managing both patient medical information and billing for services, practices with varying degrees of complexity and size are expected to comply with both laws.

HEALTH INSURANCE PORTABILITY AND ACCOUNTABILITY ACT OF 1996

HIPAA is designed to serve many purposes, though the most widely recognized purpose is to safeguard the privacy of *protected health information* (PHI), which is health information that can be individually identifiable.[122] HIPAA protection extends to information relating to the "past, present or future physical or mental health condition of an individual; the provision of healthcare services to an individual; or the past, present or future payment for the provision of healthcare to an individual."[123] The *HIPAA Privacy Rule* provides standards for the use and disclosure of PHI by entities covered by HIPAA as well as rights for individuals to control how their PHI is used.[124]

Under the *privacy rule*, a "*covered entity*" includes "health plans, healthcare clearinghouses, and any health care provider who transmits health information in electronic form in connection with a transaction for which the Secretary of HHS [U.S. Department of Health and Human Services] has adopted [HIPAA] standards."[125] Transactions by healthcare providers falling under the *HIPAA Privacy Rule* include claims for reimbursement, benefit eligibility inquiries, referral authorization requests, and other transactions for which HHS has established particular standards.[126] These transactions are covered regardless of whether they are performed by the healthcare provider themselves, a billing service, or any other third party under contract with the provider.[127] Consequently, when a covered entity contracts with a third-party entity to perform billing or other business associate activities, including claims processing, data analysis, and utilization review, the covered entity must impose specific safeguards protect PHI, and the business associate agreement between the covered entity and third-party entity cannot authorize the third party to use PHI in a way that would violate the *privacy rule*.[128]

Information that has been de-identified, however, is not covered by HIPAA. De-identification can occur either by: "(1) … a formal determination by a qualified statistician; or (2) the removal of specified identifiers of the individual and of the individual's relatives, household members,

122 "Definitions" 45 C.F.R. § 160.103 (October 1, 2008); "Health Information Privacy: The Privacy Rule" U.S. Department of Health and Human Services, 2014, http://www.hhs.gov/ocr/privacy/hipaa/administrative/privacyrule/ (Accessed 3/6/15).
123 "Definitions" 45 C.F.R. § 160.103 (October 1, 2008).
124 "Summary of the HIPAA Privacy Rule" Office of Civil Rights, Department of Health and Human Services, May 2003, http://www.hhs.gov/ocr/privacy/hipaa/understanding/summary/privacysummary.pdf (Accessed 3/6/15), p. 1.
125 "Entities Covered by the HIPAA Privacy Rule" Department of Health and Human Services, May 2003, http://www.hhs.gov/ocr/privacy/hipaa/understanding/training/coveredentities.pdfpdf (Accessed 3/6/15), p. 2.
126 Ibid, p. 5.
127 Ibid, p. 4.
128 "Standards for Privacy of Individually Identifiable Health Information" Federal Register Vol. 65, No. 250, (December 28, 2000), p. 82470, 82494-95.

and employers," but only as long as the covered entity that performed the de-identification "has no actual knowledge that the remaining information could be used to identify the individual."[129]

It is paramount that entities abide by HIPAA regulations in order to avoid penalties. If a party violates HIPAA regulations unintentionally, it can receive fines of $100-$50,000 or more per violation and up to $1.5 million per year, depending on whether the violation occurred before February 18, 2009 or after.[130] If an entity intentionally violates HIPAA, it can receive criminal penalties including fines of up to $250,000 and 10 years in prison.[131]

As the healthcare industry transitions to *electronic transactions*, HHS has implemented updated versions of HIPAA standards that regulate the transmission of specific health care information. The first of these updates was known as the *Accredited Standards Committee X12 Version 4010/4010AI*, but became increasingly less functional for the coding and transactional updates providers were required to accommodate (i.e., the coming *ICD-10 transition*). Then HHS approved *ASC X12 Version 5010*, which included technical, structural, and data content requirements; transactional business standardization; data transmission specifications, and delineation of various patient codes.[132] The transition to *HIPAA Version 5010* affected many healthcare industry stakeholders, including providers, health plans, healthcare clearinghouses, and business associates that participate in electronic transactions, such as billing/service agents and vendors.[133] According to a *2011 Medical Group Management Association report*, 45 percent of practices would have to replace their practice management systems completely to manage Version 5010, and 50.3 percent of practices would need to install upgrades to accommodate Version 5010.[134]

Despite the fact that, according to the 2011 *MGMA report*, only 34.5 percent of private physician practices did not utilize practice management vendors that planned to upgrade the practice's current system, 42.5 percent of practices had not started implementation of *Version 5010*.[135] One barrier to implementation is the cost of new *HIPAA Version 5010* software, hardware, and staff training, which may total approximately $16,575 per practice.[136] Although the HIPAA rule introducing the changes was published on January 16, 2009, the *CMS Office of E-Health*

129 "Summary of the Privacy Rule: What Information is Protected" Department of Health and Human Services, http://www.hhs.gov/ocr/privacy/hipaa/understanding/summary/ (Accessed 2/21/15).

130 "General Penalty for Failure to Comply with Requirements and Standards" 42 U.S.C. § 1320d-5(a) (2010); "Summary of the Privacy Rule: Enforcement and Penalties for Noncompliance" Department of Health and Human Services, 2015, http://www.hhs.gov/ocr/privacy/hipaa/understanding/summary/ (Accessed 2/21/15).

131 "General Penalty for Failure to Comply with Requirements and Standards" 42 U.S.C. § 1320d-5(a) (2010).

132 "Is Your Practice Ready for Version 5010" MGMA Government Affairs Department, October 2011, http://www.mgma.com/Libraries/Assets/Practice%20Resources/Publications/MGMA%20Connexion/2011/HIPAA-Version-5010-and-the-future-of-administrative-simplification---MGMA-Connexion-magazine-October-2011.pdf (Accessed 3/11/15), p. 10.

133 "New Health Care Electronic Transactions Standards: Versions 5010, D.0, and 3.0" Centers for Medicare & Medicaid Services, January 2010, http://www.cms.gov/ICD10/Downloads/w5010 BasicsFctSht.pdf (Accessed 11/29/11).

134 "Statement of the Medical Group Management Association to the National Committee on Vital and Health Statistics Subcommittee on Standards: RE: HIPAA Version 5010 " Medical Group Management Association, June 17, 2011, Englewood, CO: Medical Group Management Association, p. 5.

135 Ibid, p. 6, 8.

136 Ibid, p. 6.

Standards and Services (OESS), responsible for enforcement of compliance with electronic transaction standards, delayed enforcement until July 1, 2012,[137] partially due to industry feedback suggesting that many covered entities would be unable to comply with the new transaction standards by the original January 1, 2012 deadline.[138]

Since that final rule went into effect, HHS has begun working on another updated version, known as *HIPAA Transaction Standard 6020*, which includes revisions that satisfy a significant number of business needs and requests.[139] This update is near completion but will not be considered by HHS for adoption until it believes the industry is ready to begin another transition.[140]

HEALTH INFORMATION TECHNOLOGY FOR ECONOMIC AND CLINICAL HEALTH (HITECH) ACT

The *American Recovery and Reinvestment Act of 2009* (ARRA) made changes to HIPAA's health information privacy and security provisions.[141] The *ARRA* used the *HITECH Act* in order to promote widespread adoption of health information technology, particularly *electronic health records* (EHR).[142] Provisions in the *HITECH Act* also protect the privacy and security of PHI by allowing patients to request an audit trail that shows all disclosures of their PHI, prohibiting the sale of a patient's PHI without his or her authorization, and requiring individuals to be notified if there is an unauthorized disclosure or use of their PHI.[143] This latter provision also requires practices to publicly post information about security breaches affecting ten or more patients who cannot be directly contacted, and it requires public notification to the HHS website, prominent media outlets, and the secretary of HHS of breaches affecting 500 patients or more.[144] There are various general exceptions to the *HITECH Act* for PHI, including:

(1) Unintentional access to, acquisition of, or use of PHI by a worker of the covered entity, acting in good faith, within the scope and course of duties, as long as act does not lead to disclosure under HIPAA;

137 "Version 5010" Centers for Medicare & Medicaid Services, June 14, 2012, http://www.cms.gov/Regulations-and-Guidance/HIPAA-Administrative-Simplification/Versions5010andD0/Version_5010.html (Accessed 3/11/15).

138 "Centers for Medicare & Medicaid Services' Office of E-Health Standards and Services Announces 90-Day Period of Enforcement Discretion for Compliance with New HIPAA Transaction Standards." Centers for Medicare & Medicaid Services, Nov 17, 2011, http://www.cms.gov/ICD10/Downloads/CMSStatement5010EnforcementDiscretion111711.pdf (Accessed 11/28/11); "Health Insurance Reform; Modifications to the Health Insurance Portability and Accountability Act (HIPAA); Final Rules," 74 Fed. Reg. 3302 (January 16, 2009).

139 "ASC X12: Electronic Health Data Interchange Standards" American Society of Anesthesiologists, December 2014, https://www.google.com/url?sa=t&rct=j&q=&esrc=s&source=web&cd=1&cad=rja&uact=8&ved=0CC0QFjAA&url=https%3A%2F%2Fwww.asahq.org%2F~%2Fmedia%2Fsites%2Fasahq%2Ffiles%2Fpublic%2Fresources%2Fpractice%2520management%2F2014-12-17-asc-x12-timely-topic.pdf%3Fla%3Den&ei=tI30VKCAK8zCggT4moTgCQ&usg=AFQjCNEy9a5vZK8FXnO9Xxrxp6TLAte1iw (Accessed 3/2/15) p. 2.

140 Ibid.

141 "American Recovery and Reinvestment Act of 2009" Pub. L.111-5, § 3009, 123 Stat. 115, 242 (February 17, 2009); "Stimulus Package Includes New HIPAA Security Rules: Small Practices Face Greatest Financial Impact" By Sheri Porter, AAFP News Now, March 18, 2009, http://www.aafp.org/online/en/home/publications/news/news-now/government-medicine/20090318hipaa-security-rules.html (Accessed 5/10/10).

142 "American Recovery and Reinvestment Act of 2009" Pub. L.111-5, § 13001 et seq., 123 Stat. 115, 226 (February 17, 2009).

143 "Health Information Technology for Economic and Clinical Health Act" Pub. L. 111-5, § 13405, 123 Stat. 115, 264 (February 17, 2009).

144 "Health Information Technology for Economic and Clinical Health Act" Pub. L. 111-5, § 13402, 123 Stat. 115, 260 (February 17, 2009).

(2) Inadvertent disclosure from one worker of the covered entity to another, when both workers were authorized to access information and no future disclosure occurs; and
(3) Unauthorized disclosure to an unauthorized person, when there is reasonable belief that the recipient would not retain information.[145]

In 2013, HHS issued its final omnibus rule modifying HIPAA, with the rule amending the HITECH Act to "strengthen the privacy and security protection for individuals' health information; modify the rule for Breach Notification for unsecured [PHI] under the HITECH Act[;]" "modify [HIPAA] to strengthen privacy protections for genetic information […]; and make certain other modifications to the [HIPAA Rules] to improve their workability and effectiveness and to increase flexibility for and decrease burden on the regulated entities."[146] Essentially, this updated final rule provides greater privacy protections for patients, provides patients with more rights to their own information, and strengthens enforceability by the government while affirming proposed or interim rules from 2009.[147] The rule amended the requirements of business associates, which have been responsible for many large breaches, to include security and privacy obligations and imposed direct liability on these business associates for compliance with certain HIPAA requirements.[148]

The definition of a business associate now includes vendors that deal with PHI on behalf of a covered entity; businesses that perform patient safety activities, health information organizations, e-prescribing gateways, data transmission services that access PHI regularly, personal health record providers for covered entities, and subcontractors of business associates.[149] Under the new rule, individual patients have the right to request electronic copies of their health information and to restrict disclosures to a health plan regarding treatment that they paid for out of pocket.[150] HHS also adopted additional HITECH improvements that were not included in the 2009 adoption, including enforcement of noncompliance with HIPAA rules due to willful neglect.[151] The HITECH Act's goal was to incorporate electronic health records into the healthcare industry, and it attempted to do this by providing incentives to organizations that complied with its requirements. These incentives reimburse organizations through Medicare and Medicaid as long as the organization follows the meaningful use standards.[152]

145 "Investigating Privacy Breaches Under HITECH and HIPAA" By Barry Herrin and Allyson Jones Labban, Smith Moore Leatherwood, 2008, p. 17, 22, 25.
146 "Modifications to the HIPAA Privacy, Security, Enforcement, and Breach Notification Rules Under the Health Information Technology for Economic and Clinical Health Act and the Genetic Information Nondiscrimination Act; Other Modifications to the HIPAA Rules" Federal Register Vol. 78, No. 17 (January 25, 2013), p. 5566.
147 "New Rule Protects Patient Privacy, Secures Health Information" U.S. Department of Health and Humans Services, January 17, 2013, http://www.hhs.gov/news/press/2013pres/01/20130117b.html (Accessed 2/21/15).
148 Ibid.
149 "Deadline Ahead: Last-Minute HIPAA Business Associate Compliance" By Steven Wu, Journal of AHIMA, September 11, 2013, http://journal.ahima.org/2013/09/11/deadline-ahead-last-minute-hipaa-business-associate-compliance/ (Accessed 2/21/15).
150 "New Rule Protects Patient Privacy, Secures Health Information" Department of Health and Humans Services, January 17, 2013, http://www.hhs.gov/news/press/2013pres/01/20130117b.html (Accessed 2/21/15).
151 "Modifications to the HIPAA Privacy, Security, Enforcement, and Breach Notification Rules Under the Health Information Technology for Economic and Clinical Health Act and the Genetic Information Nondiscrimination Act; Other Modifications to the HIPAA Rules" Federal Register Vol. 78, No. 17 (January 25, 2013), p. 5566.
152 See the Increased Reimbursement to Encourage Implementation of Electronic Health Records (EHR) Through Meaningful Use section of Chapter 2, *Reimbursement Environment*, for more information on the application of HITECH with the meaningful use EHR program.

RED FLAGS RULE

On November 9, 2007, the FTC and other agencies published the Red Flags Rule, which listed *red flags*, or warnings, that indicated the possibility of identity theft and mandated the implementation of an identity theft prevention program.[153] In 2013, the FTC issued a guide to help organizations and businesses determine whether they were subject to the rule and comply with it.[154] The rule applies to financial institutions including creditors, which are defined as "any person who regularly extends, renews, or continues credit; any person who regularly arranges for the extension, renewal, or continuation of credit; or any assignee of any original creditor who participates in the decision to extend, renew, or continue credit" and covered accounts, which include:

(1) "Consumer account you offer customers that's primarily for personal, family or household purposes that involves or is designed to permit multiple payments or transactions; or
(2) Any other account that a financial institution or creditor offers or maintains for which there is a reasonably foreseeable risk to customers or to the safety and soundness of the financial institution or creditor from identity theft, including financial, operational, compliance, reputation, or litigation risks."[155]

Healthcare institutions will have to (1) review their billing practices and payment procedures and (2) create a program to ensure compliance.[156] Written compliance programs must include strategies and procedures for identifying existing *red flags*, avoiding future *red flags* violations, preventing and mitigating identity theft, and developing and implementing a procedure for re-evaluating and updating program protocols.[157] Although varying degrees of detail are required depending on organizational complexity, all enterprises, healthcare and otherwise, may be subject to regulation under the Red Flags Rules.[158]

The Red Flags Rules were updated in 2013 to include four elements that create the framework for dealing with the possibility of identity theft. These elements require that:

(1) A program must include reasonable policies and procedures to identify the red flags of identity theft that may occur in an organization's day-to-day operations;
(2) A program must be designed to detect the red flags the organization has identified; A program must spell out appropriate actions an organization will take when it detects red flags; and
(3) A program must detail how an organization will keep its red flag program current to reflect new threats.[159]

153 "Identify Theft Red Flags and Address Discrepancies Under the Fair and Accurate Credit Transactions Act of 2003; Final Rule" Federal Register Vol. 72, No. 217 (November 9, 2007), p. 63718.
154 "Fighting Identity Theft with the Red Flags Rule: A How-to Guide for Business" Federal Trade Commission, May 2013, http://www.ftc.gov/tips-advice/business-center/guidance/fighting-identity-theft-red-flags-rule-how-guide-business (Accessed 2/21/15).
155 Ibid.
156 Ibid.
157 Ibid.
158 Ibid.
159 "Identity Theft Red Flag Rules; Final Rule" Federal Register Vol. 78, No. 76 (April 19, 2013), p. 23645-46.

Compliance with the Red Flags Rule is critical to ensure that patient information is protected from identity theft and other potential fraud. Utilizing the various processes outlined by the FTC will help health businesses and organizations avoid threats against their protected information.

THE PATIENT SAFETY AND QUALITY IMPROVEMENT ACT OF 2005

The *Patient Safety and Quality Improvement Act* (PSQIA) of 2005, which became effective on January 19, 2009, established a voluntary reporting system for medical errors to increase the availability of such quality reporting and to more efficiently address issues related to patient care and quality.[160] Under *PSQIA*, confidentiality provisions to protect "*patient safety work product*" were established such that reporting organizations may maintain compliance with *HIPAA* and other regulations, guidelines, and rules.[161] *Patient safety work product* includes any information that is collected while reporting and analyzing patient safety events.[162] Under *PSQIA*, Patient Safety Organizations are charged with collecting and analyzing data under the supervision of the Agency for Healthcare Research and Quality.[163]

FRAUD AND ABUSE LAWS

With the increase in the corporatization of medicine, governmental authorities have engaged in heightened regulatory scrutiny of healthcare transactions to prevent fraud and abuse within the healthcare industry. These fraud and abuse enforcement regulations have enabled the government to recover billions of dollars. In December 2014, the Office of the Inspector General (OIG) released a statement announcing that approximately $4.9 billion would be returned to federal coffers as a result of fraud and abuse enforcement in FY2014.[164] See the table below for a more extensive list of total indictments, convictions, civil suits, and monetary collections from fraud and abuse legal proceedings from 1997-2014.

FALSE CLAIMS ACT (FCA)

The *False Claims Act* (FCA) is a federal statute that creates civil liability for any person who "knowingly presents, or causes to be presented, to an officer or employee of the United States government or a member of the Armed Forces of the United States a false or fraudulent claim for

160 "Patient Safety and Quality Improvement; Final Rule" Federal Register Vol. 73, No. 226 (November 21, 2008), p. 70732; "Health Information Privacy: Understanding Patient Safety Confidentiality" Department of Health and Human Services, 2010, http://www.hhs.gov/ocr/privacy/psa/understanding/index.html (Accessed 2/4/10).

161 "Patient Safety and Quality Improvement; Final Rule" Federal Register Vol. 73, No. 226 (November 21, 2008), p. 70734; "Patient Safety and Quality Improvement Act of 2005" Agency for Healthcare Research and Quality, December 2012, http://archive.ahrq.gov/news/newsroom/press-releases/2008/psoact.html (Accessed 3/16/15).

162 "Patient Safety and Quality Improvement; Final Rule" Federal Register Vol. 73, No. 226 (November 21, 2008), p. 70739.

163 "Health Information Privacy: Understanding Patient Safety Confidentiality" Department of Health and Human Services, 2010, http://www.hhs.gov/ocr/privacy/psa/understanding/index.html (Accessed 2/4/10).

164 "Nearly $5 Billion to be Returned to Taxpayers as a Result of OIG Work in FY 2014" Office of Inspector General, News Release, December 10, 2014, http://oig.hhs.gov/newsroom/news-releases/2014/sar14fall.asp (Accessed 2/25/15).

Table 3-1: Total Indictments, Convictions, Civil Suits, and Monetary Collections From Fraud and Abuse Legal Proceedings, 1997-2014[165]

Year	Total Criminal Indictments	Total Convictions	Total Civil Matters Pending	Monetary Collections (Millions)
1997[166]	282	363	4,010	$1,200
1998[167]	322	326	3,741	$480
1999[168]	371	396	2,278	$524
2000[169]	457	467	1,995	$1,200
2001[170]	445	465	1,746	$1,700
2002[171]	361	480	1,529	$1,800
2003[172]	362	437	1,277	$1,800
2004[173]	1,002	459	1,362	$605
2005[174]	935	523	1,334	$1,470
2006[175]	836	547	2,016	$2,200
2007[176]	878	560	743	$1,800
2008[177]	957	588	1,311	$1,000
2009[178]	1,014	583	1,155	$1,630
2010[179]	1,116	726	1,290	$2,500
2011[180]	1,110	743	1,069	$2,400
2012[181]	1,131	826	1,023	$3,000
2013[182]	1,013	718	1,079	$2,600
2014[183]	849	760	2,771	$3,311
Total	**13,441**	**9,967**	**31,729**	**$31,220**

165 "Health Care Fraud and Abuse Control Program Report" Office of Inspector General, 2014, http://oig.hhs.gov/reports-and-publications/hcfac/index.asp (Accessed 2/25/15).

166 "Health Care Fraud and Abuse Control Program Annual Report For FY 1997" Department of Health and Human Services and Department of Justice, January 1998, http://oig.hhs.gov/publications/docs/hcfac/hcfacreport1997.PDF (Accessed 3/6/15), p. 1.

167 "Health Care Fraud and Abuse Control Program Annual Report For FY 1998" Department of Health and Human Services and Department of Justice, February 1999, http://oig.hhs.gov/publications/docs/hcfac/HCFAC%20Annual%20Report%20FY%201998.htm (Accessed 3/6/15).

168 "Health Care Fraud and Abuse Control Program Annual Report For FY 1999" Department of Health and Human Services and Department of Justice, January 2000, http://oig.hhs.gov/publications/docs/hcfac/HCFAC%20Annual%20Report%20FY%201999.htm (Accessed 3/6/15).

169 "Health Care Fraud and Abuse Control Program Annual Report For FY 2000" Department of Health and Human Services and Department of Justice, January 2001, http://oig.hhs.gov/publications/docs/hcfac/HCFAC%20Annual%20Report%20FY%202000.htm (Accessed 3/6/15).

170 "Health Care Fraud and Abuse Control Program Annual Report For FY 2001" Department of Health and Human Services and Department of Justice, April 2002, http://oig.hhs.gov/publications/docs/hcfac/HCFAC%20Annual%20Report%20FY%202001.htm (Accessed 3/6/15).

171 "Health Care Fraud and Abuse Control Program Annual Report For FY 2002" Department of Health and Human Services and Department of Justice, September 2003, http://oig.hhs.gov/publications/docs/hcfac/HCFAC%20Annual%20Report%20FY%202002.htm (Accessed 3/6/15).

172 "Health Care Fraud and Abuse Control Program Annual Report For FY 2003" Department of Health and Human Services and Department of Justice, December 2004, http://oig.hhs.gov/publications/docs/hcfac/hcfacreport2003A.htm (Accessed 3/6/15).

173 "Health Care Fraud and Abuse Control Program Annual Report For FY 2004" Department of Health and Human Services and Department of Justice, September 2005, http://oig.hhs.gov/publications/docs/hcfac/hcfacreport2004.htm (Accessed 3/6/15).

174 "Health Care Fraud and Abuse Control Program Annual Report For FY 2005" Department of Health and Human Services and Department of Justice, August 2006, http://oig.hhs.gov/publications/docs/hcfac/hcfacreport2005.pdf (Accessed 3/6/15), p. 1.

175 "Health Care Fraud and Abuse Control Program Annual Report For FY 2006" Department of Health and Human Services and Department of Justice, November 2007, http://oig.hhs.gov/publications/docs/hcfac/hcfacreport2006.pdf (Accessed 3/6/15), p. 1.

176 "Health Care Fraud and Abuse Control Program Annual Report For FY 2007" Department of Health and Human Services and Department of Justice, November 2008, http://oig.hhs.gov/publications/docs/hcfac/hcfacreport2007.pdf (Accessed 3/6/15), p. 1.

177 "Health Care Fraud and Abuse Control Program Annual Report For FY 2008" Department of Health and Human Services and Department of Justice, September 2009, http://oig.hhs.gov/publications/docs/hcfac/hcfacreport2008.pdf (Accessed 3/6/15), p. 1.

178 "Health Care Fraud and Abuse Control Program Annual Report For FY 2009" Department of Health and Human Services and Department of Justice, May 2010, http://oig.hhs.gov/publications/docs/hcfac/hcfacreport2009.pdf (Accessed 3/6/15), p. 1.

179 "Health Care Fraud and Abuse Control Program Annual Report For FY 2010" Department of Health and Human Services and Department of Justice, January 2011, http://oig.hhs.gov/publications/docs/hcfac/hcfacreport2010.pdf (Accessed 3/6/15), p. 1.

180 "Health Care Fraud and Abuse Control Program Annual Report For FY 2011" Department of Health and Human Services and Department of Justice, February 2012, http://oig.hhs.gov/publications/docs/hcfac/hcfacreport2011.pdf (Accessed 3/6/15), p. 1.

181 "Health Care Fraud and Abuse Control Program Annual Report For FY 2012" Department of Health and Human Services and Department of Justice, February 2013, http://oig.hhs.gov/publications/docs/hcfac/hcfacreport2012.pdf (Accessed 3/6/2015), p. 1.

182 "Health Care Fraud and Abuse Control Program Annual Report For FY 2013" Department of Health and Human Services and Department of Justice, February 2014, http://oig.hhs.gov/publications/docs/hcfac/FY2013-hcfac.pdf (Accessed 3/6/15), p. 1.

183 "Health Care Fraud and Abuse Control Program Annual Report For FY 2014" Department of Health and Human Services and Department of Justice, March 2015, http://oig.hhs.gov/publications/docs/hcfac/FY2013-hcfac.pdf (Accessed 3/6/15), p. 1.

payment or approval."[184] Since Congress substantially amended the FCA in 1986, it has developed into one of the most important enforcement methods used by the government to combat healthcare fraud, particularly when used in conjunction with the federal physician self-referral (Stark) law and the federal Anti-Kickback statute.[185] In particular, physician acceptance of kickbacks (that is, monetary bribes, free travel, and various other prerequisites) from pharmaceutical and medical device manufacturers, as well as health systems, has come under increased scrutiny as violations of the FCA.[186] The 1986 amendments strengthened the statute's *qui tam*, or whistleblower, provision,[187] allowing any private citizen to enforce the FCA by filing a complaint against a party alleging fraud against the federal government.[188] *Qui tam* actions are often brought by former employees, but they can also be brought by competitors.[189] The DOJ assumes primary responsibility for prosecuting the claim if it intervenes,[190] and the whistleblower is entitled to a portion of any recovery the government obtains.[191] Potential liability can be significant since the FCA provides for treble damages plus an additional penalty for each false claim.[192]

One of the primary provisions contained in the FCA is the prohibition against provider *upcoding*, defined as the "practice of improperly assigning a diagnosis code to a patient discharge that is not supported by the medical record for the purpose of obtaining a higher level of reimbursement from Medicare for that hospital discharge than the hospital would otherwise receive."[193]

Another critical FCA provision is the prohibition against submitting claims to the federal government for *outlier payments*. The *outlier* and *stop-loss* payments refer to the remuneration providers receive for complicated or/or costly procedures that are not sufficiently covered by the Diagnostic Related Groups (DRG) formula used for hospital inpatient reimbursement.[194] Specifically, outlier payments consist of remunerations from Medicare, while stop-loss payments consist of reimbursements from managed care organizations.

In 2013, the OIG investigated outlier payments to hospitals following a 2003 policy change from CMS to ensure better accuracy of outlier payments.[195] The investigation, published in a 2013 study, found that the majority of hospitals received outlier payments and some received significantly higher proportions of reimbursements from these outlier payments. Specifically, these payments averaged 12.8% of Medicare inpatient prospective payment system reimbursements in 158 hospitals, compared to only 2.2% for all other hospitals. The study found

184 "Civil Actions for False Claims" 31 U.S.C. § 3729(a) (1994).
185 "Health Care Fraud and Abuse: Practical Perspectives" By Linda A. Baumann, Health Law Section of the American Bar Association, Washington, DC: BNA Books, 2002, p. 112-113.
186 "Anti-Kickback Enforcement and Legislation Developments: What Drug, Medical Device and Biologics Companies Must Know" By Karen Gibbs, BNA Pharmaceutical Law & Industry Report, Vol. 6, No. 10 (March 7, 2008), http://www.crowell.com/documents/Anti-Kickback-Enforcement-and-Legislation-Developments_Pharmaceutical-Law_Gibbs.pdf (Accessed 9/02/09), p. 1-2.
187 "The 1986 False Claims Act Amendments: A Retrospective Look at Twenty Years of Effective Fraud Fighting In America" Taxpayers Against Fraud, 2006, http://www.taf.org/retrospective.pdf (Accessed 9/2/09), p. 5.
188 "Civil Actions for False Claims" 31 U.S.C. § 3730(b) (1994).
189 "Qui Tam Actions Under the False Claims Act" By James G. Gumbert, Medical Journal-Houston, July 2003, p. 1.
190 "Civil Actions for False Claims" 31 U.S.C. § 3730(c)(1) (1994).
191 "Civil Actions for False Claims" 31 U.S.C. § 3730(d)(1) (1994).
192 "Civil Actions for False Claims" 31 U.S.C. § 3729(a) (1994).
193 "Five Tenet Hospitals in Florida Pay United States $4.3 Million for Allegedly Violating False Claims Act" Department of Justice, February 10, 2003, http://www.justice.gov/archive/opa/pr/2003/February/03_civ_085.htm (Accessed 2/23/15).
194 See Chapter 2, *Reimbursement Environment*.
195 "Medicare Hospital Outlier Payments Warrant Increased Scrutiny" Office of Inspector General, November 13, 2013, http://oig.hhs.gov/oei/reports/oei-06-10-00520.pdf (Accessed 2/23/15), p. ii.

that the high-outlier hospitals charged substantially more to Medicare for the same DRGs than did all others.

As detailed below, the federal government has utilized and modified the FCA as a basis for increasing enforcement of fraud and abuse laws and heightened scrutiny of healthcare arrangements.

Fraud Enforcement and Recovery Act of 2009 (FERA)

In 2009, the federal government enacted the *Fraud Enforcement and Recovery Act of 2009* (FERA), which changes what the United States Supreme Court has interpreted to be the *FCA's* definition of "knowingly" to ensure the designation is more in line with the intent of the law.[196] Under the new definition the government need only prove by a preponderance of the evidence that a person who acts "knowingly," "(1) has actual knowledge of the information; (2) acts in deliberate ignorance of the truth or falsity of the information; or (3) acts in reckless disregard of the truth or falsity of the information,"[197] thereby reducing the government's burden of proof by removing the requirement of showing specific intent to defraud.[198]

FERA also expanded the definition of "claim" to include any request for money or property offered to a government employee or official.[199] The definition now includes any attempt to defraud the government regardless of whether the government currently has title to the money, and the government need not prove any specific intent to defraud the government.[200] Further, organizations are only liable if they "knowingly" retain improper payments.[201]

Another FERA amendment to the FCA was related to *civil investigative demands* (CIDs).[202] Similar to a subpoena, the U.S. Attorney General can use CIDs to gather evidence without court approval prior to filing an official complaint against parties suspected of violating the FCA.[203] The amendment also expands the definition of "official use" to allow the government to use the information obtained through CID communications with other government departments.[204]

Health Care Fraud Prevention and Enforcement Action Team (HEAT)

In May 2009, HHS Secretary Kathleen Sebelius and Attorney General Eric Holder announced the establishment of HHS's *Healthcare Fraud Prevention and Enforcement Action Team* (HEAT), a group comprised of both HHS and DOJ investigators.[205] Funded through the *Health Care Fraud and Abuse Control* (HCFAC) *Program*, HEAT focuses on fraud prevention and

196 "Fraud Recovery Bill Has Healthcare Implications" By Ben Amirault, Health Leaders Media, April 29, 2009, http://www.healthleaders media.com/content/PHY-232249/Fraud-Recovery-Bill-Has-Healthcare-Implications.html (Accessed 5/6/10).
197 "Fraud Enforcement and Recovery Act" Pub. L. No. 111-21, § 4, 123 Stat. 1617, 1622 (January 6, 2009).
198 "Fraud Recovery Bill Has Healthcare Implications" By Ben Amirault, Health Leaders Media, April 29, 2009, http://www.healthleaders media.com/content/PHY-232249/Fraud-Recovery-Bill-Has-Healthcare-Implications.html (Accessed 5/6/10).
199 "Fraud Enforcement and Recovery Act" Pub. L. No. 111-21, § 4, 123 Stat. 1617, 1622 (January 6, 2009).
200 "Fraud Enforcement and Recovery Act" Pub. L. No. 111-21, § 4, 123 Stat. 1617, 1622 (January 6, 2009).
201 "Concerns with Proposed Amendments to the Fraud Enforcement and Recovery Act of 2009" By American Hospital Association et al., To the Members of the United States Senate, April 21, 2009, http://www.aha.org/aha/letter/2009/090421-FCA-Sen-ltr.pdf (Accessed 05/05/09), p. 1.
202 "Fraud Enforcement and Recovery Act" Pub. L. No. 111-21, § 4, 123 Stat. 1617, 1623 (January 6, 2009).
203 "Fraud Enforcement and Recovery Act" Pub. L. No. 111-21, § 4, 123 Stat. 1617, 1623-24 (January 6, 2009).
204 "Fraud Enforcement and Recovery Act" Pub. L. No. 111-21, § 4, 123 Stat. 1617, 1624 (January 6, 2009).
205 "HEAT Task Force" Stop Medicare Fraud, http://www.stopmedicarefraud.gov/aboutfraud/heattaskforce/ (Accessed 2/25/15).

elimination by identifying patterns of suspected fraudulent activity, and acts through the *Medicare Fraud Strike Force*, which was established in 2007 to combat Medicare fraud through Medicare data analysis techniques focusing on community policing.[206] Between 2008 and 2011, HEAT was able to increase its criminal healthcare fraud charges 75%,[207] and in 2012, HEAT's *Medicare Fraud Strike Force* coordinated the largest healthcare fraud takedown across seven cities that involved $452 million in fraudulent billing by 107 individuals.[208] As of December 31, 2014, the *Medicare Fraud Strike Force* has teams operating in nine cities that have accumulated 1,227 criminal actions, 1,773 indictments, and $1.579 billion in recovered fraudulent charges.[209]

Dodd-Frank Act

Signed into law on July 21, 2010, the *Dodd-Frank Act* expanded the scope of the FCA's protections from employer retaliation and created additional protections and financial incentives for whistle-blowing employees who disclose violations of federal securities and consumer protection laws.[210] In addition, the *Dodd-Frank Act* expands the scope of potential whistleblowers under the FCA to include both current and former employees, vendors, and independent contractors.[211] Furthermore, *Dodd-Frank* provides employees with a three-year statute of limitations to bring an FCA civil claim against the employer for retaliatory actions.[212] *Dodd-Frank* applies to any type of financial fraud by a company under the jurisdiction of the *Securities and Exchange Commission* (SEC) or the *Commodities Futures Trading Commission* (CFTC), whereas the FCA applies only to financial fraud against the government.[213] For example, under *Dodd-Frank*, the government can bring claims against an employer for off-label pharmaceutical marketing, defective pricing, or falsely charging for goods or services that it did not provide (similar to filing false Medicare claims).[214]

ANTI-KICKBACK STATUTE

Enacted in 1972, the federal Anti-Kickback statute makes it a felony for any person (including a physician, allied health professional, or paraprofessional with a Medicare provider number) to "*knowingly and willfully*" solicit or receive or to offer or pay any "remuneration" directly or indirectly in exchange for the referral of a patient for a healthcare service paid for by a federal

206 "Statement of William Corr on Efforts to Combat Health Care Fraud and Abuse Before Committee on Appropriations Subcommittee on Labor, Health and Human Services, Education, and Related Agencies" Department of Health and Human Services, March 4, 2010, http://www.hhs.gov/asl/testify/2010/03/t20100304a.html (Accessed 3/11/2015).
207 "HEAT Task Force" Stop Medicare Fraud, http://www.stopmedicarefraud.gov/aboutfraud/heattaskforce/ (Accessed 2/25/15).
208 "Historic Medicare Fraud Strike Force Takedown" Federal Bureau of Investigation, U.S. Department of Justice, Posted on FBI News Blog, May 2, 2012, http://www.fbi.gov/news/news_blog/strike-force-takedown-050212 (Accessed 2/25/15).
209 "Medicare Fraud Strike Force" Office of Inspector General, December 31, 2014, http://oig.hhs.gov/fraud/strike-force/ (Accessed 2/25/15).
210 "Dodd-Frank Wall Street Reform and Consumer Protection Act" Pub. L. 111-203, § 1079A(c), 124 Stat. 1376, 2079-2080 (July 21, 2010); (July 21, 2010); "Dodd-Frank: The Spillover Impact on Nonprofit Healthcare" By Michael Peregrine and Timothy Cotter, American Health Lawyers Association, American Health Lawyers Weekly, Vol. VIII, No. 29, July 30, 2010, http://www.mwe.com/info/pubs/The_Spillover_Impact_On_Nonprofit_Healthcare.pdf (Accessed 3/11/2015), p. 3.
211 "Dodd-Frank Wall Street Reform and Consumer Protection Act" Pub. L. 111-203, §§ 929F, 1079A, 124 Stat. 1376, 1854, 2079 (July 21, 2010).
212 "Dodd-Frank Wall Street Reform and Consumer Protection Act" Pub. L. 111-203, § 1079A, 124 Stat. 1376, 2079 (July 21, 2010).
213 "Dodd-Frank: Picking Up Where SOX Fell Short" By Lynne Ann Anderson and Meredith R. Murphy, New Jersey Labor and Employment Law, New Jersey State Bar Association, Spring 2012, p. 19.
214 Ibid.

healthcare program.[215] Violations of the Anti-Kickback statute are punishable by either a prison sentence up to five years, criminal fines up to $25,000, or both.[216]

In 1987, Congress amended the original 1972 version of the Anti-Kickback statute with the passage of the *Medicare and Medicaid Patient and Program Protection Act of 1987* (MMPPPA), which allows for exclusion from the Medicare and Medicaid program as an alternative civil remedy to criminal penalties.[217] Also, under the MMPPPA, the "*intent*" requirement under the Anti-Kickback statute changed from a party who "knows or has reason to know" that a particular billing or referral action might be considered fraud, to any party who "knows or should know."[218] The *Balanced Budget Act of 1997* added a civil monetary penalty of treble damages, or three times the illegal remuneration, plus $50,000 per violation. Civil monetary penalties may be a more effective way of enforcing the statute's prohibition, as the government need not prove the Anti-Kickback violation by the criminal standard of beyond a reasonable doubt.[219]

The ACA made additional changes to the intent standard for the Anti-Kickback Statute. First, the ACA amended the statute to specify that a person need not have actual knowledge of the statute or a specific intent to commit a violation of the statute in order for the government to prove a violation of the statute occurred.[220] Second, the ACA added that a "claim that includes items or services resulting from a violation [of the statute] constitutes a false or fraudulent claim for purposes" of the FCA.[221]

Regulatory and Court Interpretations of Statute

The OIG periodically issues *Special Fraud Alerts*, which are public announcements that provide insight into how the OIG believes the statute should be applied to particular business arrangements and which arrangements will violate the statute. The OIG has issued *Special Fraud Alerts* on a number of topics, including joint venture arrangements, clinical laboratory services, and rental agreements for space in physician offices.[222]

Beyond the issuance of *Special Fraud Alerts*, the OIG has adopted and advocated for expansive interpretations of the statute, such as the *one purpose test*, which has been followed by multiple federal appellate courts.[223] Because of these expansive interpretations, detailed below, as well as

215 "Criminal Penalties for Acts Involving Federal Health Care Programs" 42 U.S.C. § 1320a-7b(b) (1997).
216 Ibid.
217 "Medicare and Medicaid Patient & Program Protection Act of 1987" Pub. L. 100-93 § 2, 101 Stat. 680, 680-684 (August 18, 1987); "Medicare and State Health Care Programs: Fraud and Abuse OIG Safe Harbor Provisions" Federal Register Vol. 56 (July 29, 1991), p. 35952.
218 "The Criminalization of American Medicine: 1965-1993" By Madeleine P. Cosman, The Kaiser Papers, September 11, 2000, http://businesspractices.kaiserpapers.org/criminalizationofamericanmedicine.html (Accessed 08/17/12).
219 "Federal Anti-Kickback Statute Primer" By Robert G. Homchick, American Health Lawyers Association, https://www.healthlawyers.org/Events/Programs/Materials/Documents/FC12/101_homchick_williams.pdf (Accessed 3/11/2015), p. 9; "Teaching the Anti-Kickback Statute: How to Advise Clients" By Robert Miller, American Health Lawyers Association, https://www.healthlawyers.org/hlresources/Academics/LawProfessors/AdviceColumns/Pages/Teaching_the_Anti-Kickback_Statute.aspx (Accessed 3/11/2015).
220 "Health Care Reform: Substantial Fraud and Abuse and Program Integrity measures Enacted" McDermott Will & Emery, April 12, 2010, http://www.mwe.com/info/news/wp0410a.pdf (Accessed 3/2/15) p. 3; "Patient Protection and the Affordable Care Act," Pub. L. 111-148, § 6402, 124 Stat. 119, 759, (March 23, 2010).
221 Ibid.
222 "Special Fraud Alerts" Office of Inspector General, https://oig.hhs.gov/compliance/alerts/index.asp (Accessed 2/12/15).
223 "U.S. v. Greber" 760 F.2d 68, 72 (3d Cir. 1985); "Medicare and Medicaid Programs; Fraud and Abuse OIG Anti-Kickback Provisions" Federal Register Vol. 74 (January 23, 1989), p. 3088.

heightened regulatory scrutiny, healthcare industry actors and their advisors should be highly cognizant that many financial relationships could violate the Anti-Kickback statute.[224]

Thornton Letter—Office of the Inspector General

The increased OIG review and overall heightened amount of regulatory scrutiny of the U.S. healthcare industry has coincided with recent surges in exempt hospital/physician practice transactions. While issues surround the legal permissibility of the payment of consideration for *intangible assets* in exempt hospital/physician practice transactions is not new, the *concern* as to when payments of consideration for physician practice *intangible assets* would be legally permissible under the Anti-Kickback statute[225] and the *Internal Revenue Code* (IRC)[226] has gained less attention since the 1990s. This regulatory scrutiny was particularly prevalent during the period immediately following the much-publicized December 22, 1992 letter from D. McCarty Thornton, Esq. to T. J. Sullivan, Esq.,[227] the history and evolution of which is instructive. That December 22, 1992 letter stated that, "accordingly, when attempting to assess the fair market value attributable to a physician's practice, it may be necessary to exclude from consideration any amounts which reflect, facilitate or otherwise relate to the continuing treatment of the former practice's patients."[228] Thornton further stated that, "specific items that we believe would raise a question as to whether payment was being made for the value of a referral stream would include, among other things: payment for goodwill."[229]

At the time of its issuance, many asserted that Thornton's statements should be interpreted to mean that hospitals could legally pay *only* for the *tangible assets* of a physician practice. However, the letter did not constitute, in and of itself, a regulatory ruling regarding the legal permissibility of including payment of consideration for *intangibles* in the transaction price. Rather, it was simply an *advisory admonition* that payments for these items "may," or "would likely," be held to a higher level of scrutiny, which provides insight into OIG enforcement trends but is not binding authority.[230] Subsequent to the December 1992 letter, in a November 2, 1993 letter responding to John E. Steiner, Esq.,[231] Thornton further explained his position regarding the payment for intangibles, "clarifying" that:

224 "OIG Advisory Opinion No. 04-08" Office of Inspector General, Advisory Opinion, June 30, 2004, http://oig.hhs.gov/fraud/docs/advisoryopinions/2004/AdvOp04-08B.pdf (Accessed 5/10/10), p. 3.
225 "Criminal Penalties for Acts Involving Federal Healthcare Programs" 42 U.S.C. § 1320a-7b (2010).
226 "Taxes on Excess Benefit Transactions" 26 U.S.C. § 4958 (2011).
227 "The Application of the Medicare and Medicaid Anti-Kickback Statute" By D. McCarty Thornton, Associate General Counsel, Inspector General Division, U.S. Department of Health and Human Services, To T.J. Sullivan, Technical Assistant, office of the Associate Chief Counsel, Internal Revenue Service, December 22, 1992, http://oig.hhs.gov/fraud/docs/safeharborregulations/acquisition122292.htm (Accessed 4/18/12), p. 1.
228 "The Application of the Medicare and Medicaid Anti-Kickback Statute" By D. McCarty Thornton, Associate General Counsel, Inspector General Division, U.S. Department of Health and Human Services, To T.J. Sullivan, Technical Assistant, office of the Associate Chief Counsel, Internal Revenue Service, December 22, 1992, http://oig.hhs.gov/fraud/docs/safeharborregulations/acquisition122292.htm (Accessed 4/18/12), p. 3.
229 Ibid.
230 "Fraud and Abuse Considerations in Establishing Integrated Delivery Systems" By Carrie Valiant, AHLA Seminar Materials, 1993, p. 6-7.
231 "RE: Requesting Assistance in Interpreting the Scope of Prohibited Referrals under the Medicare and Medicaid Anti-Kickback Statute with Respect to the Acquisition of Physician Practices" by D. McCarty Thornton, Associate General Counsel, Inspector General Division, U.S. Department of Health and Human Services, To John E. Steiner, Jr., Esq., Assistant General Counsel, American Hospital Association, November 2, 1993, http://oig.hhs.gov/fraud/docs/safeharborregulations/acquisition110293.htm (Accessed 5/10/12), p. 1.

> "I would like to emphasize that the position I articulated in the December 22, 1992 letter to T. J. Sullivan remains the same. *I did **not** state that payments for intangible assets are illegal per se.* Nor have I indicated approval of any particular acquisition practices or valuation methodologies. Since payments for items other than the hard assets of a physician practice *could* be a payment to induce referrals or could be in return for future referrals, any such payments are subject to scrutiny to determine whether they violate the Anti-Kickback statute. The fact that the parties may identify the purpose of the payment as something other than a payment for referrals is not determinative."[232] [Emphasis added].

Thereafter, in the seminar materials for Thornton's 1994 presentation before the American Health Lawyers Association (AHLA), he continued to "clarify" that:

> "Often times, what the hospital is really interested in is the future flow of business from the practice to the hospital. When the CEO of the hospital sits down to think about doing such an acquisition, and calculating the price that he or she is willing to pay, what they are really thinking about is what the flow of business is going to look like from the group practice to the hospital over the next 15, 20, 25 years, however long they figure the doctors are going to be around to refer business. What is it worth to the hospital to lock in the stream of business? It is illegal under the Anti-Kickback statute to pay doctors now for the flow of business that you expect from them in the next 15 to 20 years. Everyone knows this, at least everyone experienced in the health care bar, so you never see payments allocated to the value of the future referral stream. What we have seen is that the value of the future referral stream sometimes is disguised as things like goodwill of the patients to the group practice, the value of patient records, the value of an ongoing business, etc. These are all intangibles. *I am **not** saying that it is unlawful to pay for intangibles,* but we see the valuation of these intangibles puffed up through creative accounting games to disguise payment for what is often one of the primary intentions of the hospital, that is, to lock in the referral stream from the practice to the hospital."[233] [Emphasis added].

It is important to note that the matter of the recipient of the economic benefit derived from the *intangible asset* in question is the often overlooked and misunderstood gravamen of the entire issue as to the legal permissibility regarding the payment of consideration for *goodwill* and *intangible assets*. With careful consideration of the fact that the *intangible asset* being valued does not constitute a disguised payment to physicians for future referrals to the hospital, which would constitute remuneration under the Anti-Kickback statute, and instead reflects only the current *Fair Market Value* of those *intangible assets* typically found to exist in physician practice enterprises, it would comport with the statements made in Thornton's continued "clarification" in his 1994 AHLA presentation, which stated that exempt hospital organizations can, in fact, pay for the intangible assets of a physician practice, to wit:

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232 Ibid, p. 2.

233 "Impact of the Anti-Kickback Statute and the Stark Amendment on Vertically Integrated Delivery Systems in the Health Care Industry" By D. McCarty Thornton, American Health Lawyers Association Seminar Materials, 1994, p. 3.

> "In December 1992 I wrote a letter to the IRS that has gotten a fair amount of publicity in the trade press. *There has been somewhat of an* ***overreaction*** *to this letter, because I am not saying you can never pay for goodwill, that you can never pay for the value of an ongoing business unit, etc.* Our concern is where the payment for intangibles is used as a disguise for the intention of the parties to recompensate the practice for the future flow of patients from the practice to the hospital. That would be illegal."[234] [Emphasis added].

The evolving nature of Thornton's comments demonstrates misinterpretations of the December 1992 letter by some in the valuation community immediately following its initial issuance.

"*One Purpose" Test*

The *one purpose* test, established in *United States v. Greber*, is a prominent example of courts adopting an expansive interpretation of the Anti-Kickback statute. Under the *one purpose* test, healthcare providers violate the Anti-Kickback statute if even one purpose of the arrangement in question is to offer illegal remuneration.[235] Subsequently adopted by the OIG, under the one purpose test providers can reasonably expect referrals to result from a business arrangement, but will such arrangements survive regulatory scrutiny if the expectation must not be a reason for entering into the arrangement?[236] Critics of the one purpose test claim that it treats a legitimate relationship with a referral component in the same manner as an arrangement primarily intended to violate the statute and increase the potential for fraud.[237] Opponents also argue that it is impossible for providers to expect referrals while also not considering referrals when entering into a business arrangement.[238]

Special Fraud Alert: Physician-Owned Distributorships

In 2013, the OIG issued a Special Fraud Alert regarding Physician-Owned Distributorships (PODs) that gain revenue from selling or arranging the sale of medical devices ordered and used by physician-owners on their own patients.[239] The OIG is concerned that such POD arrangements contain questionable features including, but not limited to:

(1) Selecting investors because they are in a position to generate substantial business for the entity;
(2) Requiring investors who cease practicing in the service area to divest their ownership interests; and
(3) Distributing returns on investment compared to the level of risk involved.[240]

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234 Ibid, p. 4.
235 "The Hypocrisy of the One Purpose Test in Anti-Kickback Enforcement Law" By Eugene E. Elder, BNA Health Care Fraud Report, Vol. 4, No. 15 (July 26, 2000), http://www.akingump.com/files/Publication/ef37d179-30e2-4266-b4f8-a8481641073c/Presentation/PublicationAttachment/eada4c55-dae7-498d-befa-adefb6d82b9d/445.html (Accessed 10/06/09), p. 3; "U.S. v. Greber" 760 F.2d 68, 72 (3d Cir. 1985).
236 "Medicare and Medicaid Programs; Fraud and Abuse OIG Anti-Kickback Provisions" Federal Register Vol. 54 (January 23, 1989), p. 3088.
237 "United States v. Dan Anderson" American Hospital Association et al., Brief Amici Curiae, June 6, 2000, www.hospitalconnect.com/aha/advocacy-grassroots/advocacy/legal/anderson200066.html (Accessed 02/27/05), p. 1.
238 "The Hypocrisy of the One Purpose Test in Anti-Kickback Enforcement Law" By Eugene E. Elder, BNA Health Care Fraud Report, Vol. 4, No. 15 (July 26, 2000), http://www.akingump.com/files/Publication/ef37d179-30e2-4266-b4f8-a8481641073c/Presentation/PublicationAttachment/eada4c55-dae7-498d-befa-adefb6d82b9d/445.html (Accessed 10/06/09), p. 546.
239 "Special Fraud Alert: Physician-Owned Entities" Office of Inspector General, Department of Health and Human Services, March 26, 2013, p. 1.
240 Ibid, p. 2.

If a POD displays questionable features, OIG is usually concerned that medical judgment is corrupt, medical devices are over-utilized, Federal healthcare programs or beneficiaries are overcharged, or competition is unfair.[241] The Fraud Alert contains a non-exhaustive list of suspicious characteristics that could be cause for investigation into a POD and reiterates the OIG's position that it is "inherently suspect" of PODs under the federal Anti-Kickback Statute.[242] Furthermore, the Fraud Alert notes that OIG considers the intent of both parties, regardless of whether the party contracting with the POD is a physician, hospital, or ambulatory service center.[243] Physicians and their advisers may find it beneficial for outside counsel to examine any potential PODs to determine whether or not their arrangement may implicate many of the concerns noted by the OIG.

Safe Harbors

Due to the broadness of the Anti-Kickback statute, legitimate business arrangements by healthcare providers may be prohibited. For example, under a literal interpretation of the statute, a physician would not be allowed to receive dividend payments from a publicly traded pharmaceutical company if the physician prescribed products produced by the company.[244] In response to these and other harmless arrangements, Congress created a number of statutory exceptions and gave HHS authority to protect other business arrangements through *safe harbors*.[245] *Safe harbors* detail specific regulatory criteria that must be met to shield the parties to a business arrangement from liability, and they are meant to protect practices unlikely to result in fraud or abuse.[246] The failure to comply with every requirement of a *safe harbor* does not mean that the arrangement is illegal,[247] so long as there is a low risk of fraud and abuse.[248]

The MMPPPA directed HHS to promulgate regulations specifying payment practices that did not violate the Anti-Kickback statute. Congress created the following statutory exemptions from the statute to protect legitimate business arrangements, including:

(1) Properly disclosed discounts;
(2) Payments to bona fide employees for employment;
(3) Certain payments to group purchasing organizations;
(4) Co-insurance waivers to Medicare services for patients qualifying for certain public health service programs;

241 Ibid, p. 2.
242 Ibid, p. 3-4.
243 Ibid, p. 4.
244 "Medicare and Medicaid Programs; Fraud and Abuse OIG Anti-Kickback Provisions: Supplementary Information; II. Provisions of the Proposed Rule" Federal Register Vol. 54 (July 23, 1989), p. 3088
245 "Exceptions" 42 C.F.R. § 1001.952 (June 11, 2009).
246 "Medicare and State Health Care Programs: Fraud and Abuse; Clarification of the Initial OIG Safe Harbor Provisions and Establishment of Additional Safe Harbor Provisions. Under the Anti-Kickback Statute; Final Rule" Federal Register Vol. 64, No. 223 (November 19, 1999), p. 63518.
247 Ibid, p. 63519
248 "OIG Letter Re: Malpractice Insurance Assistance" By Lewis Morris, Office of the Inspector General, January 15, 2003, http://oig.hhs.gov/fraud/docs/alertsandbulletins/MalpracticeProgram.pdf (Accessed 3/11/2015); "OIG Advisory Opinion 07-10" Office of the Inspector General, Advisory Opinion, https://oig.hhs.gov/fraud/docs/advisoryopinions/2007/AdvOpn07-10A.pdf (Accessed 3/11/2015), p. 1-2; "OIG Advisory Opinion 08-14" Office of the Inspector general, Advisory Opinion (October 2, 2008) http://oig.hhs.gov/fraud/docs/advisoryopinions/2008/AdvOpn08-14.pdf (Accessed 3/11/2015), p. 5; "OIG Advisory Opinion 09-07" Office of the Inspector General, Advisory Opinion (June 30, 2009), http://oig.hhs.gov/fraud/docs/advisoryopinions/2009/AdvOpn09-07.pdf (Accessed 5/7/10), p. 6.

(5) Payment practices specified by the HHS secretary in regulations promulgated under the MMPPPA or nonmonetary remuneration necessary and used solely to receive and transmit electronic prescription information in accordance with the standards promulgated under 42 U.S.C. 1395w-104;
(6) Certain risk-sharing and arrangements with managed care organizations;
(7) Waiver or reduction by pharmacies of any cost-sharing imposed under Medicare Part D which has met certain conditions under 42 U.S.C. 1320a-7a(i)(6)(A);
(8) Any remuneration between a federally qualified health center and a Medicare Advantage organization pursuant to a written agreement; and
(9) Any remuneration between a healthcare center entity and any entity providing goods, items, services, donations, loans, or a combination thereof to that entity pursuant to a contract, lease, grant, loan, or other agreement if such agreement contributes to the ability of the healthcare center to serve an underserved population.[249]

The *safe harbors* to the Anti-Kickback statute were intended to "permit individuals and entities to freely engage in business practices and arrangements that encourage competition, innovation and economy."[250] Since 1989, HHS has created a number of *safe harbors*, and it also clarified existing *safe harbors* in 1999. The 1991 *safe harbors* included promulgations protecting investments in large publicly-held healthcare companies and investments in small healthcare joint ventures.[251] In 1999, HHS added *safe harbors* protecting investments in healthcare entities located in underserved areas, investments in ASCs, and investments in group practices.[252] In 2007, HHS promulgated *a safe harbor* related to arrangements related to *federally qualified health centers* (FQHC), which serves as the most recent *safe harbor* added to the Anti-Kickback statute.[253] However, new *safe harbors* may be on the horizon. On October 3, 2014, HHS proposed new *safe harbors* related to emergency ambulance services, Medicare Part D cost-sharing waivers and gap discounts, local transportation provided to federal healthcare program beneficiaries, and limited arrangements between FQHCs and Medicare Advantage organizations.[254]

The most important *safe harbors* for the purposes of *physician/hospital integration* protect certain *physician investment interests*, which Congress intended to safeguard because "[it] did not intend to bar all investments by physicians in other health care entities,"[255] and certain business investments "represent the extension of a physician's office space and not a means to profit from referrals."[256] Further, CMS believed that the risk of improper referrals was relatively

249 "Criminal Penalties for Acts Involving Federal Health Care Programs" 42 U.S.C. § 1320a-7b(b)(3) (1997).
250 "Medicare and Medicaid Programs; Fraud and Abuse OIG Anti-Kickback Provisions: Supplementary Information; II. Provisions of the Proposed Rule" Federal Register Vol. 54 (July 23, 1989), p. 3088.
251 "Medicare and State Health Care Programs: Fraud and Abuse OIG Safe Harbor Provisions" Federal Register Vol. 56 (July 29, 1991), p. 35952.
252 "Medicare and State Health Care Programs: Fraud and Abuse; Clarification of the Initial OIG Safe Harbor Provisions and Establishment of Additional Safe Harbor Provisions Under the Anti-Kickback Statute; Final Rule" Federal Register Vol. 64 (November 19, 1999), p. 63532, 63534, 63540.
253 "Safe Harbor Regulations" Office of Inspector General, U.S. Department of Health and Human Services, 2015, https://oig.hhs.gov/compliance/safe-harbor-regulations/ (Accessed 3/6/15).
254 "Medicare and State Health Care Programs: Fraud and Abuse; Revisions to Safe Harbors Under the Anti-Kickback Statute, and Civil Monetary Penalty Rules Regarding Beneficiary Inducements and Gainsharing" Federal Register, Vol. 79, No. 192, (October 3, 2014), p. 59718.
255 "Medicare and Medicaid Programs; Fraud and Abuse OIG Anti-Kickback Provisions" Federal Register, Vol. 54 (January 23, 1989), p. 3088
256 "Medicare and State Health Care Programs: Fraud and Abuse; Clarification of the Initial OIG Safe Harbor Provisions and Establishment of Additional Safe Harbor Provisions Under the Anti-Kickback Statute; Final Rule" Federal Register, Vol. 64, No. 223 (November 19, 1999), p. 63535-63536.

low *when the physician personally performed services at his or her own facility*, such as an ASC, and on his or her own patients.[257] Additionally, the investment safe harbors were enacted with the intent of protecting arrangements that "[could] significantly reduce costs for Federal health care programs, while simultaneously benefiting patients."[258] In particular, HHS wanted to avoid "chill[ing] group practice integration that [was] crucial in an increasingly managed care environment."[259]

There are a total of twenty-five safe harbors under the Anti-Kickback statute. Many of these safe harbors focus on the traditional concept of FMV and the separate and distinct threshold of *commercial reasonableness*. These thresholds are discussed in-depth in the Physician Compensation Restrictions section below, and in *Financial Valuation of Enterprises, Assets, and Services* in *Consulting with Professional Practices*.

While the above exemptions allow federally funded healthcare programs to reduce their potential liability under the Anti-Kickback statute, many healthcare transactional arrangements business interactions may still be suspect under the Stark Law.

STARK LAW

The federal physician self-referral, or *Stark law*, prohibits physicians from referring Medicare or Medicaid patients to an entity for designated health services if the physician, or an immediate family member, has a financial relationship with that entity.[260] Since its promulgation in 1989, the Stark law has gone through multiple revisions that have both increased the scope of its provisions and added exceptions to what kind of transactions the prohibitions apply. This continued evolution of the Stark Law has coincided with increasing regulatory scrutiny under the Stark Law, making compliance with this scheme an increasingly pressing issue for healthcare providers.

Whether an arrangement is subject to the Stark Law rests in part on whether the arrangement fits within the definition of the core terms constituting the Stark prohibition. HHS defines physician under Stark law as a "doctor of medicine or osteopathy, a doctor of dental surgery or dental medicine, a doctor of podiatric medicine, a doctor of optometry, or a chiropractor, as defined in section 1861(r) of the [Social Security] Act."[261] HHS defines designated health services (DHS) as "any of the following services…payable, in whole or in part, by Medicare…

(1) Clinical Laboratory Services;
(2) Physical Therapy, Occupational Therapy, and Outpatient Speech-Language Pathology Services;
(3) Radiology and Certain Other Imaging Services;
(4) Radiation Therapy Services and Supplies;
(5) Durable Medical Equipment and Supplies;

257 Ibid.
258 Ibid, p. 63536.
259 "Medicare and Medicaid Programs; Physicians' Referrals to Health Care Entities With Which They Have Financial Relationships; Final Rule" Federal Register, Vol. 66, No. 3 (Jan 4. 2001), p. 895.
260 "Limitation on Certain Physician Referrals" 42 U.S.C. 1395nn(a)(1)(A) (2012).
261 "Definitions" 42 C.F.R. § 411.351 (October 1, 2014).

(6) Parenteral and Enteral Nutrients, Equipment, and Supplies;
(7) Prosthetics, Orthotics, and Prosthetic Devices and Supplies;
(8) Home Health Services;
(9) Outpatient Prescription Drugs; and
(10) Inpatient & Outpatient Hospital Services."[262]

Of particular note under Stark is that services provided at an ASC and billed as part of the ACS's facility fee do not constitute DHS—and therefore do not fall under the scope of the Stark law—unless that service falls within the ten types listed above.[263]

HHS defines financial relationship as either: (1) a "direct or indirect ownership or investment interest" in an entity furnishing DHS or (2) a "direct or indirect compensation arrangement" with an entity furnishing DHS.[264]

Prohibitions of physician self-referral are similar to the Anti-Kickback legislation, in that both laws prohibit conduct that induces physicians and other healthcare providers to profit from referring patients to healthcare entities based on financial motives. The difference between the two statutes is that the self-referral prohibition addresses the financial incentives of the physician who makes the referral, and the Anti-Kickback statute is concerned with the financial relationship between healthcare providers and individuals other than physicians.[265] The other important difference between the regulations is that the self-referral prohibitions apply only to Medicare and Medicaid, but the Anti-Kickback legislation applies to all federally-funded healthcare programs.[266]

Regulatory Evolution of the Stark Law

The physician self-referral prohibitions are named after the legislation's chief supporter, Congressman Fortney "Pete" Stark (D-CA). Congressman Stark supported the legislation based on studies indicating that despite the broad scope of the Anti-Kickback statute, self-referrals were prevalent in the healthcare industry.[267] One such study, published by the OIG in 1989, reported on physician investments in healthcare facilities and found that patients at physician-owned laboratories received more services than other Medicare patients.[268] Since then, the Stark law has undergone numerous revisions that have both expanded the scope of the law as well as the exceptions to the law. Of note in this evolution is the Stark IV rule, which refers to the

262 Ibid.
263 "Medicare and Medicaid Programs; Physicians' Referrals to Health Care Entities with Which They Have Financial Relationships" Federal Register, Vol. 66, No. 3, (January 4, 2001), p. 923; "Regulatory Issues in Ambulatory Surgery Center Acquisitions" By Patricia O. Powers & Nora L. Liggett, Waller Lansden Dortch & Davis, LLP, ABA Health eSource, Vol. 9, No. 8, (April 2013), http://www.americanbar.org/content/newsletter/publications/aba_health_esource_home/aba_health_law_esource_1304_powers.html (Accessed 3/10/15).
264 "Financial Relationship, Compensation, and Ownership or Investment Interest" 42 C.F.R. § 411.354(a)(1) (January 1, 2014).
265 "Limitation on Certain Physician Referrals" 42 U.S.C. § 1395nn (2012); "Criminal Penalties for Acts Involving Federal Health Care Programs" 42 U.S.C. § 1320a-7b(b) (2012).
266 Ibid.
267 "Health Care Fraud and Abuse: Practical Perspectives" By Linda A. Baumann, Health Law Section of the American Bar Association, Washington, DC: BNA Books, 2002, p. 52.
268 "Financial Arrangements Between Physicians and Health Care Businesses" By Richard P. Kusserow, Office of Inspector General, May 1989, https://oig.hhs.gov/oei/reports/oai-12-88-01410.pdf (Accessed 3/6/2015), p. iii.

changes made to the Stark law in the 2009 Inpatient Prospective Payment System.[269] Most notably, Stark IV modified the stand in the shoes provision, changed the definition of *entity* and prohibited per-click leasing under four of the exceptions to the Stark law.

Stand in the Shoes

The first *stand in the shoes* provisions were implemented on September 5, 2007, when CMS issued the final rule establishing the Stark II Phase III regulations, which contained many changes that were predicted to have a significant impact on healthcare provider relationships.[270] One requirement, as set out in the Phase I regulations, stipulated that at least two financial relationships between the physician and the DHS entity must exist in order for an indirect compensation arrangement to exist.[271] The Phase III regulations changed the definition of an indirect compensation arrangement so that physician members, employees, and contractors of the physician organization were now deemed to *stand in the shoes* of the physician organization, that is, they would have the same direct compensation arrangement as the physician organization itself.[272] As a result, a hospital that had a contract for professional services with a physician group, which was considered to be an indirect relationship under the Phase I regulations, would now be considered to have a direct compensation arrangement.[273] Under this revision of the rule, a physician organization would no longer be considered an intervening entity for purposes of establishing an indirect compensation arrangement, and arrangements between providers and DHS entities would need to be structured differently to avoid Stark liability.[274] This change applied to physician-owners, physician-employees, and physician-contractors of a physician organization.[275] However, other arrangements, such as an arrangement between a DHS entity, a leasing company, and a physician, would still be analyzed as an indirect compensation arrangement under the Stark Law.[276]

In Stark IV, CMS modified the *stand in the shoes* provision first introduced in Stark II, Phase III for situations in which a physician organization employs *both* physician owners and nonphysician owners. In these circumstances, DHS entities are permitted to treat the nonphysician owners as standing in the shoes of the physician organization so that two different

269 "Medicare Program; Changes to the Hospital Inpatient Prospective Payment Systems and Fiscal Year 2009 Rates; Payments for Graduate Medical Education in Certain Emergency Situations; Changes to Disclosure of Physician Ownership in Hospitals and Physician Self-Referral Rules; Updates to the Long-Term Care Prospective Payment System; Updates to Certain IPPS-Excluded Hospitals; and Collection of Information Regarding Financial Relationships Between Hospitals" Federal Register Vol. 73, No. 161 (August 19, 2008), p. 48434.

270 "Medicare Program; Physicians' Referrals to Health Care Entities with Which They Have Financial Relationships (Phase III); Final Rule" Federal Register Vol.72, No. 171, (September 5, 2007), p. 51012.

271 "Phase III Regulations Result in Dramatic Changes to Stark Law" By J. Kelly Barnes, et al., BNA Health Law Reporter, Vol. 16, No. 40, October 11, 2007, p. 1220-1221.

272 "Medicare Program; Physicians' Referrals to Health Care Entities with Which They Have Financial Relationships (Phase III); Final Rule" Federal Register Vol.72, No. 171, (September 5, 2007), p. 51028.

273 "Phase III Regulations Result in Dramatic Changes to Stark Law" By J. Kelly Barnes, et al., BNA Health Law Reporter, Vol. 16, No. 40, October 11, 2007, p. 1221.

274 "Phase III Regulations Result in Dramatic Changes to Stark Law" By J. Kelly Barnes, et al., BNA Health Law Reporter, Vol. 16, No. 40, October 11, 2007, p. 1221.

275 "Medicare Program; Physicians' Referrals to Health Care Entities with Which They Have Financial Relationships (Phase III); Final Rule" Federal Register Vol.72, No. 171, (September 5, 2007), p. 51028.

276 Ibid, p. 51028-51029.

compensation analyses are not required.[277] Exempted from the Stark IV provisions are arrangements that meet the requirements of the academic medical centers exception.[278]

Expansion of "Entity" to Include Under Arrangement Service Providers

Stark IV also modified the legal permissibility of *under arrangement transactions* such that both the *physician-owned entity* that *provides the service*, as well as the *enterprise* (typically the hospital) that *bills for the service*, are considered DHS entities for purposes of *Stark Law*.[279] This provision precludes *physician-owned entities* from performing services under arrangement with the hospital unless the *physician-owned entity* can satisfy one of the *ownership exceptions* under Stark. Specifically, any *physician-owned entity* that performs a service under arrangement for a hospital that is then billed by that hospital is considered a DHS entity, even if that physician-owned entity would not have been considered a DHS entity if the service was performed outside of the hospital setting. The only exception to the Stark IV prohibitions against under arrangements is for lithotripsy services, a procedure to break up stones in urinary organs.[280] Additionally, those physician-owned entities that fall within the Stark rural provider exception will generally survive scrutiny.

Prohibition of "Per-Click" Arrangements and Percentage-Based Rent

Stark IV also modified the exceptions for space and equipment leases, fair market value compensation, and indirect compensation arrangements to prohibit basing the charge for rented space and equipment on a *per-click*, or per-unit basis.[281] Accordingly, physicians and DHS entity lessors may not charge physician lessees rent based on the number of services provided by the lessees that are referred to them by the lessors. CMS concluded that on-demand time-based rental arrangements were also considered per-click arrangements for purposes of the Stark IV prohibitions.[282]

Similarly, Stark IV also prohibited calculating rental charges based on a percentage of revenues earned in the rented space or with the rented equipment, regardless of whether the services were referred from the lessor.[283] Excluded from this prohibition are arrangements in which physicians pay on a percentage basis for management and billing services.[284] CMS also stated that the rule would not prohibit gainsharing arrangements as long as they are properly structured incentive payment and shared saving programs.[285]

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277 "Medicare Program; Changes to the Hospital Inpatient Prospective Payment Systems and Fiscal Year 2009 Rates; Payments for Graduate Medical Education in Certain Emergency Situations; Changes to Disclosure of Physician Ownership in Hospitals and Physician Self-Referral Rules; Updates to the Long-Term Care Prospective Payment System; Updates to Certain IPPS-Excluded Hospitals; and Collection of Information Regarding Financial Relationships Between Hospitals" Federal Register, Vol.73, No.161 (August 19, 2008), p. 48693.

278 Ibid.

279 Ibid, p. 48731.

280 "Medicare Program; Changes to the Hospital Inpatient Prospective Payment Systems and Fiscal Year 2009 Rates; Final Rule," Federal Register Vol. 73, No. 161 (Aug. 19, 2008), p. 48729; "Lithotripsy" Medline Plus Medical Encyclopedia, U.S. National Library of Medicine, National Institutes of Health December 18, 2009, http://www.nlm.nih.gov/medlineplus/ency/article/007113.htm (Accessed 8/17/12).

281 "Stark Rule Proposals Finalized" By Cathy Dunlay and Kevin Hilvert, Schottenstein Zox & Dunn, August 13, 2008, http://www.szd.com/resources.php?NewsID=1184&method=unique (Accessed 8/14/08), p. 2-3.

282 "Medicare Program; Changes to the Hospital Inpatient Prospective Payment Systems and Fiscal Year 2009 Rates; Final Rule," Federal Register Vol. 73, No. 161 (Aug. 19, 2008), p. 48719.

283 Ibid, p. 48709.

284 Ibid, p. 48710.

285 Ibid, p. 48711.

Exceptions to Stark Law

The very broad prohibition of physician self-referrals is limited by a number of statutory exceptions. The exceptions are intended to promote practice integration and to protect arrangements in which there is little risk of abuse.[286] Similar to concerns on the restrictive nature of the Anti-Kickback statute, Congress intended to protect group practices to avoid loss of integration.[287] There are thirty-six total exceptions to the Stark law, and the statute gives the secretary of HHS the authority to promulgate additional exceptions.[288] A significant difference between the Anti-Kickback legislation and Stark is that, under Stark, any financial relationship between a healthcare entity and a physician must fall within one of the statutory or regulatory exceptions in order to avoid scrutiny.[289]

The thirty-six exceptions to the Stark law are divided into smaller subsets based on certain categories of applicability, to wit: (1) exceptions that apply to both ownership/investment interests and compensation arrangements;[290] (2) exceptions that apply to only ownership/ investment interests;[291] and (3) exceptions that apply to only compensation arrangements.[292] Exceptions that apply to both ownership/investment interests and compensation agreements include exceptions for:

(1) Physician services;
(2) In-office ancillary services;
(3) Services furnished by organization to enrollee of health plan;
(4) Academic medical centers;
(5) Implants furnished by an ASC;
(6) EPO and other dialysis-related drugs;
(7) Preventative screening tests, immunizations, and vaccines;
(8) Eyeglasses and contact lenses following cataract surgery; and
(10) Intra-family rural referrals.[293]

Exceptions that apply to only ownership or investment interests include exceptions for:

(1) Publicly traded securities;
(2) Mutual funds; and
(3) Specific providers (for example, rural providers, hospitals located in Puerto Rico, and whole hospital ownership).[294]

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286 "Health Law: Cases, Materials and Problems" By Barry R. Furrow et al., Seventh Edition, St. Paul, MN: West Publishing, 2013, p. 1146.
287 "Medicare and Medicaid Programs; Physicians' Referrals to Health Care Entities With Which They Have Financial Relationships; Final Rule" Federal Register Vol. 66, No. 3 (January 4. 2001), p. 895.
288 "General Exceptions to the Referral Prohibition Related to both Ownership/Investment and Compensation" 42 C.F.R. §§ 411.355-411.357 (October 1, 2014); "Limitation on Certain Physician Referrals" 42 U.S.C. § 1395nn (2012).
289 "Health Care Fraud and Abuse: Practical Perspectives" By Linda A. Baumann, Health Law Section of the American Bar Association, Washington, DC: BNA Books, 2002, p. 106.
290 "General Exceptions to the Referral Prohibition Related to both Ownership/Investment and Compensation" 42 C.F.R. § 411.355 (October 1, 2014).
291 "Exceptions to the Referral Prohibition Related to Ownership or Investment Interests" 42 C.F.R. § 411.356 (October 1, 2014).
292 "Exceptions to the Referral Prohibition Related to Compensation Arrangements" 42 C.F.R. § 411.357 (October 1, 2014).
293 "General Exceptions to the Referral Prohibition Related to both Ownership/Investment and Compensation" 42 C.F.R. § 411.355 (October 1, 2014).
294 "Exceptions to the Referral Prohibition Related to Ownership or Investment Interests" 42 C.F.R. § 411.356 (October 1, 2014).

There are a total of thirty-six exceptions to the Stark law, and the secretary of HHS has the authority to promulgate additional exceptions.

42 C.F.R. §§ 411.355-411.357; 42 U.S.C. § 1395nn.

Exceptions that apply to only compensation relationships include exceptions for the following situations, described in Exhibit 3-2, below:

Exhibit 3-2: Stark Exceptions relating to Compensation Relationships[295]

Rental of office space	Medical staff incidental benefits
Rental of equipment	Risk sharing arrangements
Bona fide employment relationships	Compliance training
Personal service arrangements	Indirect compensation arrangements
Physician recruitment	Referral services
Isolated transactions	Obstetrical malpractice insurance subsidies
Certain arrangements with hospitals	Professional courtesy
Group practice arrangements with a hospital	Retention payments in underserved areas
Payments by a physician	Community-wide health information systems
Charitable donations by a physician	Electronic prescribing items and services
Nonmonetary compensation	Electronic health records and services
Fair market value compensation	

Further, the *whole hospital exception* allowed physicians to refer patients to hospitals in which they have an ownership interest so long as the physicians are authorized to perform services at the hospital and the *ownership or investment interest is in the **entire** hospital*.[296] Like the Anti-Kickback statute, many of these exceptions under the Stark law incorporate the traditional concept of FMV and the separate and distinct threshold of *commercial reasonableness*. These concepts and thresholds are discussed more thoroughly in the Physician Compensation Restrictions section below.

ACA Restrictions on Stark "Whole Hospital" Exception

The ACA included a set of requirements that significantly narrowed the applicability of the whole hospital exception and rural hospital exception for most hospitals.[297] In response to this statutory mandate, CMS released two Final Rules to implement the ACA provisions. CMS's first Final Rule, which was published on November 24, 2010, promulgated restrictions for the use of the whole hospital exception as well as the requirements for obtaining *grandfather status.*[298] CMS's second Final Rule, which was published November 30, 2011,[299] established the exemption application process for physician-owned hospitals in existence prior December 31,

295 "Exceptions to the Referral Prohibition Related to Compensation Arrangements" 42 C.F.R. § 411.357 (October 1, 2014).
296 "Limitation on Certain Physician Referrals" 42 U.S.C. § 1395nn(d)(3) (2009).
297 "A Guide to Complying with Stark Physician Self-Referral Rules" By Frances R. Fernald, Washington, D.C.: Atlantic Information Services, Inc., 2010, p. 400:216-400:218.
298 "Medicare Program: Hospital Outpatient Prospective Payment System and CY 2011 Payment Rates; Ambulatory Surgical Center Payment System and CY 2011 Payment Rates; Payments to Hospitals for Graduate Medical Education Costs; Physician Self-Referral Rules and Related Changes to Provider Agreement Regulations; Payment for Certified Registered Nurse Anesthetist Services Furnished in Rural Hospitals and Critical Access Hospitals; Final Rule" Federal Register, Vol. 75, No. 226 (November 24, 2010) p. 72240-72241.
299 "Medicare and Medicaid Programs: Hospital Outpatient Prospective Payment; Ambulatory Surgical Center Payment; Hospital Value-Based Purchasing Program; Physician Self-Referral; and Patient Notification Requirements in Provider Agreements; Final Rule" Federal Register, Vol. 76, No. 230 (November 30, 2011) p. 74523.

2010 that were considering facility expansion.[300] However, CMS's second Final Rule stated that expansions may only be granted for a facility's main campus and that reviews are subject to community input as mandated by the ACA.[301] Prior to the ACA's restriction on physician ownership and investment in hospitals, the *Medicare Prescription Drug, Modernization, and Improvement Act of 2003* (MMA) placed a temporary 18-month moratorium on the development of new physician-owned specialty/surgical hospitals, which officially ended on June 8, 2005.[302]

By narrowing both the whole hospital and rural provider exceptions, the ACA indirectly prohibits the establishment of physician-owned hospitals that were not Medicare-certified by December 31, 2010.[303] To avoid this prohibition, hospitals with a Medicare Provider Agreement prior to December 31, 2010, can be granted *grandfather status* and allowed to continue to participate in Medicare if the following five criteria are met:

(1) The hospital is located in a county with a population growth rate of at least 150 percent of the state's population growth over the last five years;
(2) The hospital has a Medicaid inpatient admission percentage of at least the average of all hospitals in the county;
(3) The hospital does not discriminate against beneficiaries of Federal health care programs;
(4) The hospital is located in a state with below-national-average bed capacity; and
(5) The hospital has a bed occupancy rate greater than state average.[304]

Even if physician-owned hospitals are granted *grandfather status*, these hospitals are nevertheless subject to further restrictions contained in the final rules. In particular, physician-owned hospitals that are granted *grandfather status* are restricted on the total percentage in which individual physicians may own or invest in a hospital, while its existing, invested physicians are limited to their individual ownership or investment percentages as of March 23, 2010.[305] Additionally, if a grandfathered physician-owned hospital is approved for an exception to the expansion limits, the physician-owned hospital may not grow more than 200 percent from its baseline number of operating rooms, procedure rooms, and beds.[306]

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300 Ibid, p. 74518-74525.

301 "Medicare and Medicaid Programs: Hospital Outpatient Prospective Payment; Ambulatory Surgical Center Payment; Hospital Value-Based Purchasing Program; Physician Self-Referral; and Patient Notification Requirements in Provider Agreements; Final Rule" Federal Register Vol. 76, No. 230 (November 30, 2011), p. 74523-74524; "Patient Protection and Affordable Care Act" Pub. L. No. 111-148, § 6001, 124 Stat. 119, 687-688 (March 23, 2010).

302 "The Medicare Prescription Drug, Modernization, and Improvement Act of 2003" Pub. L. No. 108-173, § 507, 117 Stat. 2066, 2295 (December 8, 2003).

303 "Patient Protection and Affordable Care Act, Sec. 6001" Pub. Law 111-148, 124 Stat. 119,684-89 (March 23, 2010), as amended by "Health Care and Education Reconciliation Act, Sec.1106" Pub. Law 111-152, § 1106, 124 Stat. 1029, 1049-50 (March 30, 2010). [The HCERA changes the effective date to December 31, 2010.] "Physician Ownership of Hospitals Significantly Impacted by Health Care Reform Legislation" By Craig A. Conway, J.D., LL.M., Health Law & Policy Institute, University of Houston Law Center, http://www.law.uh.edu/healthlaw/perspectives/2010/%28CC%29%20Stark.pdf (Accessed 3/11/15) p. 2.

304 "Patient Protection and Affordable Care Act" Pub. L. No. 111-148, § 6001, 124 Stat. 119, 684-689 (March 23, 2010), as amended by "Health Care and Education Reconciliation Act" Pub. L. No. 111-152, § 1106, 124 Stat. 1029, 1049-1050 (March 30, 2010).

305 "Medicare Program: Hospital Outpatient Prospective Payment System and CY 2011 Payment Rates; Ambulatory Surgical Center Payment System and CY 2011 Payment Rates; Payments to Hospitals for Graduate Medical Education Costs; Physician Self-Referral Rules and Related Changes to Provider Agreement Regulations; Payment for Certified Registered Nurse Anesthetist Services Furnished in Rural Hospitals and Critical Access Hospitals; Final Rule" Federal Register Vol. 75, No. 226 (November 24, 2010), p. 72242.

306 "Medicare and Medicaid Programs: Hospital Outpatient Prospective Payment; Ambulatory Surgical Center Payment; Hospital Value-Based Purchasing Program; Physician Self-Referral; and Patient Notification Requirements in Provider Agreements; Final Rule" Federal Register Vol. 76, No. 230 (November 30, 2011), p. 74524.

Stark Self-Referral Disclosure Protocol

In recent years, CMS has increased both its level of enforcement and its auditing efforts for federal *fraud and abuse* laws, which has led to the recovery of billions of dollars in civil and criminal penalties.[307] As part of its increasing levels of fraud and abuse scrutiny, CMS has shifted away from its traditional *pay and chase* auditing method, instead implementing new technology and programs to recover additional funds, e.g., using *predictive modeling software*, and identify fraudulent billings before payments are disbursed.[308] CMS has also established a method for providers to voluntarily report their own violations in exchange for lesser sanctions. Promulgated by the ACA, the *Self-Referral Disclosure Protocol* (SRDP) serves as a *reporting mechanism* for providers who suspect that they may be in violation of the *Stark Law* to *voluntarily disclose* their conduct in exchange for *reduced financial liability*.[309] As of March 2015, 69 SDRP settlements have been published, with several of the voluntary disclosing providers having been assessed a mere fraction of their potential Stark liability.[310]

In addition to the federal *Stark Law* prohibitions, forty-two states and the District of Columbia have laws prohibiting *limiting self-referrals*.[311]

CIVIL MONETARY PENALTIES

The Social Security Act (SSA) § 1128 gives the Secretary of HHS authorization to seek civil monetary penalties (CMPs) against physicians, hospitals, and other healthcare providers that violate any fraud and abuse laws related to the Federal healthcare programs. According to the SSA, HHS's OIG can seek different amounts and types of CMPs depending on the type and severity of the violation. Most CMP cases are settled without a final judgment; otherwise, an administrative law judge will issue a decision that is appealable.[312] Furthermore, OIG encourages self-disclosure of potential fraudulent behavior, and any self-disclosures and cooperation are taken into account when determining CMPs against a party.[313]

Gainsharing

The gainsharing component of the CMP regulation provides civil penalties against a hospital if the hospital knowingly makes a payment, directly or indirectly, to a physician as an inducement to reduce or limit services provided with respect to individuals who are entitled to Medicare or

307 "Inspector General: Audits, Legal Actions May Net Up to $3.4 Billion" Office of Inspector General, June 1, 2011, http://oig.hhs.gov/newsroom/news-releases/2011/sar_release.asp (Accessed 11/18/11).

308 "Is There A Statistician In The House?" By Allyson Jones Labban, Smith Moore Leatherwood, Health Care Law Note, July 2011, http://www.healthcarelawnote.com/articles/2011/201107.asp (Accessed 8/8/12); "From 'Pay and Chase' to 'Catch and Keep:' CMS to Introduce Anti-Fraud Predictive Modeling July 1" Bradley Arant Boult Cummings LLP, June 28, 2011, http://www.babc.com/files/Uploads/Documents/Health%20Care%20Alert_June%2028%202011.pdf (Accessed 8/8/12).

309 "Patient Protection and Affordable Care Act" Pub. L. No. 111-148, § 6409. 124 Stat. 119, 772-773 (March 23, 2010); "Self-Referral Disclosure Protocol" Centers for Medicare & Medicaid Services, December 27, 2011 https://www.cms.gov/PhysicianSelfReferral/98_Self_Referral_Disclosure_Protocol.asp#TopOfPage (Accessed 02/10/12).

310 "Self-Referral Disclosure Protocol Settlements" Centers for Medicare & Medicaid Services, http://www.cms.gov/Medicare/Fraud-and-Abuse/PhysicianSelfReferral/Self-Referral-Disclosure-Protocol-Settlements.html# (Accessed 3/6/15).

311 For an in-depth discussion of state self-referral prohibitions, see the Anti-Kickback and Self-Referral Laws section below.

312 "Civil Monetary Penalties and Affirmative Exclusions" Office of Inspector General, U.S. Department of Health and Human Services, http://oig.hhs.gov/fraud/enforcement/cmp/background.asp (Accessed 2/26/2015).

313 Ibid.

Medicaid or are under the direct care of the physician.[314] Furthermore, it provides civil penalties against a physician if the physician knowingly accepts receipt of any payments described above.[315] Recently, the statute was amended such that only payments to limit or reduce *medically necessary* services would result in civil penalties, effective April 16, 2015.[316]

Beneficiary Inducement

The beneficiary inducement component of the CMP regulation provides civil penalties in instances where an individual or entity transfers compensation to an individual eligible for Medicare or Medicaid that the transferring individual or entity knows or should know is likely to influence the eligible individual to order or receive from a particular provider any item or service for which payment may be made under Medicare or Medicaid.[317] Together, these regulations expand hospital and physician fraud and abuse liability beyond what may typically be enforced through the Anti-Kickback Statute and Stark law, and, as such, physicians and hospitals should attempt to structure arrangements so as to comply with CMP provisions.

CMS Reimbursement Monitoring Programs

Within the past ten years, CMS has instituted several *fraud and abuse* monitoring programs that *review*, or *audit*, reimbursements to providers for submitted *Medicare and Medicaid* claims. CMS initiated *Medicare and Medicaid payment audits* to identify fraudulent billing practices and recoup claim reimbursements based on fraud; once uncovered, providers may be subject to *repayment, regulatory sanctions, and civil fines*. Most allegations are resolved through negotiation and settlement with the OIG before a formal hearing occurs; however, providers have the right to appeal determinations made by OIG.[318] The Medicare recovery audit programs have recovered $7.4 billion in improper payments made by the Medicare program between 2010 and the first quarter of 2014.[319]

Recovery Audit Contractors (RACs)

Promulgated by the *Medicare Modernization Act of 2003 (MMA)* as a three-year demonstration project beginning in 2005, the *RAC program* is now a permanent monitoring program within CMS that is tasked with improving payment accuracy and increasing program transparency. RACs perform this function by identifying improper Medicare *overpayments* and *underpayments* to providers based on three categories of errors: (1) payment for *medically unnecessary services*; (2) payment for *incorrectly coded services*; and (3) payment for *services not supported by*

314 "Civil Monetary Penalties" 42 U.S.C. § 1320a-7a(b)(1) (2014).
315 "Civil Monetary Penalties" 42 U.S.C. § 1320a-7a(b)(2) (2014).
316 "Medicare Access and CHIP Reauthorization Act of 2015" H.R. 2, 114th Congress, § 512 (January 6, 2015); "Summary: H.R.2—114th Congress (2015-2016)" Library of Congress, 2015, https://www.congress.gov/bill/114thcongress/housebill/2 (Accessed 4/22/2015). The revision applies to payments made on or after the date of the enactment of the act, which was signed into law on April 16, 2015.
317 "Civil Monetary Penalties" 42 U.S.C. § 1320a-7a(a)(5) (2014).
318 "Civil Monetary Penalties and Affirmative Exclusions" Office of Inspector General, http://oig.hhs.gov/fraud/enforcement/cmp/index.asp (Accessed 11/18/2011).
319 "CMS Efforts to Reduce Improper Payments in the Medicare Program" By Shantanu Agrawal, M.D., To Subcommittee on Energy Policy, Health Care and Entitlements, Committee on Oversight and Government Reform, House of Representatives, Washington, D.C.: Department of Health & Human Services, May 20, 2014, p. 7.

sufficient documentation.[320] An *overpayment* occurs when CMS reimburses a provider an excess amount for a given claim, resulting in a provider owing Medicare the overpaid amount. Conversely, an *underpayment* occurs when the Medicare reimbursement received by a provider is less than the cost of providing care, resulting in Medicare owing the provider additional reimbursement funds.[321] RAC reviews are becoming increasingly common for providers. A recent report from the *Government Accountability Office* (GAO) noted that, on a national level, RACs reviews increased from 1,358,097, in fiscal year 2011, to 2,107,455, in fiscal year 2012, representing an increase of 55%.[322] Further, RACs are required to refer potential cases of healthcare fraud to CMS, which serves as another method for federal authorities to identify fraud and abuse.[323] Because of the increasing prevalence of RAC audits and their use to identify fraud and abuse, physicians and other providers should be aware of their potential impact on the revenue cycle.

Audit Medicaid Integrity Contractors (Audit MICs)

In a March 2012 report titled "*Early Assessment of Audit Medicaid Integrity Contractors,* the OIG assessed the efforts of the *Medicaid Integrity Contractors* (MICs), which conduct "*post-payment audits*" on reimbursements to providers in the Medicaid program, as part of its examination of the effectiveness of the *Medicaid Integrity Program*.[324] Of the 370 identified audits conducted through March 2012 (i.e., identifying a potential of $80 million in overpayments), 81 percent of those audits were unable, or unlikely, to discover overpayments to Medicaid providers.[325] The remaining 11 percent of the 370 audits accounted for *$6.9 million in overpayments*, $6.2 million of which were attributed to program areas that had previously been identified as vulnerable to *overpayments.*[326] The OIG concluded that the MICs' audits were hindered by CMS's selection of poorly identified *audit targets*, as MICs are not contracted to identify targets for potential fraud, but to audit targets provided to them by CMS.[327] The *March 2012 Report* further indicated that *audit targets* were mistakenly selected, due either to incorrect data or the improper application of state policies for identifying audit targets.[328] As CMS refines its MIC program, physicians may expect an increase in audits from these contractors in ways similar to the increase in RAC audits.

320 "Implementation of Recovery Auditing at the Centers for Medicare and Medicaid Services: FY 2010 Report to Congress" By Centers For Medicare & Medicaid Services, To U.S. Congress, Washington, D.C., 2011, p. 2.
321 "Implementation of Recovery Auditing at the Centers for Medicare and Medicaid Services: FY 2010 Report to Congress" By Centers For Medicare & Medicaid Services, To U.S. Congress, Washington, D.C., 2011, p. 2; "Underpayment By Medicare and Medicaid Factsheet" American Hospital Association, December 2010, http://www.aha.org/content/00-10/10medunderpayment.pdf (Accessed 12/1/11).
322 "Medicare: Further Action Could Improve Improper Payment Prevention and Recoupment Efforts" By Kathleen M. King, To Subcommittee on Energy Policy, Health Care and Entitlements, Committee on Oversight and Government Reform, House of Representatives, Washington, D.C.: United States Government Accountability Office, May 20, 2014, p. 13.
323 "Statement of Work for the Recovery Audit Program" Centers for Medicare & Medicaid Services, https://www.cms.gov/Research-Statistics-Data-and-Systems/Monitoring-Programs/recovery-audit-program/downloads/090111RACFinSOW.pdf (Accessed 3/10/15) p. 29.
324 "National Medicaid Audit Program" Centers for Medicare & Medicaid Services, November 2012, http://www.cms.gov/medicare-medicaid-coordination/fraud-prevention/provider-audits/downloads/mip-audit-fact-sheet.pdf (Accessed 3/6/15); "Early Assessment of Audit Medicaid Integrity Contractors" By Daniel R. Levinson, Office of the Inspector General, March 2012, OEI-05-10-00210, p. 1.
325 "Early Assessment of Audit Medicaid Integrity Contractors" By Daniel R. Levinson, Office of the Inspector General, March 2012, OEI-05-10-00210, p. 17.
326 "Early Assessment of Audit Medicaid Integrity Contractors" By Daniel R. Levinson, Office of the Inspector General, March 2012, OEI-05-10-00210, p. 17.
327 Ibid, p. 11-12.
328 Ibid, p. 11-12.

Comprehensive Error Rate Testing (CERT) Program

CMS created the *Comprehensive Error Rate Testing* (CERT) program to determine improper *Medicare fee-for-service payments*, a critical step in identifying the scope of fraud and abuse in the Medicare program.[329] CMS provides data obtained through the *CERT program* to Congress, giving Congress an estimate of the annual amount of improper Medicare payments made to providers during a given year. However, a March 2012 OIG report entitled, *Review of CERT Errors Overturned Through the Appeals Process for Fiscal Years 2009 and 2010*, suggested that this estimate *did not account* for any *payment errors* that were *overturned through the appeals process* and may, therefore, have *inflated* the number of improper payments made in a given year.[330] Error rate data discovered by the CERT program, particularly data relating to claims or providers with a "high propensity for error," can provide insight into claim types likely to be reviewed by RACs in the future.[331]

Medicare-Medicaid (Medi-Medi) Data Match Program

CMS operates the *Medicare-Medicaid (Medi-Medi) Data Match Program* to allow state and federal collaboration to identify areas of potential fraud, abuse, and waste in Medicare and Medicaid billing.[332] The *Medi-Medi* program initially started in 2001 as a *pilot program* in one state and expanded significantly over the course of a decade, garnering annual funding of $60 million over the past several years.[333] The goal of the program is to *analyze Medicare and Medicaid claims data collectively* to better identify potentially fraudulent billing activities that may be missed when analyzing *Medicare* and *Medicaid* claims data separately.[334] State participation in the *Medi-Medi* program is voluntary, and states must fund their own program.[335] Physicians should note if their state of licensure participates in this program and, if so, may find it beneficial to use program data to examine its own billing practices.

PHYSICIAN COMPENSATION RESTRICTIONS

Generally

Many different healthcare transactions, e.g., physician compensation arrangements, medical directorships, and lease agreements, are scrutinized under the traditional concept of FMV and the

329 "Comprehensive Error Rate Testing (CERT)" Centers for Medicare & Medicaid Services, May 15, 2012, http://www.cms.gov/Research-Statistics-Data-and-Systems/Monitoring-Programs/CERT/index.html?redirect=/CERT/ (Accessed 5/23/12); "Review of CERT Errors Overturned Through the Appeals Process for Fiscal Years 2009 and 2010" By Daniel R. Levinson, Office of the Inspector General, March 2012, A-01-11-00504, p. 1.

330 "Review of CERT Errors Overturned Through the Appeals Process for Fiscal Years 2009 and 2010" By Daniel R. Levinson, Office of the Inspector General, March 2012, A-01-11-00504, p. 1.

331 "Statement of Work for the Recovery Audit Program" Centers for Medicare & Medicaid Services, https://www.cms.gov/Research-Statistics-Data-and-Systems/Monitoring-Programs/recovery-audit-program/downloads/090111RACFinSOW.pdf (Accessed 3/10/15) p. 1.

332 "The Medicare-Medicaid (Medi-Medi) Data Match Program" By Daniel R. Levinson, Office of the Inspector General, April 2012, OEI-09-08-00370, p. 1, citing; "Medicare Program Integrity Manual, Chapter 4, Section 4.2" Centers for Medicare & Medicaid Services, September 30, 2011.

333 "The Medicare-Medicaid (Medi-Medi) Data Match Program" By Daniel R. Levinson, Office of the Inspector General, April 2012, OEI-09-08-00370, p. 1-2.

334 Ibid, p. 1.

335 Ibid, p. 17.

separate and distinct threshold of *commercial reasonableness*.[336] Under federal *fraud and abuse* laws, healthcare transactions must be simultaneously at FMV and also *commercially reasonable* in order to be deemed legally permissible. A failure to meet these two thresholds may result in Stark or Anti-Kickback violations and may also lead to FCA violations if the healthcare provider knowingly submits a claim for reimbursement to a government entity for services under impermissible compensation arrangements.[337]

> Compensation arrangements for physician and executive services must be both at FMV and commercially reasonable to avoid liability under the Stark law, the Anti-Kickback statute, and the FCA.
>
> ***Lewis Lefko, Jan. 24, 2008.***

The test for commercial reasonableness is a threshold that is related but distinct from that of the standard of FMV. FMV looks to the reasonableness of the "*range of dollars*" paid for a product or service; the standard of commercial reasonableness looks to the *reasonableness of the business arrangement generally*.[338]

Definitions of Fair Market Value

Federal fraud laws define *fair market value* somewhat differently than it is defined by traditional business valuation principles. Under Stark II Phase I, the Health Care Financing Administration (HCFA; now CMS) defined FMV as "the value in arm's-length transactions, consistent with the general market value."[339]

General market value is defined as:

> "[T]he price that an asset would bring as a result of bona fide bargaining between well-informed buyers and sellers who are not otherwise in a position to generate business for the other party, or the compensation that would be included in a service agreement as a result of bona fide bargaining between well-informed parties to the agreement who are *not otherwise in a position to generate business for the other party*, on the date of acquisition or the asset or at the time of the service agreement."[340] [Emphasis added].

Elaborating on that definition in 2001, HCFA provided the following guidance for determining when a payment for services provided is at FMV:

> "We believe the relevant comparison is aggregate compensation paid to physicians practicing in similar academic settings located in similar environments. Relevant factors include geographic location, size of the academic institutions, scope of clinical and academic programs offered, and the nature of the local health care marketplace... we

336 "All Eyes on Physician-Hospital Arrangements," By Lewis Lefko, HealthLeaders Media, Jan. 24, 2008, www.healthleadersmedia.com (Accessed September 18, 2008).
337 "False Claims" 31 U.S.C. § 3729(a) (2009); "United States of America v. Peter Rogan" 459 F.Supp. 2d 692, 717 (N.D. Ill. 2006); the impact of fraud and abuse regulation on structuring physician compensation plans is discussed further in *Compensation and Income Distribution* in *Consulting with Professional Practices*.
338 "Tread Carefully When Setting Fair Market Value: Stark Law Must Be Considered" By Joyce Frieden, OB/GYN News, Vol. 38, No. 2 (November 1, 2003), p. 26, http://findarticles.com/p/articles/mi_m0CYD/is_21_38/ai_110804605/ (Accessed 05/17/10).
339 "Medicare and Medicaid Programs; Physicians' Referrals to Health Care Entities with Which They Have Financial Relationships, Federal Register, Vol. 66, No. 3 (January 4, 2001), p. 944.
340 "Financial Relationships Between Physicians and Entities Furnishing Designated Health Services; Definitions" 42 C.F.R § 411.351 (2014).

> intend to accept any method [for establishing FMV] that is commercially reasonable and provides us with evidence that the compensation is comparable to what is ordinarily paid for an item or service in the location at issue, by parties in arm's-length transactions who are not in a position to refer to one another... The amount of documentation that will be sufficient to confirm FMV... will vary depending on the circumstances in any given case; that is, there is no rule of thumb that will suffice for all situations."[341]

In 2004, CMS noted that valuation methods under Stark law, "must exclude valuation where the parties to the transaction are at arm's-length but in a position to refer each other."[342] Because FMV under Stark law does not "necessarily comport with the usage of the term in standard valuation techniques and methodologies," a purely market-driven determination of FMV may not always be considered commercially reasonable for the purposes of federal fraud laws.[343] For example, even if an arrangement meets traditional FMV standards, if it does not meet commercial reasonableness standards, it may not withstand scrutiny under Stark.

In the Stark II Phase II legislation, dated March 2004, CMS stated that it "will consider a range of methods of determining [FMV] and that the appropriate method will depend on the nature of the transaction, its location, and other factors."[344] Additionally in the Stark II Phase II legislation, CMS created a voluntary safe harbor provision within the regulatory definition of FMV for hourly payments to physicians for their personal services, which could have been used with regard to any hourly compensation paid by any DHS entity.[345] Under the FMV safe harbor, there were two methodologies that would result in an hourly arrangement being considered to be at FMV: (1) when the physician's hourly rate is less than or equal to the hourly rate for emergency room physician services in the relevant geographic market (provided there are at least three hospitals with emergency rooms) or (2) when the physician's hourly rate is calculated by averaging the 50th percentile of the national compensation level for physicians with the same specialty (or general practice if specialty is not identified) in at least four of six listed salary surveys, then dividing that figure by 2,000 hours.[346] Subsequently, the United States Appellate Court for the D.C. Circuit discerned in *Renal Physicians Association v. HHS* that these two safe harbor tests would also result in the consideration of an agreement being presumptively reasonable.[347]

Concerns about the impracticality and infeasibility of the CMS FMV voluntary safe harbor forced CMS to eliminate that provision in the September 2007 Stark II Phase III rule. At that time, however, CMS emphasized that it planned to continue to scrutinize the FMV of arrangements and indicated that "[p]arties to a transaction may calculate FMV 'using any

341 "Medicare and Medicaid Programs; Physicians' Referrals to Health Care Entities with Which They Have Financial Relationships, Federal Register, Vol. 66, No. 3 (January 4, 2001), p.916, 944.

342 "Medicare Program; Physicians' Referrals to Health Care Entities with Which They Have Financial Relationships (Phase II) Federal Register, Vol. 69, No. 59 (March 26, 2004) p. 16107.

343 "Medicare Program; Physicians' Referrals to Health Care Entities with Which They Have Financial Relationships (Phase II) Federal Register, Vol. 69, No. 59 (March 26, 2004) p. 16107; "Successful Medical Practice Valuation" By Reed Tinsley, Physician's News Digest, July 2008, http://www.physiciansnews.com/business/708tinsley.html (Accessed 9/19/2008).

344 "Medicare Program; Physicians' Referrals to Health Care Entities with Which They Have Financial Relationships (Phase II) Federal Register, Vol. 69, No. 59 (March 26, 2004) p. 16107.

345 "Financial Relationships Between Physicians and Entities Furnishing Designated Health Services; Definitions" 42 C.F.R § 411.351 (2014); "Medicare Program; Physicians' Referrals to Health Care Entities with Which They Have Financial Relationships (Phase II) Federal Register, Vol. 69, No. 59 (March 26, 2004) p. 16092.

346 "Medicare Program; Physicians' Referrals to Health Care Entities with Which They Have Financial Relationships (Phase II) Federal Register, Vol. 69, No. 59 (March 26, 2004) p. 16092.

347 "Renal Physicians Association v. U.S. Department of Health and Human Services et al." 489 F.3d 1267, 1269-1270 (D.C. Cir. 2007).

commercially reasonable methodology that is appropriate under the circumstances and otherwise fits [within] the definition' of FMV for purposes of Stark."[348]

Further, in the Stark II Phase III provisions, CMS stated, in response to a request for confirmation as to whether a FMV hourly rate could be used to compensate physicians for both physician clinical and administrative services and whether that hourly rate could be used to determine an annual salary, that:

> "A fair market value hourly rate may be used to compensate physicians for both administrative and clinical work, provided that the rate paid for clinical work is fair market value for the clinical work performed and the rate paid for administrative work is fair market value for the administrative work performed We note that the fair market value of administrative services may differ from the…value of clinical services. A fair market value hourly rate may be used to determine an annual salary, provided that the multiplier used to calculate the annual salary accurately reflects the number of hours actually worked by the physician."[349]

FMV is also an important requirement under several Anti-Kickback safe harbors.[350] Although FMV is not specifically defined within the Anti-Kickback statute,[351] the OIG has provided guidance on this issue and stated in Thornton's widely circulated 1992 letter (see the Thornton Letter—Office of the Inspector General section above).

Definitions of Commercial Reasonableness

HHS has interpreted *commercially reasonable* to mean that an arrangement appears to be "a sensible, prudent business agreement, from the perspective of the particular parties involved, even in the absence of any potential referrals."[352] The Stark II Phase II commentary also suggests that, "an arrangement will be considered 'commercially reasonable' in the absence of referrals if the arrangement would make commercial sense if entered into by a reasonable entity of similar type and size and a reasonable physician of similar scope and specialty, even if there were no potential DHS referrals."[353]

When determining the commercial reasonableness of a compensation arrangement, one should consider: (1) if it is necessary to have a physician perform a certain service and (2) if it is necessary to have a *physician of that specialty* perform a certain service. For example, the FMV compensation for more specialized physicians and surgeons generally is higher than that of general practitioners and nonphysician practitioners. As a result, if a specialized physician is

348 "Medicare Program; Physicians' Referrals to Health Care Entities with Which They Have Financial Relationships (Phase III); Final Rule" Federal Register, Vol. 72, No. 171 (September 5, 2007) p. 51015.
349 Ibid, p. 51016.
350 "Exceptions" 42 C.F.R. § 1001.952 (2013); "Health Care Compliance Forum" Fair Market Value: The Lawyer's Perspective, By Kimberley Elting, et. al., Jones Day, Arizona, October 25-27, 2006.
351 "Health Care Compliance Forum" Fair Market Value: The Lawyer's Perspective, By Kimberley Elting, et. al., Jones Day, Arizona, October 25-27, 2006.
352 "Medicare and Medicaid Programs; Physicians' Referrals to Health Care Entities with Which They Have Financial Relationships" Federal Register, Vol. 63, No. 6 (January 9, 1998) p. 1700.
353 "Medicare Program; Physicians' Referrals to Health Care Entities with Which They Have Financial Relationships (Phase II) Federal Register, Vol. 69, No. 59 (March 26, 2004) p. 16093.

receiving compensation within the higher range of FMV to perform duties that a less skilled practitioner could perform for less compensation, the arrangement may not be deemed to be commercially reasonable despite the fact that it is within the range of FMV for that specialist. In such situations, there tends to be a *presumption of fraud* unless the healthcare provider can demonstrate that using the physician specialist was *reasonably necessary* for specified reasons (for example, experience) or that the position's requirements could not have been done sufficiently by a less-skilled practitioner.

The IRS has listed several specific factors to weigh in determining the commercial reasonableness of a physician compensation arrangement:

(1) Specialized training and experience of the physician;
(2) The nature of duties performed and the amount of responsibility;
(3) Time spent performing duties;
(4) Size of the organization;
(5) The physician's contribution to profits;
(6) National and local economic conditions;
(7) Time of year when compensation is determined;
(8) Whether the compensation is in part or in whole payment for a business or assets; and
(9) Salary ranges for equally qualified physicians in comparable organizations.[354]

The IRS also will examine the independence of the board or committee that establishes a physician's compensation arrangement.[355]

Specific Application of Fraud Laws to Hospital-Physician Relationships

As discussed in the Recovery Audit Contractors section above, the increased regulatory scrutiny of healthcare transactions often implicates numerous hospital-physician relationships, including physician compensation practices and lease agreements. With regard to FMV under Stark Law and the Anti-Kickback Statute, a 2002 Federal District court stated, "payments exceeding FMV are in effect deemed 'payment for referrals.'"[356] Later courts have evolved from this rigid framework and developed more analytical approaches to determining whether or not a particular hospital-physician relationship will survive fraud and abuse scrutiny. In particular, courts are evaluating, under Stark and the Anti-Kickback Statute, whether *physicians are actually performing the services outlined in the agreement*. In circumstances where the physicians are not actually performing required services or obligated under their agreement, courts have found that the arrangement does not satisfy the commercial reasonableness threshold.[357] For this reason, a typical medical director or physician executive agreement requires that contemporaneous logs are kept documenting the number of actual hours worked, as well as the physician's fulfillment

354 "Physician Compensation Arrangements: Management and Legal Trends" By Daniel K. Zismer, Gaithersburg, MD: Aspen Publishers, Inc., 1999, p. 204; "Reasonable Compensation" By Jean Wright and Jay H. Rotz, in Exempt Organizations Continuing Professional Education, 1993, http://www.irs.gov/pub/irs-tege/eotopici93.pdf (Accessed 3/10/15).
355 "Reasonable Compensation" By Jean Wright and Jay H. Rotz, in Exempt Organizations Continuing Professional Education, 1993, http://www.irs.gov/pub/irs-tege/eotopici93.pdf (Accessed 3/10/15).
356 "American Lithotripsy Society v. Thompson," 215 F.Supp.2d 23, 27 (D.D.C. July 12, 2002).
357 "U.S. ex rel. Roberts v. Aging Care Home Health, Inc., et al.," 474 F.Supp. 2d 810, 818 (W.D. La. Feb. 16, 2007); see also "United States of America v. Peter Rogan" 459 F.Supp. 2d 692, 722 (N.D. Ill. 2006).

of the *tasks, duties, responsibilities, and accountabilities* which are set forth in the compensation agreement for the given position.[358]

McLeod Regional Medical Center

One of the earliest and most widely circulated *qui tam* actions regarding the applicability of the fraud and abuse laws relating to physician compensation is the 1998 case *United States ex rel. Richard Raugh v. McLeod Regional Medical Center of the Pee Dee, Inc., McLeod Physician Services, Inc., D. Laurenece McIntosh, and Ernst and Young, LLP*. Raugh, an *individual whistleblower* under the FCA, and the previous head of the physician network development at McLeod, filed suit against *McLeod Regional Medical Center*, a tax exempt organization, alleging that *McLeod* submitted false claims to Medicare in violation of the *Stark Law* and the *Anti-Kickback statute* related to its purchase of several physician practices and the execution of subsequent employment arrangements. Additionally, the relator alleged that McLeod's purchase of the physician practices exceeded FMV, stating that the compensation paid to the physicians under the terms of the physician employment agreements evidenced intent to buy future referrals, an unlawful practice under the Anti-Kickback statute.[359] Specifically, as the DOJ explained:

> "[t]he claims for services referred, ordered or arranged by those physicians were alleged to be false in three respects: First, Section 1877 of the Social Security Act, 42 USC 139nn (also known as Stark II) prohibited McLeod from billing Medicare for items or services referred or ordered by physicians with whom it had such financial relationships. Second, McLeod forfeited its right to submit those claims to the federal health care programs by paying remuneration intended to induce those and other referrals in violation of the Anti-Kickback Statute, 42 USC 1320a-7(b). And third, McLeod certified falsely on Medicare cost reports that the services identified or summarized were not provided or procured through payment directly or indirectly of a kickback or billed in violation of federal law."[360]

The case settled for $15,485,000 in October 2002.[361] It is of particular note that although the relator was released from criminal and civil liability stemming from his previous role as head of physician network development, he received no financial share of the settlement paid by McLeod.[362]

U.S. v. SCCI Hospital Houston

Another key milestone in the development of the *commercial reasonableness* threshold for purposes of the *Stark Law* is the *U.S. v. SCCI Hospital Houston* case*,* wherein the government's

358 "Fair Market Valuation Report - United States v. SCCI" In "US ex rel. Kaczmarczyk, et. al v. SCCI Hospital Ventures, Inc." Civ. No. H-99-1031, (July 12, 2005), p. 4, 6.

359 "Spotlight on Compensation Practices: Where We Have Been and Where Are We Going?" By Bernadette M. Broccolo, Esq., presented at "Hospitals and Health Systems Law Institute" February 10-11, 2005, Tucson, AZ, p.70.

360 "McLeod Regional Medical Center to Pay U.S. Over $15 Million to Resolve False Claims Act Allegations," Department of Justice, Press Release, November 1, 2002, http://www.justice.gov/opa/pr/2002/November/02_civ_634.htm (Accessed 9/19/2012).

361 "McLeod Regional Medical Center to Pay U.S. Over $15 Million to Resolve False Claims Act Allegations" Department of Justice, News Release, November 1, 2002, http://www.justice.gov/opa/pr/2002/November/02_civ_634.htm (Accessed 9/19/12); "Spotlight on Compensation Practices: Where We Have Been and Where Are We Going?" By Bernadette M. Broccolo, Esq., presented at "Hospitals and Health Systems Law Institute" February 10-11, 2005, Tucson, AZ,, p.70.

362 Ibid.

expert proposed a more detailed analysis for determining whether a given compensation arrangement was *commercially reasonable*. In *SCCI Hospital Houston*, the U.S. challenged the *commercial reasonableness* of the compensation paid by the hospital to three physician medical directors.[363] The government's financial expert stated that *commercial reasonableness* of a medical director arrangement depended upon the agreement being "essential to the functioning of the hospital,"[364] and emphasized that there had to be "sound business reasons for paying medical director fees to referring physicians."[365] To examine these thresholds, the government's expert analyzed several factors in assessing the *commercial reasonableness* of the compensation, including:

(1) The size of the hospital, number of patients, patient acuity levels, and patient needs;
(2) The quality of activities and involvement of medical staff in need of medical direction;
(3) The number of regular committees and meetings requiring physician involvement; and
(4) The quality of hospital management and interdisciplinary coordination of patient services.[366]

While medical director compensation may be based on either (1) an hourly payment, with the maximum number of hours specified in the contract or (2) an annual payment that is determined by a projected number of hours multiplied by a hourly rate consistent with FMV, it may be critical to surviving regulatory scrutiny for the employer to track *and* document the *actual number* of hours the medical director spends performing the services, i.e., "[j]ustifying the need for...medical director services goes hand-in-hand with showing that the services are actually furnished. Any situation with more than one medical director for a single department is likely to be viewed with suspicion. If such arrangements exist, hospitals should be especially thorough in demonstrating the necessity for the arrangements."[367]

U.S. v. Covenant Medical Center

Hospitals and physicians face significant liability for violating the regulatory thresholds of *commercial reasonableness* and FMV, as illustrated by the 2009 case, *U.S. v. Covenant Medical Center*. In *U.S. v. Covenant Medical Center*, which settled for $4.5 million, the DOJ alleged that Iowa's *Covenant Medical Center* compensated five referring physicians at rates far exceeding FMV.[368] The DOJ alleged that the five referring physicians—specifically, two orthopedic surgeons, two neurosurgeons, and a gastroenterologist—were among the highest-paid physicians in the entire U.S., making as much as $2.1 million despite the hospital's tax exempt status.[369]

363 "U.S. ex rel. Kaczmarczyk, et al. v. SCCI Hospital Ventures, Inc.," Civ. No. H-99-1031, (July 12, 2005), Fair Market Valuation Report—Kathy McNamara, p. 4.
364 Ibid.
365 "U.S. ex rel. Kaczmarczyk, et al. v. SCCI Hospital Ventures, Inc.," Civ. No. H-99-1031, (July 12, 2005), Fair Market Valuation Report—Kathy McNamara, p. 4; "Fair Market Value in Health Care Transactions," By Lewis Lefko, Haynes and Boone, LLP, July 20, 2007, http://www.worldservicesgroup.com/publications.asp?action=article&artid=2086 (Accessed 10/9/2009).
366 Fair Market Valuation Report - United States v. SCCI, In "U.S. ex rel. Kaczmarczyk, et al. v. SCCI Hospital Ventures, Inc.," Civ. No. H-99-1031, (July 12, 2005), p. 4.
367 "Health Care Fraud and Abuse: Practical Perspectives" By Linda A. Baumann, Washington, D.C.: American Bar Association Health Law Section & The Bureau of National Affairs, Inc., 2002, p. 281.
368 "Covenant Medical Center to Pay U.S. $4.5 Million to Resolve False Claims Act Allegations," Press Release, Department of Justice, August 25, 2009, http://www.usdoj.gov/opa/pr/2009/August/09-civ-849.html (Accessed 8/31/09).
369 "Covenant Medical Center to Pay U.S. $4.5 Million to Resolve False Claims Act Allegations," Press Release, Department of Justice, August 25, 2009, http://www.usdoj.gov/opa/pr/2009/August/09-civ-849.html (Accessed 8/31/09).; "Covenant to Pay Feds $4.5M to Settle Fraud Allegations" Waterloo Cedar Falls Courier, August 25, 2009, http://www.wcfcourier.com/articles/2009/08/25/news/breaking_news/doc4a94156271f78380125347.txt (Accessed 8/31/09).

The DOJ cited significant discrepancies between the compensation paid to the five Covenant physicians in comparison to the compensation paid to physicians in the region and around the country, leading the DOJ to conclude that the hospital was paying the physicians for referrals in violation of the *Stark Law*.[370]

U.S. v. Bradford Regional Medical Center

In addition to *hospital-physician compensation arrangements* facing increased scrutiny for potential *Stark Law* and *Anti-Kickback statute* violations, *hospital-physician lease arrangements* have also come under heightened scrutiny for Stark and Anti-Kickback violations in recent years. Perhaps the most widely publicized case involving such an arrangement is the 2010 case *U.S. v Bradford Regional Medical Center,* a *qui tam action* in which the Court found that a non-compete clause of a *lease agreement* between two physicians and *Bradford Regional Medical Center* constituted an *indirect financial relationship*, whereby the consideration provided under the sublease *explicitly* took into account anticipated referral volumes, in violation of the *Stark Law*.[371]

The Court analyzed the legal permissibility of the lease arrangement, and applied *Stark's* definition of FMV and the *value or volume standard* (i.e., if the consideration takes into account the *value* or *volume* of referrals, then the arrangement is not consistent with FMV) to determine whether the agreement accounted for anticipated referrals.[372] Although the Court did not conclude *as a matter of law* that the defendants "*knowingly or willfully*" paid and received remuneration under the arrangement, in violation of the Anti-Kickback statute, the Court did find that the arrangement considered *value or volume of referrals* to determine the amount of compensation received by the physicians.[373] Significantly, when applying a *Bradford* analysis to future hospital/physician lease arrangements, advisers should note that in making its determination that the financial relationship at issue in *Bradford* did not fall within the FMV *exception* to the *Stark Law*, the district court looked to the Defendant's expert report, which specifically stated that referrals were taken into account when valuing the consideration paid for the nuclear camera sublease:

> "When modified to reflect the aforementioned incremental/variable costs for providing the MRI and CT services the following table shows the expected quantitative revenues (000's omitted) that would accrue to the Hospital with the non-competition agreement in place and a comparison of those benefits to the amounts payable under the non-competition agreement. This is based on the assumption that the Physicians would likely refer this business to the Hospital in the absence of a financial interest in their own facilities or services, although they

370 "Covenant Medical Center to Pay U.S. $4.5 Million to Resolve False Claims Act Allegations," Press Release, Department of Justice, Aug. 25, 2009, http://www.usdoj.gov/opa/pr/2009/August/09-civ-849.html (Accessed 9/4/09); "Iowa Hospital Pays $4.5 Million in Fraud Case," By Nigel Duara, Associated Press, August 25, 2009(Accessed 8/31/09).

371 Report of Charles T. Day, CPA, in "U.S. ex rel. Singh v. Bradford Regional Medical Center," Civ. No. 1:04-cv-00186-MBC, (W.D. Pa. September 10, 2008), p. 17.

372 "U.S. ex rel. Singh v. Bradford Regional Medical Center" 752 F.Supp.2d 602, 634-635 (W.D. Pa. 2010).

373 "U.S. ex rel. Singh v. Bradford Regional Medical Center" 752 F.Supp.2d 602, 634-635, 640 (W.D. Pa. 2010).

> are not required to do so by virtue of any of the covenants contained in the Agreements or otherwise."[374]

U.S. ex rel. Drakeford v. Tuomey

In *United States ex rel. Drakeford v. Tuomey Healthcare System, Inc.* (Tuomey), Michael Drakeford, M.D. alleged that Tuomey, a private, non-profit community hospital in South Carolina, violated Stark when it entered into more than fifteen employment agreements, all of which were designed to induce and maintain referral relationships.[375] Tuomey entered into compensation contracts with area physicians, conferring salary and benefits to those physicians in excess of the net collections received from their professional practices.[376] Tuomey would then generate two billings to Medicare, one for the professional services rendered and a second "*facility fee*" assessed because Tuomey provided the space, nurses, equipment, and other items for the physicians' practices.[377] The court found that the facility component of the physicians' personally performed services and the resulting fee constituted a "*referral*" as defined by Stark and its regulations.[378] In doing so, the court relied on the OIG's official commentary, which stated:

> "We have concluded that when a physician initiates a designated health service and personally performs it him or herself, that action would not constitute a referral of the service to an entity…However, in the context of inpatient and outpatient hospital services, there would still be a referral of any hospital service, technical component, or facility fee billed by the hospital in connection with the personally performed service. Thus, for example, in the case of an inpatient surgery, there would be a referral of the technical component of the surgical service, even though the referring physician personally performs the service."[379]

Accordingly, failure by a physician (with whom the hospital has a financial relationship) to *personally perform* the technical (facility) components of treating a patient for which Medicare is subsequently billed constitutes a non-compliant referral under the *Personal Services Arrangement* (PSA) exception to Stark, because "the personal services exception does not extend to a facility fee a hospital bills for a facility component resulting from a personal performed service."[380]

This lawsuit also demonstrates the OIG and DOJ's increased focus regarding the benchmark salary rates utilized in determining the fair market value of physician compensation. The court in *Tuomey* established physician compensation in the 75th percentile as the benchmark for *Stark* scrutiny, likely responding to the case's expert reports, which noted that that the 75th percentile

374 Report of Charles T. Day, CPA, in "U.S. ex rel. Singh v. Bradford Regional Medical Center," Civ. No. 1:04-cv-00186-MBC, (W.D. Pa. September 10, 2008), p. 17.
375 "United States ex rel. Drakeford v. Tuomey Healthcare Systems, Inc." 675 F.3d 394, 399 (4th Cir. 2012).
376 Ibid.
377 Ibid.
378 "United States ex rel. Drakeford v. Tuomey Healthcare Systems, Inc." 675 F.3d 394, 406-407 (4th Cir. 2012).
379 "United States ex rel. Drakeford v. Tuomey Healthcare Systems, Inc." 675 F.3d 394, 406-07 (4th Cir. 2012); "Medicare and Medicaid Programs; Physicians' Referrals to Health Care Entities with Which They Have Financial Relationships, Federal Register, Vol. 66, No. 3 (January 4, 2001), p. 941.
380 "United States ex rel. Drakeford v. Tuomey," 675 F.3d 394, 406 (4th Cir. 2012).

was at the high end of what was considered to be FMV for physician compensation.[381] Nevertheless, the government's expert witness, Kathy McNamara, actually stated that annual compensation may exceed the 75th percentile and survive Stark scrutiny. Her report stated:

> "…[A]n employer is not categorically prevented from paying above the 75th percentile in total compensation. Applying the 'supportable rate' to very high production (either collections or Work RVUs) will result in defendable and FMV compensation, sometimes even above the 90th percentile total cash compensation."[382]

Together, these two elements significantly expand the scope of physician contracts that could be subject to Stark scrutiny.

U.S. v. Campbell

Like *Tuomey*, the 2011 case, *U.S. v. Campbell,* explores the possibility of *Stark* violations arising through referrals for DHS services by physicians to healthcare enterprises with which they have a *fixed compensation arrangement*.[383] In *Campbell*, the *University of Medicine and Dentistry of New Jersey* (UMDNJ) operated a university hospital accredited and licensed as a Level 1 Trauma Center, requiring the hospital to perform a requisite number of cardiac procedures each year to maintain its accreditation level. In an effort to increase the number of cardiac procedures that were both referred to, and performed at, the hospital, UMDNJ engaged in a recruitment initiative, which included "enter[ing] into part-time employment contracts with local community cardiologists in private practices, who had patients they could refer to University Hospital for cardiac-related procedures."[384] One cardiologist, *Dr. Joseph Campbell,* entered into an employment contract with UMDNJ, which contained a compensation provision of $75,000 annually to Dr. Campbell for his *part-time services*.[385] These services included: teaching and lecturing for hospital fellows and medical students; interpreting hospital electrocardiograms; attending weekly cardiology conferences; supporting research efforts; and completing Medicare time studies.

Stemming from a federal investigation into UMDNJ's employment and referral practices, UMNDJ entered into a settlement with the federal government, paying approximately $8.33 million in FCA damages for *knowingly* submitting claims to Medicare in violation of the Stark Law.[386] After settling with UMNDJ, the U.S. brought an action against Campbell *individually*, alleging that: (1) Campbell's primary service for UMDNJ was *referring* cardiology patients to the hospital from his private cardiology practice and (2) Campbell failed to perform the majority of the services identified in his employment agreement with UMDNJ, receiving compensation of

381 U.S. ex rel. Drakeford v. Tuomey Healthcare Systems, Inc., Kathleen McNamara Expert Report, In "United States ex rel. Drakeford v. Tuomey Healthcare Systems, Inc.," No. 3:05-cv-02858 (D. S.C. 2010), ECF No. 358-3, p. 9; U.S. ex rel. Drakeford v. Tuomey Healthcare Systems, Inc., Steve Rice Expert Report, In "United States ex rel. Drakeford v. Tuomey Healthcare Systems, Inc.," No. 3:05-cv-02858 (D. S.C. 2010), ECF No. 302-47, p. 31.

382 U.S. ex rel. Drakeford v. Tuomey Healthcare Systems, Inc., Kathleen McNamara Expert Report, In "United States ex rel. Drakeford v. Tuomey Healthcare Systems, Inc.," No. 3:05-cv-02858 (D. S.C. 2010), ECF No. 358-3, p. 10.

383 "U.S. v. Campbell et al." 2011 U.S. Dist. LEXIS 1207 (D. N.J. January 4, 2011) p. 5.

384 Ibid, p. 2.

385 Ibid, p. 2.

386 Ibid, p. 3.

$70,000.[387] This case stands for the proposition that healthcare providers, including *individual physicians*, may open themselves up to potential *Stark* liability by referring patients to healthcare entities with which they have a financial relationship if a fixed compensation amount can be seen as remuneration for patient referrals in the absence of services performed by the physician as called for in the employment agreement.

U.S. ex rel. Baklid-Kunz v. Halifax

In *U.S. ex. rel. Baklid-Kunz v. Halifax*, a 2012 *qui tam* case involving *Stark* and the FCA,[388] the U.S. government alleged that *Halifax* violated the FCA by submitting, and causing others to submit, false and fraudulent Medicaid claims arising from *improper referrals*.[389] In the Halifax case, certain oncologists were paid incentive bonuses from an incentive pool, which comprised 15% of the operating margin of the medical oncology program.[390] The bonus pool was then divided between the oncologists based upon each oncologist's personally performed services.[391] On the government's motion for summary judgment, Halifax contended that this incentive bonus complied with the productivity bonus provisions of the bona fide employee exception to the Stark law, which requires that a productivity bonus be based on services personally performed by a physician.[392] However, the Court disagreed with Halifax, and held that the bonus pool was comprised of certain revenues from services that the oncologists did not personally perform, such as outpatient prescription drugs and other outpatient services not personally performed by the oncologists.[393] Accordingly, the Court found that Halifax did, in fact, violate the Stark law and the FCA.[394] Similarly, the Court denied Halifax's motion for summary judgment related to three neurosurgeons that, in certain years, were paid more than twice as much as neurosurgeons at the 90th percentile of their specialty, despite the fact that the neurosurgeons' collections fell below that measure.[395]

Shortly thereafter, in March 2014, Halifax agreed to settle with the US government for $85 million to resolve remaining allegations of violations of the FCA and Stark Law.[396] Accordingly, hospitals and providers should be careful to ensure that any bonus pool from which physicians are compensated contains only revenues derived from services that were personally performed by the physicians receiving productivity bonus compensation.

387 Ibid, p. 3.
388 "U.S. ex. rel. Baklid-Kunz v. Halifax Hospital Medical Center" Case No. 6:09-cv-1002-Orl-31DAB (M.D. Fla. March 19, 2012), Order on Motion to Dismiss the Complaint in Intervention, p. 2.
389 "U.S. ex. rel. Baklid-Kunz v. Halifax Hospital Medical Center" Case No. 6:09-cv-1002-Orl-31DAB (M.D. Fla. February 18, 2011), Plaintiff's Second Amended Complaint, p. 1-2.
390 "U.S. ex. rel. Baklid-Kunz v. Halifax Hospital Medical Center" Case No. 6:09-cv-1002-Orl-31TBS (M.D. Fla. November 13, 2013), Order on Motion for Partial Summary Judgment, p. 4.
391 Ibid, p. 4, 16.
392 "U.S. ex. rel. Baklid-Kunz v. Halifax Hospital Medical Center" Case No. 6:09-cv-1002-Orl-31TBS (M.D. Fla. November 13, 2013), Order on Motion for Partial Summary Judgment, p. 16; "Bona Fide Employment Relationships" 42 U.S.C. § 1395nn(e)(2) (2013).
393 "U.S. ex. rel. Baklid-Kunz v. Halifax Hospital Medical Center" Case No. 6:09-cv-1002-Orl-31TBS (M.D. Fla. November 13, 2013), Order on Motion for Partial Summary Judgment, p. 15-16.
394 Ibid, p. 17.
395 "U.S. ex. rel. Baklid-Kunz v. Halifax Hospital Medical Center" Case No. 6:09-cv-1002-Orl-31TBS (M.D. Fla. November 18, 2013), Order on Motion for Summary Judgment, p. 10-11.
396 "Florida Hospital System Agrees to Pay the Government $85 Million to Settle Allegations of Improper Financial Relationships with Referring Physicians" Department of Justice, March 11, 2014, http://www.justice.gov/opa/pr/florida-hospital-system-agrees-pay-government-85-million-settle-allegations-improper (Accessed 3/4/15).

U.S. ex rel. Heesch v. Diagnostic Physicians Group

In the 2013 case *U.S. ex rel. Heesch v. Diagnostic Physicians Group*, the U.S. and a relator challenged the legality of a physician/clinic relationship whereby a diagnostic clinic's compensation to a physician group allegedly included a percentage of the money collected from Medicare for tests and procedures the providers referred to the clinic.[397] Specifically, the U.S. alleged that the physicians "were aware that they received a financial benefit from ordering tests at [the clinic] that they did not receive from referring tests to other clinics and hospitals."[398] In July 2014, the parties settled the matter out of court, with the defendant physicians and the clinic paying $24.5 million and entering into a corporate integrity agreement with the government for a five-year period.[399]

U.S. ex rel. Parikh v. Citizens Medical Center

The *U.S. ex rel. Parikh v. Citizens Medical Center* case involved physician relators that alleged Citizens Medical Center (CMC) had a kickback scheme with a group of five cardiologists.[400] Specifically, the relators alleged that the cardiologists were hired at CMC with salaries that more than doubled from the time when the cardiologists were employed privately, as well as with insurance coverage, malpractice coverage, dictation services, and rental of office space at below-market rates.[401] The relators alleged that CMC provided these services and salaries to the cardiologists in an effort to induce the cardiologists to refer patients to CMC, and explained that CMC reaped enormous profits from the cardiologists' referrals.[402]

Importantly, the relators specifically alleged that the cardiologists' practice have systematically lost money, as much as $400,00 in 2008 and $1,000,000 in 2010, while CMC prospered as a result of the increased referrals.[403] Importantly, the Court stated:

> "Relators have made several allegations that, if true, provide a strong inference of the existence of a kickback scheme. Particularly, the Court notes Relators' allegations that the cardiologists' income more than doubled after they joined Citizens, even while their own practices were costing Citizens between $400,000 and $1,000,000 per year in net losses. Even if the cardiologists were making less than the national median salary for their profession, the allegations that they began making substantially more money once they were employed by Citizens [are] sufficient to allow an inference that they were receiving improper remuneration. This inference is particularly strong given that it would make little apparent economic sense for Citizens to employ the cardiologists at a loss unless

397 "U.S. ex rel. Heesch v. Diagnostic Physicians Group" Civil Action No. 11-364-KD-B (S.D. Ala. August 8, 2013), U.S. Complaint in Intervention, p. 2.
398 "U.S. ex rel. Heesch v. Diagnostic Physicians Group" Civil Action No. 11-364-KD-B (S.D. Ala. August 8, 2013), U.S. Complaint in Intervention, p. 29.
399 "Alabama Hospital System and Physician Group Agree to Pay $24.5 Million to Settle Lawsuit Alleging False Claims for Illegal Medicare Referrals" Department of Justice, July 21, 2014, http://www.justice.gov/opa/pr/alabama-hospital-system-and-physician-group-agree-pay-245-million-settle-lawsuit-alleging (Accessed 3/10/15).
400 "U.S. ex rel. Parikh v. Citizens Medical Center" Case No. 6:10-cv-00064, (S.D. TX. September 20, 2013), Memorandum and Order, p. 25.
401 Ibid.
402 Ibid
403 Ibid, p. 26-27.

> it was doing so for some ulterior motive—a motive Relators identify as a desire to induce referrals."[404]

After the defendants' failed appeal to the 5th Circuit Court of Appeals on their qualified immunity defense, the parties settled their claims on February 27, 2015.[405]

U.S. ex rel. Williams v. Banks-Jackson-Commerce Hospital & Nursing Home Authority

Not only hospitals, but also individual physicians have become targets of federal fraud and abuse enforcement agencies. In *United States ex rel. Williams v. Banks-Jackson-Commerce Hospital & Nursing Home Authority*, an individual physician agreed to pay $200,000 to the U.S. to settle allegations regarding improper kickbacks and billing practices, in violation of the FCA, Stark law, and Anti-Kickback statute.[406] The physician involved in the Banks-Jackson case, Dr. Narasimhulu Neelargaru, allegedly *over-read* electrocardiogram tests, and billed Medicare for these *over-readings*.[407] Although the hospital involved in the lawsuit settled the claims against it in 2010, Dr. Neelargaru and the federal government engaged in litigation for nearly four years until the parties settled their claims on September 22, 2014.[408] Accordingly, physicians should be aware that hospitals are not the only entities that federal fraud and abuse authorities are pursuing.

OIG Guidance Relating to Physician Compensation

The OIG has also issued pronouncements relating to scrutiny of physician compensation arrangements. On September 20, 2007, the OIG issued Advisory Opinion No. 07-10, regarding the compensation paid for physician services related to on-call coverage.[409] The opinion stated that the key inquiry for determining whether the compensation arrangement for providing emergency on-call coverage violates the Anti-Kickback statute, "is whether compensation is: (i) [at] fair market value in an arm's length transaction for actual and necessary items or services; and, (ii) not determined in any manner that takes into account the volume or value of referrals or other business generated between the parties."[410]

Although the OIG found that the subject arrangement did not "fit squarely into the terms of the safe harbor" for personal services and management contracts, because the amount of compensation was not set in advance and varied monthly, the compensation arrangement was nevertheless deemed low risk because:

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404 Ibid, p. 27-28.
405 "U.S. ex rel. Parikh v. Citizens Medical Center" Case No. 13-41088, (5th Cir. October 1, 2014), Appeal from the United States District Court for the Southern District of Texas, p. 9; "U.S. ex rel. Parikh v. Citizens Medical Center" Case No. 6:10-cv-00064, (S.D. TX. September 20, 2013), Order of Dismissal on Settlement Announcement, p. 1.
406 "Hospital and Cardiologist Settle False Claims Act Case" The United States Attorney's Office: Northern District of Georgia, Sept. 22, 2014, http://www.justice.gov/usao/gan/press/2014/09-22-14.html (Accessed 10/10/14).
407 "U.S. ex rel. Ralph D. Williams v. Banks-Jackson-Commerce Hosp. & Nursing Home Auth. et al." Case No. 1:08-CV-3235-TWT (N.D. Ga. October 16, 2008) Qui Tam Complaint, p. 17-18.
408 "U.S. ex rel. Ralph D. Williams v. Banks-Jackson-Commerce Hosp. & Nursing Home Auth. et al." Case No. 1:08-CV-3235-TWT (N.D. Ga. September 29, 2014) Order, p. 2.
409 "OIG Advisory Opinion No. 07-10" Office of Inspector General, Advisory Opinion, September 27, 2007, oig.hhs.gov/fraud/docs/advisoryopinions/2007/AdvOpn07-10A.pdf (Accessed 5/10/10) p. 1.
410 Ibid, p. 6-7.

(1) The per diem rates were at FMV without regard to referrals;
(2) The physicians were required to treat any patient who entered the emergency department until discharge with no additional compensation;
(3) The physicians provided certain volunteer (uncompensated) services;
(4) The emergency department was understaffed prior to on-call compensation being paid, therefore, the likelihood that the arrangement was instituted to provide remuneration to physicians for referrals was minimized; and
(5) All physicians were given a chance to participate in the on-call program on equal ground, and the program was not being used to reward physicians for referrals.[411]

Providers and their advisers may consider utilizing OIG Advisory Opinion 07-10 and the rationales behind the favorable ruling in crafting physician compensation arrangements that work to minimize the risk of fraud and abuse enforcement action.

STATE FRAUD AND ABUSE STATUTES

To better control healthcare fraud and abuse, and to take advantage of potential federal incentives, many states have implemented laws modeled after the federal False Claims Act, Stark Law, and Anti-Kickback Statute. These state laws range in level of severity and similarity to these federal laws, with some states having lenient laws that do not rise to the level of the federal standards and others with equal or greater standards than federal laws.

State False Claims Acts

Violations of state false claims acts can result in fines from $1,000 to $15,000 per false claim.[412] Although the state statutes commonly mirror the federal FCA, some differences can include expanded liability provisions, jurisdictional bars and scope of employment limitations for whistleblowers, and damage and penalty provisions.[413] Violation of these state statutes may carry significant penalties, as illustrated by the *HCA, Inc.* settlement, wherein the DOJ and the State of Tennessee settled a qui tam lawsuit for $16.5 million against *HCA, Inc.* after allegations that *HCA* entered into improper financial transaction where it traded office space rental payments in *excess of* FMV to induce physician referrals to its facilities.[414]

Following the passage of the *Deficit Reduction Act* (DRA) by Congress in 2005, the number of state false claims acts was expected to increase, because the act incentivized state governments to enact state false claims acts similar in scope to the federal FCA by promising to return 10 percent of the funds recovered from Medicaid enforcement actions to the state.[415] Prior to the *DRA's* enactment, all recovered money only went to the federal government.[416] The *DRA* also required entities receiving more than $5 million annually from Medicaid establish an employee

411 Ibid, p. 8-10.
412 "Health Care Fraud: Enforcement and Compliance" By Robert Fabrikant et al., New York, NY: Law Journal Press, 2007, p. 4-72.4.
413 Ibid, p. 4-72.4-72.6.
414 "Hospital Chain HCA Inc. Pays $16.5 Million to Settle False Claims Act Allegations Regarding Chattanooga, Tenn., Hospital," Department of Justice, September 19, 2012, http://www.justice.gov/opa/pr/2012/September/12-civ-1133.html (Accessed 9/21/12).
415 "Deficit Reduction Act of 2005" Pub. L. 109-171, § 6031, 120 Stat. 4, 72-73 (February 8, 2006).
416 "Health Law Update - The Deficit Reduction Act of 2005: New Medicaid Fraud and Abuse Provisions" Bass, Berry & Sims, May 31, 2006, www.bassberry.com/.../Health%20Law%20Update%20May%2031%202006.pdf (Accessed 05/10/10).

education plan regarding state and federal false claims acts and whistleblower protections.[417] The required education plan must offer information to employees regarding the federal FCA, administrative remedies for false claims and statements, any civil or criminal penalties under state false claims acts, and any whistleblower protections under federal and state law.[418] Since its implementation in January 2007, many states have strengthened their existing false claims laws to make match the incentive requirements, and more states have developed their own false claims acts.[419]

The OIG for HHS is charged with reviewing state false claims laws to ensure they meet the criteria related to the DRA incentive program. Programs must:[420]

(1) Establish liability to the state for false or fraudulent claims described in the FCA with respect to any expenditures related to the state Medicaid plans described in section 1903(a) of SSA;
(2) Contain provisions that are at least as effective in rewarding and facilitating qui tam actions for false or fraudulent claims as those described in the FCA;
(3) Contain a requirement for filing an action under seal for sixty days with review by the state attorney general; and
(4) Contain a civil penalty that is not less than the amount of the civil penalty authorized under the FCA.[421]

Thirty states, including the District of Columbia, have enacted some form of a false claims act under the encouragement of the federal FCA to create state laws to better monitor potential false claims.[422] The FCA has been amended many times by various legislative acts since 1986, including the *Fraud Enforcement and Recovery Act of 2009* (FERA), the ACA, and the *Dodd-Frank Wall Street Reform and Consumer Protection Act of 2010* (the Dodd-Frank Act).[423] However, in 2013 OIG declared that any previously approved state false claims acts had to be amended and resubmitted to the OIG for review.[424] Of the thirty states with laws, twenty-eight have submitted their laws for OIG review, and only eighteen have been approved as meeting all the necessary requirements to qualify for incentives.[425] For the complete list of states with False Claims Act Legislation, see Exhibit 3-3, below.

417 "Deficit Reduction Act of 2005" Pub. L. 109-171, § 6032, 120 Stat. 4, 73-74 (February 8, 2006).
418 Ibid.
419 "Health Law Update - The Deficit Reduction Act of 2005: New Medicaid Fraud and Abuse Provisions" Bass, Berry & Sims, May 31, 2006, www.bassberry.com/.../Health%20Law%20Update%20May%2031%202006.pdf (Accessed 05/10/10).
420 "State False Claims Act Reviews" Office of Inspector General, 2015, http://oig.hhs.gov/fraud/state-false-claims-act-reviews/index.asp (Accessed 2/23/15).
421 Ibid.
422 "States with False Claims Acts" Taxpayers Against Fraud Education Fund, 2015, http://www.taf.org/states-false-claims-acts (Accessed 2/23/15).
423 "State False Claims Act Reviews" Office of Inspector General, 2015, http://oig.hhs.gov/fraud/state-false-claims-act-reviews/index.asp (Accessed 2/23/15).
424 Ibid.
425 "State False Claims Act Reviews" Office of Inspector General, http://oig.hhs.gov/fraud/state-false-claims-act-reviews/index.asp (Accessed 2/23/15).

Exhibit 3-3: States With False Claims Act Legislation[426]

California	Minnesota
Colorado	Montana
Connecticut	Nevada
Delaware	New Hampshire
District of Columbia	New Jersey
Florida	New Mexico
Georgia	New York
Hawaii	North Carolina
Illinois	Oklahoma
Indiana	Rhode Island
Iowa	Tennessee
Louisiana	Texas
Maryland	Virginia
Massachusetts	Washington
Michigan	Wisconsin

State Anti-Kickback and Self-Referral Laws

Forty-two states and the District of Columbia have laws prohibiting kickbacks and limiting self-referrals. For the complete list, see Exhibit 3-4, below.

Exhibit 3-4: States with Self-Referral and Anti-Kickback Legislation[427]

Alabama (Anti-Kickback)	Montana
Arizona	Nevada
Arkansas	New Hampshire
California	New Jersey
Colorado	New Mexico (Anti-Kickback)
Connecticut	New York
Delaware (Anti-Kickback)	North Carolina
Florida	Ohio
Georgia (self-referral)	Oklahoma
Hawaii (self-referral)	Pennsylvania
Illinois	Rhode Island (Anti-Kickback)
Indiana	South Carolina
Kansas	South Dakota
Kentucky	Tennessee (self-referral)
Louisiana	Texas (Anti-Kickback)
Maine (self-referral)	Utah
Maryland (self-referral)	Virginia
Massachusetts	Washington
Michigan	Washington DC (Anti-Kickback)
Minnesota (self-referral)	West Virginia
Mississippi (Anti-Kickback)	Wisconsin
Missouri	

426 "State False Claims Acts" The False Claims Act Legal Center, Taxpayers Against Fraud Education Fund, http://www.taf.org/states-false-claims-acts (Accessed 2/23/15).

427 "Health Cost Containment and Efficiencies: Combating Health Care Fraud and Abuse" NCSL Briefs for State Legislators, September 2010, http://www.ncsl.org/portals/1/documents/health/Fraud-2010.pdf (Accessed 2/21/15) p. 3.

Updates to State Self-Referral Laws

Many states have their own version of the federal self-referral law (Stark Law). These state self-referral laws vary in degree of coverage; some mirror the federal language in prohibiting the majority of self-referrals, some prohibit all self-referrals, some prohibit any physician ownership in care facilities, some only require disclosure of financial interests to patients, and some states have no self-referral laws. Over the past few years, many states have expanded or updated their self-referral laws to accommodate ACA initiatives and further control potential fraud and abuse. When claims arise in states that have their own self-referral laws, both the federal and state governments are able to prosecute and collect from the offending party.

New Jersey Update to "Codey Act"

After the 2007 decision in *Health Net of New Jersey, Inc. v. Wayne Surgical Center, LLC*, physicians in New Jersey who referred patients to an ASC in which they had an ownership interest were suddenly at risk of being in violation of New Jersey's anti-self-referral law, the *Codey Law*.[428] Most unexpectedly, the *Health Net* decision rejected a widely relied upon 1997 New Jersey Board of Medical Examiners (BME) advisory opinion, which held that an ASC constitutes an "extension of the physician's medical office," such that the arrangement did not violate the Codey Law.[429]

After the ruling in *Health Net*, the BME adopted emergency rules declaring that doctors who referred patients to physician-owned ASCs were not in danger of violating the law.[430] In response, legislators in New Jersey, led by Senate President Richard Codey (the namesake of the original law), proposed an amendment to the *Codey Law* that would allow self-referral to physician-owned ASCs.[431]

In 2009, the New Jersey legislature amended the *Codey Law* to permit physician referrals to ASCs in which they have a financial interest, on the following conditions:

(1) The physicians personally perform the procedure;
(2) The physicians' remuneration as an owner is directly proportional to their ownership interest (rather than the amount of the physician's referrals);
(3) All patient-related decisions at facilities with non-physician owners are made by physicians; and
(4) The physicians inform the patients of their ownership share at the time of referral.[432]

428 "New Jersey Court Rules that Physician Referrals to Ambulatory Surgical Center in Which They Own an Interest Violates Codey Act" By Flaster Greenberg, Health Care Alert Newsletter, December 2007, http://www.flastergreenberg.com/Uploads/FileManager/client%20alerts/healthcarealertdec07.pdf (Accessed 4/18/08); "New Jersey Codey Act" N.J. Stat. Ann. § 45:9-22.4 et seq. (1992).

429 "New Jersey Court Rules that Physician Referrals to Ambulatory Surgical Center in Which They Own an Interest Violates Codey Act" By Flaster Greenberg, Health Care Alert Newsletter, December 2007, http://www.flastergreenberg.com/Uploads/FileManager/client%20alerts/healthcarealertdec07.pdf (Accessed 4/18/08).

430 "New Jersey Codey Law Update: New Jersey BME Provides 'Emergency Rules' for State's Centers, Says Referrals are Not in Violation" Surgi Strategies, January 9, 2008, http://www.surgistrategies.com/hotnews/7ch14111940.html (Accessed 2/10/10).

431 "Doctors Battle Hospitals Over ASC Ownership Restrictions" By Gregg Blesch, Modern Physician, December 8, 2008, http://www.modernphysician.com/article/20081208/MODERNPHYSICIAN/311309995/1110 (Accessed 2/10/10).

432 "New Jersey Senate Bill" No. 787, 213th Legislature, November 24, 2008.

In addition, the statute also prohibits the issuance of new registrations for surgical practices and ambulatory care facilities unless one of the limited exceptions applies.[433] Most recently in 2014, the New Jersey legislature extended the Codey Law to expand the scope of referable facilities for lithotripsy procedures.[434]

State Fraud and Abuse Cases

In 2013, Cooper Health System, a New Jersey hospital, settled allegations of inappropriate kickbacks and referrals with the U.S. and state of New Jersey after paying outside physicians $18,000 per year to sit on an advisory board and attend meetings.[435] The lawsuit against Cooper Health was brought by both federal and state attorneys because New Jersey has similar legislation to the federal Stark and Anti-Kickback laws. The original claim was brought as a qui tam action against the hospital by a physician that alleged the hospital used consulting and compensation agreements to induce referrals and hid them under the guise of advisory board compensation.[436] Additionally, the $18,000 payment to each physician-board member was found to exceed the FMV of the services rendered. The resulting $12.6 million settlement was allocated to the federal government, state government, and the initial whistle-blower physician.[437]

Similarly, in California, a health system and its affiliated hospital, Adventist Health System and White Memorial Medical Center, settled claims with the U.S. and state of California over allegations they violated the False Claims Act, Anti-Kickback Statute, and Stark Law, as well as the state law counterparts.[438] The plaintiffs alleged that Adventist improperly referred patients to White Memorial by transferring medical and non-medical supplies and inventory below FMV.[439] White Memorial was also accused of paying compensation above FMV to physicians that referred patients to the medical center.[440] The settlement between parties totaled $14.1 million, with $11.5 million paid to the U.S. government, with most of that benefiting the Medicare Trust Fund, and $2.6 million paid to the state of California's Department of Health Care Services.[441] Like the Cooper case, this case also originated with a qui tam suit, with the whistle blower receiving $2.8 million from the settlement.[442]

When advising providers regarding compliance for particular physician arrangements, advisers should note the subtle differences between federal and state fraud and abuse laws and how it may influence the legality of the arrangement.

433 Ibid.
434 "Legislature Expands Codey Law Exception for Lithotripsy Referrals" By Beth Christian, Posted on New Jersey Healthcare Blog, March 24, 2014, http://www.njhealthcareblog.com/2014/03/legislature-expands-codey-law-exception-for-lithotripsy-referrals/ (Accessed 2/26/15).
435 "Cooper Health System Pays $12.6 Million Over Kickback Case" By David Voreacos, Bloomberg Business, January 24, 2013, http://www.bloomberg.com/news/articles/2013-01-24/cooper-health-system-pays-12-6-million-to-settle-kickback-case (Accessed 2/26/15).
436 Ibid.
437 "Cooper Health System Pays $12.6 Million Over Kickback Case" By David Voreacos, Bloomberg Business, January 24, 2013, http://www.bloomberg.com/news/articles/2013-01-24/cooper-health-system-pays-12-6-million-to-settle-kickback-case (Accessed 2/26/15).
438 "Adventist Health Pays United States and State of California $14.1 Million to Resolve False Claims Act Allegations" Department of Justice, May 3, 2013, http://www.justice.gov/opa/pr/adventist-health-pays-united-states-and-state-california-141-million-resolve-false-claims-act (Accessed 2/26/15).
439 Ibid.
440 Ibid.
441 Ibid.
442 Ibid.

RACKETEER INFLUENCED AND CORRUPT ORGANIZATIONS ACT (RICO)

The Racketeer Influenced and Corrupt Organizations Act (RICO)[443] is a federal law that carries both criminal and civil penalties with the aim of protecting the public from, "parties who conduct organizations affecting interstate commerce through a pattern of criminal activity."[444] The general prohibition of RICO is against using a business to commit a crime. When applied to healthcare, RICO makes it illegal for any person to:

(1) Use or invest any income derived from a pattern of racketeering activity in an enterprise;
(2) Acquire or maintain control of any enterprise through a pattern of racketeering activity; or
(3) For any person employed by, or associated with, any enterprise to conduct the affairs of the enterprise through a pattern of racketeering activity.[445]

It is also a violation of RICO to conspire to engage in any of these three activities.[446] A pattern of racketeering activity involves committing at least two acts of racketeering activity.

RICO has been used to prosecute physicians, attorneys, and patients who conspire to defraud payors by filing false claims related to fictitious automobile accidents, billing for services not actually rendered, and unnecessarily prescribing controlled substances.[447]

ACOS AND FRAUD AND ABUSE

The Affordable Care Act initiated the development of accountable care organizations (ACOs) to enable more coordinated care for beneficiaries. In response, regulatory agencies have issued statements and proposed rules to accommodate the unique nature of these ACOs. Specific to fraud and abuse, CMS and OIG issued a joint interim final rule in October 2014, extending the waivers for Stark Law, the Anti-Kickback Statute, and certain CMP provisions related to the Medicare Shared Savings Program (MSSP) that were originally proposed in 2011.[448] These waivers are designed to ensure that the development of beneficial ACOs is not hindered by fraud and abuse laws and are MSSP specific, i.e., they do not apply to state fraud and abuse laws. The proposed waivers give the Secretary of HHS the authority to waive the federal fraud and abuse laws, even if the behavior would normally violate these laws.

There are five types of ACO fraud and abuse waivers; however, the ACO Participation waivers is likely the broadest in scope, as it waives the effects of the Stark Law, the Anti-Kickback statute, and CMP provisions for ACOs:

443 "Racketeer Influenced and Corrupt Organizations Act; Definitions" 18 U.S.C. § 1961 (2009).
444 "Health Care Fraud: Enforcement and Compliance," By Robert Fabrikant et al., New York, NY: Law Journal Press, 2007, p. 3-83-84, quoting 115 Cong. Rec. 9566, 9568 (April 18, 1969), statement of Sen. McClellan.
445 "Racketeer Influenced and Corrupt Organizations Act; Prohibited Activities"18 U.S.C. § 1962(a)-(c) (2009).
446 "Racketeer Influenced and Corrupt Organizations Act; Prohibited Activities"18 U.S.C. § 1962(d) (2009).
447 "Health Care Fraud: Enforcement and Compliance" By Robert Fabrikant et al., New York, NY: Law Journal Press, 2007, p. 3-90.
448 "Medicare Program; Final Waivers in Connection with the Shared Savings Program; Continuation of Effectiveness and Extension of Timeline for Publication of Final Rule" Federal Register, Vol. 79, No. 201 (October 17, 2014) p. 62357.

(1) That have entered into a participation agreement with the MSSP and remain in good standing;
(2) That meet certain governance, leadership, and management requirements;
(3) The ACO's governing body has made an authorized, bona fide determination that the proposed arrangement is reasonably related to the purposes of the MSSP;
(4) The proposed arrangement and its authorization by the governing body are documented; and
(5) A description of the proposed arrangement is publicly disclosed at a time and in a place and manner established in guidance issued by the Secretary of HHS.[449]

The remaining four ACO fraud and abuse waivers contain different requirements, waive different fraud and abuse laws, and are named after the certain enumerated situations to which they apply, to wit:

(1) ACO Pre-Participation Waiver;
(2) Shared Savings Distributions Waiver;
(3) Compliance with Stark Waiver; and
(4) Patient Incentive Waiver.[450]

Accordingly, for participants in certain ACOs, if the requirements of the ACO fraud and abuse waivers are met, certain provider-ACO arrangements may not be required to fit in within the exceptions or safe harbors to the aforementioned fraud and abuse laws. However, it should be noted that these fraud and abuse waivers were extended only through November 2, 2015, unless a final waiver rule becomes effective on an earlier date.[451] As such, ACOs may be well served by ensuring that any arrangements entered into under an ACO fraud and abuse waiver may be unwound, or, alternatively, fit within the exceptions or safe harbors to the aforementioned fraud and abuse laws.

FEDERAL ANTITRUST LAWS

STATUTORY BACKGROUND AND GENERAL APPLICATION

Antitrust laws aim to combat anticompetitive behavior conducted by businesses. The *Sherman Antitrust Act* (Sherman Act), which prohibits any "*contract, combination...or conspiracy, in restraint of trade or commerce*;"[452] Section 5 of the *Federal Trade Commission Act*, which prohibits "*unfair methods of competition in or affecting commerce*;"[453] and Section 7 of the *Clayton Act*, which prohibits acquisitions which are likely to "*substantially lessen competition, or tend to create a monopoly*,"[454] are the federal government's three primary means of combating unfair competition and abuse of monopolistic power. Further, Section 2 of the

449 "Medicare Program; Final Waivers in Connection with the Shared Savings Program; Interim Final Rule" Federal Register Vol. 76, No. 212, (November 2, 2011), p. 68001.
450 Ibid, p. 68000-68001.
451 "Medicare Program; Final Waivers in Connection with the Shared Savings Program; Continuation of Effectiveness and Extension of Timeline for Publication of Final Rule" Federal Register, Vol. 79, No. 201, (October 17, 2014), p. 62357.
452 "Sherman Antitrust Act" 15 U.S.C. § 1 (2013).
453 "Federal Trade Commission Act" 15 U.S.C. § 45 (2013).
454 "Clayton Act" 15 U.S.C. § 18 (2013).

Sherman Act prohibits the abuse of monopoly power across states and establishes the act as a felony.[455] In the healthcare context, these statutes have also been used to combat kickbacks and self-referral joint ventures, which have been recognized as an impediment to competition by providers outside the self-referral or kickback network,[456] as well as other anticompetitive healthcare arrangements including: physician integration under physician hospital organization models, *independent practice associations* (IPAs), and healthcare organizations negotiating on behalf of their physician members.[457]

Tests for Anticompetitive Effects

The FTC typically examines healthcare arrangements under a *rule of reason analysis*, balancing procompetitive and anticompetitive effects of the integration arrangement on the market.[458] The rule of reason test is used by antitrust authorities when the examined conduct has some level of procompetitive justification.[459] Under this test, courts analyze the whole agreement to determine whether procompetitive benefits outweigh anticompetitive effects.[460] If the court finds that the "procompetitive benefits outweigh the harm to competition," the agreement is acceptable and reasonable.[461] This test usually applies to activities such as "*information exchanges, blanket licenses, and vertical … price fixing*."[462]

In contrast, when an agreement is inherently anticompetitive and restrictive on trade, courts find it *per se* illegal.[463] A *per se* analysis enables the government to avoid costly investigations without having to show potential anticompetitive effects.[464] Examples of *per se* illegal agreements include horizontal price fixing and market allocation, tying arrangements, and some boycotts.[465] Authorities have begun to use the rule of reason test more often than the *per se* analysis when determining the legality of a healthcare agreement.[466]

ANTITRUST CASE LAW

Independent Practice Associations

In 2008, the FTC's finding of illegal price fixing by a Texas IPA was upheld by a federal appellate court.[467] The court held that negotiation (on behalf of physician members) that doesn't involve risk sharing with payors or any form of improved efficiency from clinical integration runs afoul of antitrust laws.[468] Similarly, in a separate case, the FTC also approved a final order

455 "Sherman Antitrust Act" 15 U.S.C. § 2 (2013).
456 "Health Care Fraud: Enforcement and Compliance" By Robert Fabrikant, et al., New York, NY: Law Journal Press, 2007, p. 2-60.
457 "Health Care Fraud and Abuse: Practical Perspectives, 2003 Supplement" By Linda A. Baumann, Washington, DC: BNA Books, 2003, p. 61.
458 "Greater Rochester Independent Practice Association, Inc., Advisory Opinion" By Markus H. Meier, To Christi J. Braun and John J. Miles, September 17, 2007, http://www.ftc.gov/bc/adops/gripa.pdf (Accessed 3/6/15), p. 10.
459 "Antitrust Violations" By Bahadur Khan and Nickolas Barber, American Criminal Law Review, Vol. 50, (Fall 2013) p. 642-43.
460 "Chicago Board of Trade v. United States" 246 U.S. 231, 238 (1918).
461 "Antitrust Violations" By Bahadur Khan and Nickolas Barber, American Criminal Law Review, Vol. 50, (Fall 2013) p. 643.
462 Ibid.
463 "State Oil Co. v. Khan" 522 U.S. 3, 10 (1997).
464 "Antitrust Violations" By Bahadur Khan and Nickolas Barber, American Criminal Law Review, Vol. 50, (Fall 2013) p. 644-45.
465 "Antitrust Violations" By Bahadur Khan and Nickolas Barber, American Criminal Law Review, Vol. 50, (Fall 2013) p. 646.
466 Ibid, p. 647.
467 "North Texas Specialty Physicians v. Federal Trade Commission" 528 F.3d 346, 346 (5th Cir. 2008).
468 "North Texas Specialty Physicians v. Federal Trade Commission" 528 F.3d 346, 357 (5th Cir. 2008).

that barred Minnesota Rural Health Cooperative from using "*coercive tactics or refusals to deal*" including negotiating fixed pricing, threatening contract termination with payors who refuse to deal on its terms, and refraining from individual negotiations with payors to ensure better terms and rates from insurance plans.[469] The order also forced the healthcare system to renegotiate all existing contracts with insurers and to seek approval of them from the state.[470]

Similarly, in 2009, the FTC settled a price fixing charge against Alta Bates Medical Group, a 600 physician IPA in San Francisco, CA.[471] The FTC found that Alta Bates arranged collective negotiations for fee-for-service contracts with health insurers on behalf of all its physicians.[472] Instead of consulting with the physicians to discuss pricing individually, the IPA would arrange the negotiations as a group, and then offer the negotiated contracts to the individual physicians. The FTC also charged the IPA with unlawful concerted refusal to deal when it tried to contractually exclude its physicians from providing services to a third party network of its competitor,[473] even though it the FTC was ultimately unsuccessful in this endeavor.[474] The FTC found that the IPA did not demonstrate efficiencies through clinical or financial integration in order to counter the complaint alleged against it, and, therefore, Alta Bates was prohibited "from collectively negotiating fee-for-service reimbursements and engaging in related anticompetitive conduct."[475] In order to avoid agency investigations or complaints, IPAs should consider serving as a messenger between the physicians and insurers while giving each physician the ability to accept or reject the terms.[476]

Traditionally, IPAs have only been able to negotiate on behalf of their members if the joint-contracting agreement has an element of risk-sharing built into it or if the IPA has embarked on a clinical integration scheme to improve efficiency among its members.[477] For example, the *Greater Rochester Independent Physician Association* (GRIPA) sought out an advisory opinion from the FTC staff regarding its planned agreement that involved enhanced coordinated care for patients and joint-contracting on behalf of its physicians.[478] GRIPA argued that the joint-contracting was necessary in order to achieve its quality and efficiency goals of clinical integration and get total involvement from physicians.[479] The FTC Advisory Opinion explained that the staff would not refer the agreement to the Commission, finding that enough

469 "FTC Approves Final Order Settling Charges that the Minnesota Rural Health Cooperative Fixed Healthcare Reimbursement Rates" Federal Trade Commission, January 2011, http://www.ftc.gov/news-events/press-releases/2011/01/ftc-approves-final-order-settling-charges-minnesota-rural-health (Accessed 3/6/15); "In the Matter of Minnesota Rural Health Cooperative" Federal Trade Commission Docket No. C-4311 (Dec. 28, 2010), Decision and Order, p. 3.

470 Ibid.

471 "FTC Settles Price-Fixing Charges against San Francisco Bay Area Doctors Group" Federal Trade Commission, June 4, 2009, http://www.ftc.gov/news-events/press-releases/2009/06/ftc-settles-price-fixing-charges-against-san-francisco-bay-area (Accessed 2/11/15).

472 Ibid.

473 "In the Matter of Alta Bates Medical Group, Inc." Federal Trade Commission Docket No. C-4260 (July 2009) Complaint, p. 5-6.

474 "FTC Settles Price-Fixing Charges against San Francisco Bay Area Doctors Group" Federal Trade Commission, June 4, 2009, http://www.ftc.gov/news-events/press-releases/2009/06/ftc-settles-price-fixing-charges-against-san-francisco-bay-area (Accessed 2/11/15).

475 Ibid.

476 "How Antitrust Affects Your Health: The Antitrust Laws' Impact on the Delivery of Healthcare Services in America" By Colin Kass and Ryan Blaney, Proskauer Rose LLP, Posted on Bloomberg Law, March , 2012, https://www.bloomberglaw.com/home/cd2313f81aecd63445f910ad8c22dcab/document/X7TK38O#0x0x0x2_ref (Accessed 2/4/15).

477 "Greater Rochester Independent Practice Association, Inc., Advisory Opinion" By Markus H. Meier, Letter to Christi J. Braun and John J. Miles, September 17, 2007, http://www.ftc.gov/bc/adops/gripa.pdf (Accessed 04/18/08), p. 1, 11-12; "Health Care Fraud and Abuse: Practical Perspectives, 2003 Supplement" By Linda A. Baumann, Health Law Section of the American Bar Association, Washington, DC: BNA Books, 2003, p. 61-62.

478 "FTC Staff Advise Rochester Physician Organization That It Will Not Recommend Antitrust Challenge to Proposal to Provide Member Physicians' Services Through 'Clinical Integration' Program" Federal Trade Commission , 2007, http://www.ftc.gov/news-events/press-releases/2007/09/ftc-staff-advises-rochester-physician-organization-it-will-not (Accessed 2/4/15).

479 Ibid.

procompetitive effects existed so as to not challenge the program, "unless it became apparent that GRIPA in fact was able to exercise market power or otherwise have an anticompetitive effect in the relevant market."[480] However, in the matter of Southwest Health Alliances, Inc., the FTC ruled against an IPA representing 900 physicians in Texas because the IPA's joint-contracting negotiations were not "reasonably related to any efficiency-enhancing integration among … physicians."[481]

Physician-Owned Facilities

Antitrust authorities have investigated many community hospitals for engaging in exclusionary practices in an effort to respond to the negative financial impact of physician-owned facilities (POFs).[482] Many hospitals have attempted to shut POFs, particularly specialty hospitals, out of the market, which has resulted in some POFs initiating antitrust lawsuits, claiming that such exclusionary behavior violates the Sherman Act.[483] Many of these cases have failed because, as alleged by industry commentators, antitrust authorities are protective of general hospitals that have taken measures to combat, what they claim to be, *cream skimming* by specialty hospitals.[484]

In the case of *Little Rock Cardiology Clinic PA (LRCC) v. Baptist Health*, LRCC, the owner of the cardiologic specialty hospital Arkansas Heart Hospital, filed a claim against Baptist, the area provider of general healthcare services, alleging violations of Sections 1 and 2 of the Sherman Act.[485] LRCC claimed that Baptist conspired with Blue Cross Blue Shield to restrain trade and monopolize market power for cardiology services by forming a jointly owned HMO with Blue Cross, agreeing to an exclusive in-network contract with Blue Cross, and agreeing with Blue Cross that LRCC would be removed from the Blue Cross network.[486] The District Court dismissed all the antitrust complaints brought by LRCC, finding that LRCC failed to properly define a relevant patient market through which Baptist allegedly committed exclusive dealing.[487] On appeal to the 8th Circuit Court of Appeals the decision was affirmed,[488] followed by a denial for certiorari review by the Supreme Court.[489] The Court found that LRCC had been too restrictive in its market definition of available patients, and ruled in favor of the hospital.[490] However, some courts have found in favor of POFs in cases when a general hospital abused its market power to pressure other hospitals and payors into agreeing to exclude the POF from the market.

Heartland Surgical Specialty Hospital, L.L.C. v. Midwest Division, Inc. is such a case where the Court found with the POF. In this case, Heartland alleged that the defendant hospitals and

480 "GRIPA Advisory Opinion" By Markus Meier, To Christi Braun and John Miles, September 17, 2007, http://www.ftc.gov/sites/default/files/documents/public_statements/ftc-staff-will-not-recommend-antitrust-challenge-proposal-provide-member-physicians-services-through/070921finalgripamcd.pdf (Accessed 2/4/15) p. 29.
481 "In the Matter of Southwest Health Alliances, Inc." Federal Trade Commission Complaint, FTC No. C-4327 (July 15, 2011) p. 4.
482 "Antitrust Implications of Competition Between Physician-Owned Facilities and General Hospitals: Competition or Exclusion?" By William E. Berlin, Esq., The Health Lawyer, Volume 20, No. 5 (June 2008), p. 3-5.
483 Ibid.
484 "Physician-Owned Hospital Can Pursue Antitrust Lawsuit" By Amy Lynn Sorrel, Amednews.com, Nov. 12, 2007, http://www.ama-assn.org/amednews/2007/11/12/gvsa1112.htm (Accessed 6/30/08).
485 "Little Rock Cardiology Clinic PA v. Baptist Health"591 F. 3d 591, 593-94 (Dec. 29, 2009).
486 "Little Rock Cardiology Clinic PA v. Baptist Health"591 F. 3d 591, 594 (Dec. 29, 2009).
487 "Little Rock Cardiology Clinic PA v. Baptist Health"591 F. 3d 591, 593-94 (Dec. 29, 2009).
488 "Little Rock Cardiology Clinic PA v. Baptist Health"591 F. 3d 591, 594 (Dec. 29, 2009).
489 "Little Rock Cardiology Clinic PA v. Baptist Health" 130 S. Ct. 3506, 3506 (June 28, 2010).
490 "Little Rock Cardiology Clinic PA v. Baptist Health"591 F. 3d 591, 597-98 (Dec. 29, 2009).

managed care organizations used boycotting, tortious interference with a business relationship, and civil conspiracy to exclude it from and reduce its share in the market.[491] The District Court found Heartland had demonstrated enough antitrust behavior on the part of the defendants to allow the case to proceed with the conspiracy claims.[492] Eventually, the parties settled out of court;[493] however, the District Court's ruling remains pertinent, as it is one of the relatively few instances where a Court found evidence of horizontal conspiracy, on the part of general hospitals, to exclude a POF from the market.

While antitrust challenges by POFs may not always fail, important and unresolved issues still exist that the courts have yet to determine. One of the most important elements of any antitrust challenge is the requirement of an agreement between competitors in the restraint of trade.[494] In a majority of these cases, the allegations of agreement are launched at hospital boards that are in supposed agreements with their medical staff.[495] The circuits are split, however, on whether or not a hospital and members of its medical staff can be considered separate entities for the purposes of forming an agreement to restrain trade.[496] In the absence of an agreement by separate entities, unilateral activity, as long as it is not predatory, is legal.[497] Some circuits argue that a medical staff is simply a subpart of a larger hospital entity and, therefore, cannot be judged as separate decision-making entities.[498] Therefore, the determination of whether a hospital and medical staff are a single entity is of paramount importance to these cases.

Courts also are split on the question of whether certain actions taken by hospitals in response to POFs can be considered to have legitimate business justifications.[499] If a general hospital can show that its actions are in pursuit of a legitimate business goal, such as protecting its ability to cross-subsidize unprofitable services so that the hospital may continue to provide those services to the community or to protect from cream skimming, then some courts may find the actions justified even if detrimental to the POF.[500] Interestingly, neither the DOJ's Antitrust division nor the FTC has brought an enforcement action regarding a general hospital's attempt to reduce the entry or expansion of a physician-owned hospital.[501]

"Any Willing Provider" Statutes

Since the 1980s, states have enacted *any willing provider* statutes that typically require health insurers to accept any healthcare provider into their network as long as the provider will agree to

491 "Heartland Surgical Specialty Hospital, LLC v. Midwest Division, Inc." 527 F.Supp. 2d 1257, 1264-66 (D. Kan. 2007).
492 "Heartland Surgical Specialty Hospital, LLC v. Midwest Division, Inc." 527 F.Supp. 2d 1257, 1321-1325 (D. Kan. 2007).
493 "SSH Wins Settlement in Case Brought by Specialty Hospital" Stueve, Siegel, Hanson, LLP, March 2008, http://www.stuevesiegel.com/ssh/results/ssh-wins-settlement-in-case-brought-by-specialty-hospital-against-hospitals-and-insurers/ (Accessed 3/12/15).
494 "Trust, etc., in Restraint of Trade, Illegal" 15 U.S.C. § 1 (2009).
495 "Antitrust Implications of Competition Between Physician-Owned Facilities and General Hospitals: Competition or Exclusion?" By William E. Berlin, Esq., The Health Lawyer, Volume 20, No. 5 (June 2008), p. 3-5.
496 Ibid, p. 5.
497 Ibid, p. 5.
498 Ibid, p. 5-6.
499 "Williamson v. Sacred Heart Hospital of Pensacola" 1993 WL 543002 (N.D. Fla. 1993), p. *34-37; "Antitrust Implications of Competition Between Physician-Owned Facilities and General Hospitals: Competition or Exclusion?" By William E. Berlin, Esq., The Health Lawyer, Volume 20, No. 5 (June 2008), p. 9.
500 Ibid.
501 "§ 14A.4 Application of Antitrust Principles" By John Miles, Health Care and Antitrust Law (November 2014).

the terms and conditions of the plan.[502] There are 17 states that apply these laws to hospitals and/or physicians, and even more states apply these laws to pharmacies.[503] While these statutes are beneficial for providers who are concerned they will be shut out of markets and to consumers who don't want restrictions on their available provider options, they may be detrimental to consumers and the industry, as they have the potential to interfere with consumer demand for low-priced healthcare.[504]

There is considerable opposition to any willing provider statutes because these statutes have the ability to reduce efficiency and lower care quality.[505] The FTC also recognizes that these statutes have the potential to limit competition in the healthcare sector, because without the selectivity of choosing providers, it will likely be more difficult for insurers to negotiate discounts for services, as there would be no incentive to providers to offer better rates in exchange for assurances of volume or better treatment.[506] As a result, the FTC is concerned that *any willing provider* laws are likely to cause increased costs to consumers paying for healthcare.[507] However, supporters of the laws argue that insurers can limit providers through the terms and conditions in the plan, including reimbursement rates and quality and utilization metrics.[508]

Covenants Not to Compete

Covenants not to compete are frequently used by healthcare providers to ensure their physicians do not open competing physician practices. However, covenants not to compete are often considered restrictive and disfavored as a restraint on trade and competition.[509] The American Medical Association (AMA) has previously noted that such restrictions on the practice of medicine go against public interest because the nature of healthcare is one in which quality and affordability improve with greater competition.[510] By restricting the geographic location of physicians for specific time periods, competition is reduced in the area, and quality of care may suffer.[511] Overall, state laws vary on whether they will allow such covenants and the degree to which they will enforce them.[512]

In 2010, Renown Health, a Nevada health network, acquired Sierra Nevada Cardiology Associates, one of two medical groups in the area, and, in the process of hiring the cardiologists from the group, required all of them to sign a non-compete agreement to extend two years

502 "Analysis: How Any Willing Provider Makes Health Care More Expensive" By Paul Ginsburg, American Health Insurance Plans, Posted on Washington Post, Sept. 23, 2014, http://www.washingtonpost.com/blogs/wonkblog/files/2014/09/Analysis-Any-Willing-Provider.pdf (Accessed 2/11/15) p. 1
503 Ibid.
504 Ibid.
505 Ibid.
506 "Re: Contract Year 2015 Policy and Technical Changes to the Medicare Advantage and the Medicare Prescription Drug Benefit Programs" Federal Trade Commission, March 7, 2014, http://www.ftc.gov/system/files/documents/advocacy_documents/federal-trade-commission-staff-comment-centers-medicare-medicaid-services-regarding-proposed-rule/140310cmscomment.pdf (Accessed 2/18/15) p. 3.
507 Ibid.
508 "Ch. 6 - Providers Versus Payors: Common Legal Disputes in Managed Care" By Julie Barnes, ABA Health Law Section, Managed Care Litigation, Washington D.C.: The Bureau of National Affairs, Inc., 2005, p. 373.
509 "Regional Urology, L.L.C. v. Price" 966 So. 2d 1087, 1095 (La. Ct. App. 2007) (Brown, C.J., dissenting).
510 "Regional Urology, L.L.C. v. Price" 966 So. 2d 1087, 1095-96 (La. Ct. App. 2007) (Brown, C.J., dissenting).
511 "Regional Urology, L.L.C. v. Price" 966 So. 2d 1087, 1096 (La. Ct. App. 2007) (Brown, C.J., dissenting).
512 "National Survey on Restrictive Covenants" Fox Rothschild, LLP, 2013, http://www.foxrothschild.com/uploadedfiles/practiceareas/securitiesfinancialinstitution/survey_nationalSurveyRestrictiveCovenants.pdf (Accessed 2/9/15).

beyond termination of employment.[513] A year later, Renown acquired Reno Heart Physicians, the other remaining medical group in the area, and hired its cardiologists with a two-year non-compete contract agreement.[514] The FTC investigated and found that the two acquisitions gave Renown an 88% share of the cardiology market.[515] The FTC determined that this 88% market share combined with the non-compete agreements sufficiently reduced competition for adult cardiology services in the Reno, Nevada area.[516] In the settlement that followed, Renown agreed to temporarily suspend the non-compete provisions and allow ten cardiologists to join competing groups.[517] When considering vertical or horizontal mergers, the FTC may be more critical if the mergers include agreements with covenants not to compete because these covenants can effectively limit or eliminate competition in a market area.

Hospital Acquisitions of Physician Groups

The FTC, DOJ, and state attorneys general have raised numerous complaints and initiated various investigations relating to hospital acquisitions of medical groups over the past few years. As the ACA's healthcare reform initiatives take effect, the resulting market consolidation may become increasingly relevant for healthcare groups and systems.[518] In a recent case, *St. Alphonsus Medical Center-Nampa Inc. et al. v. St Luke's Health System, Ltd. et al.*, St. Luke's, a large health system in Idaho, attempted an acquisition of Saltzer Medical Group P.A., the largest independent physician group in Idaho.[519] The acquisition gave St. Luke's 80% of the market's primary care physicians,[520] and the U.S. District Court for Idaho ultimately found that the acquisition violated Section 7 of the Clayton Act,[521] in that the arrangement would enable St. Luke's to demand higher rates for services, resulting in higher costs to consumers in the relevant geographic market despite St. Luke's argument that the agreement would create greater efficiencies through integrated electronic health records and quality-based initiatives.[522] In early 2015, the Ninth Circuit affirmed the lower court's decision.[523]

Similarly, in Florida, a court recently denied a motion to dismiss antitrust allegations against Health First, a large, fully integrated health system in the state.[524] The suit was brought by Omni Healthcare, Inc. and other physician groups who alleged that Health First excluded them from the market by refusing to include the physician groups in insurance provider networks, refusing to refer patients to the physician groups, and revoking the physicians' hospital privileges at

513 "FTC Order Will Restore Competition for Adult Cardiology Services in Reno, Nevada" Federal Trade Commission (Aug. 6, 2012) http://www.ftc.gov/news-events/press-releases/2012/08/ftc-order-will-restore-competition-adult-cardiology-services-reno (Accessed 2/11/15).
514 Ibid.
515 Ibid.
516 Ibid.
517 "In the Matter of Renown Health" Federal Trade Commission Complaint, FTC No. C-4366 (Nov. 30, 2012) p. 4-12.
518 "Antitrust Implications of the Affordable Care Act" By Toby Singer, Journal of Health and Life Sciences Law, Vol. 6, No. 2 (February 2013), p. 59.
519 "St. Luke's Health System, Ltd., and Saltzer Medical Group, P.A." Federal Trade Commission, 2014, http://www.ftc.gov/enforcement/cases-proceedings/121-0069/st-lukes-health-system-ltd-saltzer-medical-group-pa (Accessed 2/2/15).
520 "Saint Alphonsus Medical Center-Nampa Inc. v. St. Luke's Health System, Ltd." No. 1:12-CV-00560-BLW, (D. Idaho 2014), Memorandum Decision and Order, p. 3.
521 Ibid, p. 4.
522 "Saint Alphonsus Medical Center-Nampa Inc. v. St. Luke's Health System, Ltd." No. 1:12-CV-00560-BLW, (D. Idaho 2014), Memorandum Decision and Order, p. 3-4; "Saint Alphonsus Medical Center-Nampa Inc., v. St. Luke's Health System" No. 14-35173 (9th Cir. 2015), Opinion, p. 3-6.
523 "Saint Alphonsus Medical Center-Nampa Inc. v. St. Luke's Health System" No. 14-35173 (9th Cir. 2015), Opinion, p. 3-4 .
524 "Omni Healthcare, Inc. et al. v. Health First, Inc., et al." Case No. 6:13-cv-1509-Orl-37DAB (M.D. Fla. January 21, 2015), Order, p. 2.

Health First hospitals.[525] They also alleged that Health First coordinated group boycotts of physicians who would not exclusively refer their patients to Health First physicians.[526] As a result of Health First's actions, Omni Healthcare physicians claim they lost access to patients and facilities needed to operate and compete in the market.[527] These cases represent the delicate balance associated with the integration of services in furtherance of ACA initiatives, and the potential antitrust enforcement associated therewith.

Horizontal Mergers

The horizontal integration of hospitals and health systems in response to the ACA's coordination of care initiatives has come under similar antitrust scrutiny. A recent example is *Commonwealth of Massachusetts v. Partners Healthcare System, Inc.*, in which Partners, a massive health system and ACO in Massachusetts, attempted to acquire a large hospital, South Shore, and a hospital system, Hallmark Health, the combination of which would have given it a significantly greater market share in the associated market area.[528] Instead of offering structural remedies, which are the generally preferred solution for anticompetitive behavior, the Attorney General offered Partners a settlement consisting of conduct remedies.[529] Typically, this type of anticompetitive behavior is handled through structural remedies, meaning that the mergers are refused, accepted, or accepted with conditions of other divestiture.[530] The conduct remedies offered to Partners limited the health system's ability to negotiate higher physician rates or acquire additional physicians for 5-10 years, but allowed the mergers to continue.[531] However, this settlement was rejected by the Superior Court judge for its inability to demonstrate how efficiencies would be realized without increased costs to consumers.[532] The judge found that the conduct remedies alone were insufficient to effectively control Partners from obtaining more of the healthcare market, and, thus, the proposed settlement would have been against public interest.[533]

Similarly, in 2014, the 6th Circuit denied a petition from ProMedica Health System, seeking an appeal of the District Court's order to divest St. Luke's Hospital after the acquisition of St. Luke's had given ProMedica more than a 50% share in primary and secondary services and 80% share in obstetrical services.[534] The 6th Circuit noted that ProMedica failed to argue that the merger would yield procompetitive effects and conceded to the potential that the merger could

525 "Federal Judge Denies Health First's Motion to Dismiss Suit by Physicians Alleging Unlawful Exclusion" By Toby Singer and Nathaniel Harris, American Health Lawyers Association, Feb. 2. 2015, https://www.healthlawyers.org/Members/PracticeGroups/Antitrust/emailalerts/Pages/Federal_Judge_Denies_Health_Firsts_Motion_to_Dismiss_Suit_by_Physicians_Alleging_Unlawful_Exclusion.aspx (Accessed 2/11/15); "Omni Healthcare, Inc. et al. v. Health First, Inc. et al." Case No. 6:13-cv-1509-Orl-37DAB (M.D. Fl. January 21, 2015), Order, p. 2.

526 "Omni Healthcare, Inc. et al. v. Health First, Inc., et al." Case No. 6:13-cv-1509-Orl-37DAB (M.D. Fla. January 21, 2015), Order, p. 10-11.

527 Ibid, p. 11-13.

528 "Partners Ruling Could Have National Implications" By Priyanka Dayal McCluskey, Boston Globe, January 31, 2015, http://www.bostonglobe.com/business/2015/01/30/partners-ruling-could-have-national-implications/sXotXb3VEFUfyySeHMgPzO/story.html (Accessed 2/9/15).

529 Ibid.

530 "Re: Comments on the Proposed Final Judgment in Massachusetts v. Partners Healthcare System, Inc. et al., Civ. No. 14-2033 (BLS)" By John Kwoka, The American Antitrust Institute, To Honorable Judge Sanders, September 11, 2014, http://www.mass.gov/ago/docs/partners/aai.pdf (Accessed 2/2/15), p. 7.

531 "Partners Agrees to Price Cap for Hallmark Health as Part of Amended Settlement" Attorney General of Massachusetts, September 25, 2014, http://www.mass.gov/ago/news-and-updates/press-releases/2014/2014-09-25-partners-proposed-consent-judgment.html (Accessed 2/9/15).

532 "Commonwealth vs. Partners Healthcare System, Inc., & others" SUCV2014-02033-BLS2 (Mass. Dist. Ct. January 29, 2015), Memorandum of Decision and Order on Joint Motion for Entry of Amended Final Judgment by Consent, p. 28-29.

533 Ibid, p. 2.

534 "ProMedica Health System, Inc. v. FTC" 749 F.3d 559, 561 (6th Cir. 2014).

force consumers in the area to pay higher prices for services.[535] This decision was significant because the court adopted the FTC method of creating product market definitions using a cluster of services approach, despite ProMedica's insistence on using a package-deal theory. In the cluster of services approach, the FTC clusters primary and secondary services together (excluding obstetric and tertiary services) because these services have similar competitive conditions, while the package-deal theory includes all services, even though market forces do not bind these services together.[536] Also important, the court used the FTC's finding that the merger was anticompetitive by comparing market concentration levels post-merger, instead of following ProMedica's recommendation of determining consumer's next preferred choice for care, and relied extensively on the FTC and DOJ's 2010 Horizontal Merger Guidelines.[537] ProMedica has since filed a petition with the Supreme Court to review the decision, alleging that the 6th Circuit used non-accepted antitrust law practices to formulate its decision.[538]

Another case of contention is that of Phoebe Putney Health System's acquisition of Palmyra Park Hospital, Inc. in Georgia, where the only two hospitals in the area decided to merge. In 2011, the FTC challenged the proposed acquisition, citing the increase in prices that would occur for general acute-care hospital services; however, the 11th Circuit decided the deal was immune from antitrust scrutiny because of the state action doctrine.[539] Eventually, the Supreme Court reversed the 11th Circuit, finding in favor of the FTC and remanded the case for further consideration, despite the fact that the two entities had already merged at that point.[540] The FTC was unable to order divestiture because the entities had already received authorization to merge under Georgia's Certificate of Need law, and the agency believed the CON law would not authorize another buyer.[541] After a series of discussions, the FTC has announced its intention to seek a settlement, unless the parties cannot come to an agreement, in which case they will continue before an administrative law judge.[542]

The consolidation of healthcare systems has also raised concerns with antitrust authorities because such mergers are likely to have a significant effect on the markets in which they exist. In 2012, the FTC was rewarded for its investigation and complaint issued against OSF Healthcare

535 "Sixth Circuit Rules for FTC in Challenge to Ohio Hospital Merger" By Tiffany Milone and Peyton Sturges, Bloomberg BNA: Health Law Reporter, April 22, 2014, http://healthlawrc.bna.com/hlrc/4237/split_display.adp?fedfid=45362962&vname=hlrnotallissues&jd=a0e9k5y1d1&split=0 (Accessed 2/6/15).

536 Ibid.

537 "Sixth Circuit Rules for FTC In Challenge to Ohio Hospital Merger" By Tiffany Milone and Peyton Sturges, Bloomberg BNA: Health Law Reporter, April 22, 2014, http://healthlawrc.bna.com/hlrc/4237/split_display.adp?fedfid=45362962&vname=hlrnotallissues&jd=a0e9k5y1d1&split=0 (Accessed 2/6/15); "The Potential Impact of ProMedica: Health Care and Beyond" By Clifford H. Aronson, Gregory M. Luce, and Steven C. Sunshine, April 30, 2014, http://www.skadden.com/insights/potential-impact-ipromedicai-health-care-and-beyond (Accessed 3/11/15).

538 "Ohio Hospital Seeks High Court Review of Sixth Circuit Ruling Requiring Divestiture" By Peyton Sturges, Bloomberg BNA: Health Law Reporter, January 13, 2015, http://healthlawrc.bna.com/hlrc/4237/split_display.adp?fedfid=61889821&vname=hlrnotallissues&wsn=487907000&searchid=24449989&doctypeid=9&type=oadate4news&mode=doc&split=0&scm=4237&pg=0 (Accessed 2/6/15).

539 "Federal Trade Commission v. Phoebe Putney Health System" 793 F. Supp.2d 1356, 1360, 1375 (M.D. Ga. June 27, 2011); "Federal Trade Commission v. Phoebe Putney Health System" 663 F.3d 1369, 1378 (11th Cir. 2011); "FTC Halts Phoebe Putney Merger Challenge to Talk Deal" By Y. Peter Kang, Law 360, January 29, 2015, http://www.law360.com/articles/616561/ftc-halts-phoebe-putney-merger-challenge-to-talk-deal (Accessed 2/19/15).

540 "Federal Trade Commission v. Phoebe Putney Health System" 133 S. Ct. 1003, 1016-1017 (2013); "FTC Halts Phoebe Putney Merger Challenge to Talk Deal" By Y. Peter Kang, Law 360, January 29, 2015, http://www.law360.com/articles/616561/ftc-halts-phoebe-putney-merger-challenge-to-talk-deal (Accessed 2/19/15).

541 "FTC Halts Phoebe Putney Merger Challenge to Talk Deal" By Y. Peter Kang, Law 360, January 29, 2015, http://www.law360.com/articles/616561/ftc-halts-phoebe-putney-merger-challenge-to-talk-deal (Accessed 2/19/15).

542 Ibid.

System's acquisition of rival Rockford Health System when OSF announced it would no longer pursue Rockford.[543] The intended merger would have given the two hospitals joint control of more than 99% of the general acute-care services market and reduced competition from three systems to two. In response to OSF's decision to abandon the merger, the FTC dropped the complaint against OSF, noting it will continue to challenge and pursue agreements that could reduce competition.[544]

ACOs AND ANTITRUST

Since the establishment of the ACA, antitrust concerns have developed for recently formed *accountable care organizations* (ACOs). ACOs are designed to promote more efficient, coordinated care in order to reduce costs; however, they involve the integration of various healthcare entities.[545] In October 2011, the FTC and DOJ issued a joint statement that created safety zones from antitrust enforcement in order to allow MSSP ACOs more freedom to consolidate and improve coordinated care.[546] These safety zones allow ACOs' participants to have up to a 30% share of each common service within the participants' primary service areas.[547] However, the agencies stressed that if there seems to be a greater likelihood of anticompetitive effects, the organizations must also prove a greater likelihood of efficiencies in order to avoid agency interference.[548]

The joint statement also removed the mandatory antitrust review requirement for ACOs entering the MSSP, allowing ACOs to submit to such review on a voluntary basis.[549] However, these safety zones only extend to MSSP ACOs, so additional caution must be taken for commercial ACOs that are not participating in the Medicare program, although they may still utilize exceptions and safe harbors to applicable regulations and may seek use of the participation waiver in some transactions.[550] A caveat to the Statement's application states that the Joint Statement only applies to ACOs formed by collaboration among independent provider groups and not those formed by mergers because ACOs formed by mergers are evaluated under the Horizontal Merger Guidelines released by the FTC and DOJ.[551] Similarly, the Statement does not apply to a standalone integrated care organization.[552]

543 "OSF Healthcare System Abandons Plan to Buy Rockford in Light of FTC Lawsuit; FTC Dismisses its Complaint Seeking to Block the Transaction" Federal Trade Commission, April 13, 2012, http://www.ftc.gov/news-events/press-releases/2012/04/osf-healthcare-system-abandons-plan-buy-rockford-light-ftc (Accessed 3/11/15).

544 Ibid.

545 "Accountable Care Organizations (ACO)" Centers for Medicare & Medicaid Services, January 6, 2015, http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/ACO/index.html?redirect=/aco/ (Accessed 1/29/15); "Antitrust Implications of the Affordable Care Act" By Toby Singer, Journal of Health and Life Sciences Law, Vol. 6, No. 2 (February 2013), p. 59.

546 "Statement of Antitrust Enforcement Policy Regarding Accountable Care Organizations Participating in the Medicare Shared Savings Program" Federal Register, Vol. 76, No. 209 (October 28, 2011), p. 67028.

547 Ibid.

548 "Statement of Antitrust Enforcement Policy Regarding Accountable Care Organizations Participating in the Medicare Shared Savings Program" Federal Register, Vol. 76, No. 209 (October 28, 2011), p. 67029-30.

549 Ibid, p. 67029.

550 "Medicare Program; Final Waivers in Connection With the Shared Savings Program; Interim Final Rule" Federal Register Vol. 76, No. 212 (November 2, 2011), p. 68006.

551 "Rule of Reason Analysis for Accountable Care Organizations" By Gregory J Pelnar and Gretchen M. Weiss, The Antitrust Source, American Bar Association, December 2011, http://www.americanbar.org/content/dam/aba/publishing/antitrust_source/dec11_pelnar_12_21f.authcheckdam.pdf (Accessed 2/19/15) p. 3.

552 Ibid.

The final joint statement listed types of conduct that are discouraged or will likely invoke an investigation by antitrust agencies for ACOs participating in the Medicare Shared Savings Program (MSSP).[553] This list includes:

(1) Sharing competitively sensitive information;
(2) Restricting payors' ability to share the ACO's cost, quality, efficiency, and performance information with their enrollees;
(3) Exclusive contracting; and
(4) Employing anti-steering provisions.[554]

This list serves as an addendum to the rule of reason test described previously by providing more narrow conditions that are helpful for ACOs to consider when self-monitoring. Specific to ACOs, the rule of reason test requires that ACOs be sufficiently "*financially or clinically integrated*" in order to avoid agency review.[555] Otherwise, these ACOs could be found in violation of antitrust laws like the Sherman or Clayton Acts.[556] Commercial ACOs can expect that agencies will likely use a similar approach when determining potential antitrust violations, though these ACOs will be more closely monitored for compliance with market power and integration requirements.[557]

INTERNAL REVENUE SERVICE AND THE INTERNAL REVENUE CODE

IRS TAX STATUS

Healthcare providers may qualify for a federal tax exemption if they meet the IRS requirements for charitable organizations under section 501(c)(3) of the *Internal Revenue Code* (IRC).[558] In 2002, nonprofit hospitals nationwide saved an estimated $12.6 billion from tax exemptions;[559] *Forbes* estimated this savings expanded to $20 billion in 2012.[560] The benefits of federal tax exemption come with corresponding burdens. To maintain tax-exempt status, an organization has to prove that it benefits the public, is organized and operated exclusively for exempt purposes, and none of its earnings are allocated to private shareholders or individuals.[561] Exempt purposes include those that are charitable, religious, educational, and scientific. The federal tax regulations

553 "Statement of Antitrust Enforcement Policy Regarding Accountable Care Organizations Participating in the Medicare Shared Savings Program" Federal Register, Vol. 76, No. 209 (October 28, 2011), p. 67029.
554 Ibid, p. 67029-30.
555 Ibid, p. 67027.
556 "Antitrust Implications of the Affordable Care Act" By Toby Singer, Journal of Health and Life Sciences Law, Vol. 6, No. 2, February 2013, p. 60-61, 74.
557 Ibid, p. 74.
558 "Nonprofit, For-Profit, and Government Hospitals: Uncompensated Care and Other Community Benefits" Testimony of David M. Walker: Comptroller General of the United States, Before the Committee on Ways and Means of the House of Representatives, Washington, D.C.: United States Government Accountability Office (May 26, 2005), http://www.gao.gov/new.items/d05743t.pdf (Accessed 02/08/10).
559 "Nonprofit Hospitals and the Provision of Community Benefits" Congressional Budget Office, December 2006, http://www.cbo.gov/ftpdocs/76xx/doc7695/12-06-Nonprofit.pdf (Accessed 02/09/10).
560 "ObamaCare Could Cause Nonprofit Hospitals to Lose their Tax-Exempt Status: Here's How" By David Whelan, Forbes, September 17, 2012, http://www.forbes.com/sites/davidwhelan/2012/09/17/obamacare-could-cause-nonprofit-hospitals-to-lose-their-tax-exempt-status-heres-how/ (Accessed 2/21/15).
561 "Exemption Requirements—Section 501(c)(3) Organizations" Internal Revenue Service, December 7, 2009, http://www.irs.gov/charities/charitable/article/0,,id=96099,00.html (Accessed 2/9/10).

define *charitable activities* as relief of the poor, the distressed, or the underprivileged; lessening the burdens of government; lessening neighborhood tensions; and combating community deterioration and juvenile delinquency.[562] Most healthcare organizations that are tax-exempt under federal law have that status because they are classified as charitable organizations.[563]

In 1969, the IRS expanded the definition of the term "*charitable*" and declared that to qualify as a healthcare provider that promotes health as its charitable purpose, an organization must meet the community benefit standard described in revised ruling 69-545 as well as the other requirements of IRC 501(c)(3).[564] The community benefit standard lists several requirements for section 501(c)(3) qualification, such as the requirement of a community-based board without financial interests in the institution, a full-time emergency room open to all without regard to ability to pay, treatment of Medicare and Medicaid patients without discrimination, and appropriate mission-related use of net earnings.[565]

In a demonstrative case for integrating healthcare systems, the IRS granted tax-exempt status to *Friendly Hills HealthCare Network*, which included a vertically *Integrated Delivery System* (IDS), in what has been considered as a landmark determination in defining what constitutes *community benefit*. The IRS granted tax-exempt status after identifying several critical elements regarding *Friendly Hills HealthCare Network's* acquisitions and medical practice operations:

(1) The stated goal of the reorganization into the IDS was to "enhance the accessibility, quality and cost-efficiency of services rendered to the community;"
(2) The *community benefit* provided by the IDS against the private benefits provided to the physicians by *Friendly Hills HealthCare Network* was considered by the IRS to be part *purchase* and part *donation*; and
(3) The board of directors had established a "*20 percent safe harbor*" of physician membership on the board.[566]

In granting tax-exempt status, the IRS required the IDS to treat Medicaid patients, provide charity care, and engage in medical research in addition to maintaining an open medical staff and 24-hour emergency room.[567]

562 Ibid.
563 "The Law of Tax-Exempt Healthcare Organizations" By Thomas K. Hyatt and Bruce R. Hopkins, Hoboken, NJ: John Wiley & Sons Publishers, 1995, p. 13.
564 "Health Care Provider Reference Guide" By Janet E. Gitterman and Marvin Friedlander, Internal Revenue Service, 2004, http://www.irs.gov/pub/irs-tege/eotopicc04.pdf (Accessed 02/09/10).
565 "Revenue Ruling 69-545" Internal Revenue Service, 1969, http://www.irs.gov/pub/irs-tege/rr69-545.pdf (Accessed 3/16/15);"IRS Begins Hospital Community Benefit Compliance Initiative" By David Flynn, ABA Health eSource, June 2006, http://www.abanet.org/health/esource/Volume2/vol2no10/flynn.html (Accessed 02/09/10).
566 "IRS Exemption Rulings (IER): Friendly Hills Healthcare Network" U.S. Internal Revenue Service, 7 Exempt Org. Tax Rev. 490 (March 1993), p. 490-491; "Colloquium Report on Legal Issues Related to Tax Exemption and Community Benefit," National Health Lawyers Association, 1996, p. 18.
567 "IRS Exemption Rulings (IER): Friendly Hills Healthcare Network" U.S. Internal Revenue Service, 7 Exempt Org. Tax Rev. 490 (March 1993), p. 491; "Colloquium Report on Legal Issues Related to Tax Exemption and Community Benefit," National Health Lawyers Association, 1996, p. 18.

INUREMENT OF PRIVATE BENEFIT AND EXCESS BENEFIT TRANSACTIONS

In addition to the requirement that a tax-exempt organization meet *charitable purpose* standards, the IRS prohibits *excess benefit transactions* and *inurement of private benefits* between tax-exempt organizations and third parties in which "the value of the economic benefit provided exceeds the value of the consideration received for providing the benefit."[568]

According to the IRS, an "excess benefit transaction [is a] transaction in which an economic benefit is provided by an applicable tax-exempt organization, directly or indirectly, to or for the use of any disqualified person, if the value of the economic benefit provided [by the organization] exceeds the value of the consideration received for providing such benefits."[569] In addition to excess benefit transactions, the IRS has *strictly prohibited the inurement of private benefits*, i.e., when an exempt organization is "…organized or operated for the benefit of private interests…," stating:

> "[n]o part of the net earnings of a section 501(c)(3) organization may inure to the benefit of any private shareholder or individual[, whereby] a private shareholder or individual is a person having a personal and private interest in the activities of the organization."[570]

If an *exempt organization* (EO) has engaged in an *excess benefit transaction*, the IRS may impose an array of punishments, including: (1) an *excise tax* on the individual and/or the exempt organization or (2) total revocation of the organization's tax-exempt status.[571] In the final regulations published on March 28, 2008, the IRS identified five factors to be considered when determining the appropriate punishment:

(1) The size and scope of the organization's *ongoing activities*;
(2) The size and scope of the *excess benefit transaction* in relation to regular activities;
(3) Whether *excess benefit transactions* happened in the past;
(4) Whether the organization has implemented *safeguards* against this type of transaction; and
(5) Whether the *excess benefit transaction* has been corrected, or there has been a *good faith effort* to do so.[572]

In those cases in which the EO has worked to remedy the situation, IRS will give the last two factors greater weight when considering whether to allow EO's *tax-exempt status* to remain.[573]

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568 "Excess Benefit Transaction" 26 C.F.R. § 53.4958-4(a)(1) (2012).
569 "Taxes on excess benefit transaction" 26 U.S.C. § 4958(c)(1)(a) (2012).
570 "Inurement/Private Benefit - Charitable Organizations" Internal Revenue Services, February 2, 2012, http://www.irs.gov/charities/charitable/article/0,,id=123297,00.html (Accessed 8/7/2012); "Exemption from tax on corporations, certain trusts, etc." 26 U.S.C. § 501(c)(3) (2011).
571 "IRS Policing of Tax-Exempt Organizations" By Charles R. Brodbeck and Mark R. Stabile, Physician's News Digest, February 1997, http://www.physiciansnews.com/finance/297.html (Accessed 9/24/12); "Taxpayer Bill of Rights" Pub. L. 104-168, § 1311, 110 Stat. 1452, 1475-1479 (July 30, 1996).
572 "Standards for Recognition of Tax-Exempt Status if Private Benefit Exists of if an Applicable Tax-Exempt Organization Has Engaged in Excess Benefit Transaction(s)" Federal Register Vol. 73 No. 61 (March 28, 2008), p. 16522.
573 Ibid.

Despite the IRS prohibitions against *excess benefit transactions*, compensation arrangements involving tax-exempt organizations *may* include *financial incentives* if the arrangement involves "*reasonable compensation*."[574]

"REASONABLE COMPENSATION" DEFINED BY THE IRS

Under Treasury Regulation 53.4958-4, the IRS equates *reasonable compensation* to the value of services provided and further defines *reasonable compensation* as "the amount that would ordinarily be paid for like services by the enterprises (whether taxable or tax-exempt) under like circumstances."[575] Significantly, the IRS states that the valuation standard is that of "fair market value (i.e., the price at which property or the right to use property would change hands between a willing buyer and a willing seller, neither being under any compulsion to buy, sell or transfer property or the right to use property, and both having reasonable knowledge of relevant facts)."[576]

Treasury Regulation 53.4958-6 further states that, "payments under a compensation arrangement are *presumed to be reasonable...if the following conditions are satisfied:*

(1) The compensation arrangement…[is] approved in advance by an authorized body of the applicable tax-exempt organization composed entirely of individuals who do not have a conflict of interest with respect to the compensation arrangement;
(2) The authorized body obtained and relied upon appropriate data as to comparability prior to making its determination; and
(3) The authorized body adequately documented the basis for its determination concurrently with making that determination."[577] [Emphasis added].

IRS DEFINITIONS OF "BONA FIDE EMPLOYEES" AND "FORM 1099 INDEPENDENT CONTRACTORS"

What constitutes an "*employee*" versus a "*1099 independent contractor*," as set forth in 26 U.S.C. § 312(d)(2),[578] is significant for purposes of many *fraud and abuse* regulations governing healthcare providers. For example, the term "*employee*" under *Anti-Kickback statute* and *Stark law* utilizes the IRS definitions in many of its safe harbors and exceptions, respectively. To determine whether a person is a "*bona fide employee*," the IRS has developed an *11 factor test*, which can be broken down into three general categories, i.e., (1) *behavioral control*, (2) *financial control*, and (3) *type of relationship between the parties.*[579] It is not necessary that all 11 factors be met, and no single factor is dispositive in determining employment status. Rather, facts

574 In General Counsel Memorandum (GCM) 35638, published on January 28, 1974, the IRS stated that compensation arrangements involving shared savings related to quality improvements could be acceptable if they were at arm's length and were "…a means of providing reasonable compensation to employees without any potential for reducing the charitable services or benefits otherwise provided…" [emphasis added]. "Section 4958 Update" By Lawrence M. Brauer and Marvin Friedlander," in "2000 Exempt Organization (EO) CPE Text" Internal Revenue Service, 2000, p. 29.
575 "Excess benefit transaction" 26 C.F.R. § 53.4958-4(b)(ii)(A) (2012).
576 "Excess benefit transaction" 26 C.F.R. § 53.4958-4(b)(i) (2012).
577 "Rebuttable presumption that a transaction is not an excess benefit transaction" 26 C.F.R. § 53.4958-6.
578 "Effect on Earnings and Profits" 26 U.S.C. § 312(d)(2) (2012).
579 "Employer's Supplemental Tax Guide (Supplement to Publication 15 (Circular E), Employer's Tax Guide" Publication 15-A, Department of the Treasury, Internal Revenue Service, 2012, p. 7.

related to the 11 factors, taken together in the aggregate, serve as evidence of whether or not a *bona fide employee* relationship exists.[580]

INTERNAL REVENUE CODE SECTION 501(R)

In addition to the requirements outlined above, the ACA added Section 501(r) to the IRC, which provided new requirements for hospitals to satisfy in order to maintain their tax-exempt status.[581] The final regulations, published December 31, 2014, affect five categories of tax-exempt hospital operations:

(1) *Community Health Needs Assessments* (CHNA);
(2) *Financial Assistance Policies* (FAP);
(3) Limitation on Patient Charges;
(4) Billing and Collection Policies; and
(5) Miscellaneous requirements.[582]

The new 501(r) rules become enforceable "for taxable years beginning after December 29, 2015."[583]

Community Health Needs Assessments (CHNA)

In its modification to Section 501(r) of the IRC, the ACA requires charitable hospitals to conduct a CHNA every three years and adopt an appropriate implementation strategy that satisfies the needs identified in the CHNA.[584] To satisfy this statutory threshold, the final regulations provide specific requirements for charitable hospitals when conducting their CHNA. First, charitable hospitals have discretion to define their "*community*" for CHNA purposes as long as the definition does not exclude medically underserved, low-income, or minorities.[585] Second, the regulations expand the scope of "*health needs*" for a CHNA beyond financial and barriers to care, and requires hospitals to include all "*significant*" health needs in the community.[586] Notably, charitable hospitals "have flexibility to choose how best to prioritize the significant health needs of their particular communities" and may base their priorities on factors such as the burden of the health need, the "feasibility and effectiveness of possible interventions," and disparities within the community concerning a particular health need.[587] Finally, hospitals must make reasonable efforts to secure input on its CHNA from three specific sources:

580 Ibid.
581 "Patient Protection and Affordable Care Act" Pub. L. No. 111-148, § 9007, 124 Stat. 119, 855 (2010).
582 "Creeping Normality: IRS Releases Final Regulations Under Section 501(r)" McDermott Will & Emery, January 15, 2015, http://www.mwe.com/files/Uploads/Documents/Pubs/Creeping-Normality.pdf (Accessed 2/21/15).
583 "Additional Requirements for Charitable Hospitals; Community Health Needs Assessments for Charitable Hospitals; Requirement of a Section 4959 Excise Tax Return and Time for Filing the Return; Final Rule" Federal Register Vol. 79, No. 250 (December 31, 2014) p. 78996.
584 "Patient Protection and Affordable Care Act" Pub. L. No. 111-148, § 9007, 124 Stat. 119, 856 (2010).
585 "Additional Requirements for Charitable Hospitals; Community Health Needs Assessments for Charitable Hospitals; Requirement of a Section 4959 Excise Tax Return and Time for Filing the Return; Final Rule" Federal Register Vol. 79, No. 250 (December 31, 2014) p. 78962.
586 Ibid, p. 78963.
587 Ibid, p. 78963.

(1) Government public health departments;
(2) Those in low-income, minority, or medically underserved communities; and
(3) Written comments of the hospital's previous CHNA.[588]

Financial Assistance Policies (FAP)

The ACA further modifies Section 501(r) of the IRC by requiring charitable hospitals to adopt adequate FAPs in order to maintain their 501(c)(3) status.[589] The final regulations require these policies to contain five specific elements:

(1) Eligibility criteria for financial assistance;
(2) Whether such assistance includes free or discounted care;
(3) Methodology for calculating charges and applying financial assistance;
(4) The possible collection actions a hospital may take; and
(5) A list of where the FAP is available.[590]

A charitable hospital's FAP must be available online for patients and other members of the public to access.[591] Notwithstanding a charitable hospital's FAP, a charitable hospital cannot refuse to provide emergency care based on if a patient is eligible for financial assistance.[592]

Limitation on Patient Charges

The ACA also modified Section 501(r) of the IRC by limiting what charitable hospitals can charge patients who are eligible for discounts under a hospital's FAP.[593] The final regulations implementing Section 501(r) note that patients qualifying under a hospital's FAP must pay no more than the *amounts generally billed* (AGB) to insured patients for emergency or other medically necessary care.[594] The final regulations provide three methods charitable hospitals may utilize to calculate AGB:

(1) **Look-Back Method**—AGB determined by "multiplying the hospital facility's gross charges for that care by one or more percentages of gross charges;"[595]
(2) **Prospective Method**—AGB determined by "setting AGB for that care at the amount that Medicare and the Medicare beneficiary together would be expected to pay for the care;"[596] or
(3) **Medicaid Method**—AGB determined by applicable Medicaid rates.[597]

588 Ibid, p. 78963.
589 "Patient Protection and Affordable Care Act" Pub. L. No. 111-148, § 9007, 124 Stat. 119, 856 (2010).
590 "Additional Requirements for Charitable Hospitals; Community Health Needs Assessments for Charitable Hospitals; Requirement of a Section 4959 Excise Tax Return and Time for Filing the Return; Final Rule" Federal Register Vol. 79, No. 250 (December 31, 2014) p. 78972-78977; "Creeping Normality: IRS Releases Final Regulations Under Section 501(r)" McDermott Will & Emery, January 15, 2015, http://www.mwe.com/files/Uploads/Documents/Pubs/Creeping-Normality.pdf (Accessed 2/21/15).
591 "Additional Requirements for Charitable Hospitals; Community Health Needs Assessments for Charitable Hospitals; Requirement of a Section 4959 Excise Tax Return and Time for Filing the Return; Final Rule" Federal Register Vol. 79, No. 250 (December 31, 2014) p. 78974.
592 Ibid, p. 78977.
593 "Patient Protection and Affordable Care Act" Pub. L. No. 111-148, § 9007, 124 Stat. 119, 857 (2010).
594 "Additional Requirements for Charitable Hospitals; Community Health Needs Assessments for Charitable Hospitals; Requirement of a Section 4959 Excise Tax Return and Time for Filing the Return; Final Rule" Federal Register Vol. 79, No. 250 (December 31, 2014) p. 78978.
595 Ibid, p. 78980.
596 Ibid, p. 78982.
597 "Additional Requirements for Charitable Hospitals; Community Health Needs Assessments for Charitable Hospitals; Requirement of a Section 4959 Excise Tax Return and Time for Filing the Return; Final Rule" Federal Register Vol. 79, No. 250 (December 31, 2014) p. 78979-78982; "Creeping Normality: IRS Releases Final Regulations Under Section 501(r)" McDermott Will & Emery, January 15, 2015, http://www.mwe.com/files/Uploads/Documents/Pubs/Creeping-Normality.pdf (Accessed 2/21/15).

Charitable hospitals may only utilize one methodology at a time, although a hospital is free to switch methodologies.[598] In addition, charitable hospitals must limit the amounts charged to FAP-eligible individuals "for all other medical care covered under (a charitable hospital's) FAP to less than the gross charges for that care."[599]

Billing and Collection Policies

The ACA's modifications to Section 501(r) of the IRC constrain the ability of charitable hospitals to engage in *extraordinary collection efforts* (ECA) from its patients.[600] The final regulations provide that certain actions are not ECAs under Section 501(r):

(1) Non-judicial processes, such as calling a patient or sending a bill;
(2) Placing a lien on 3rd parties who caused the patient's injuries;
(3) Charging interest on medical debt; and
(4) Filing a claim in any bankruptcy proceeding.[601]

Under Section 501(r) and its final regulations, hospitals may institute ECAs only if it uses "*reasonable efforts*" to determine a patient's eligibility under a FAP.[602] To satisfy the *reasonable efforts* requirement, charitable hospitals must allow patients 240 days after receipt of a medical bill, post-discharge, to apply for assistance under a hospital's FAP.[603] Further, charitable hospitals must send an *ECA Initiation Notice*, a written communication that notifies the patient of a hospital's option to engage in ECAs, the existence of the hospital's FAP, and how to apply for the FAP.[604] If an ECA Initiation Notice is not received within 30 days of sending, then the hospital may engage in ECAs.

Miscellaneous Requirements

Significantly, the final regulations implementing the ACA's amendments to Section 501(r) note that "*minor omissions and errors*" regarding 501(r) requirements will not doom a hospital's 501(c)(3) status.[605] To constitute a "*minor omission and error*" under 501(r), the hospital's mistake must satisfy the following conditions:

598 "Creeping Normality: IRS Releases Final Regulations Under Section 501(r)" McDermott Will & Emery, January 15, 2015, http://www.mwe.com/files/Uploads/Documents/Pubs/Creeping-Normality.pdf (Accessed 2/21/15); "Additional Requirements for Charitable Hospitals; Community Health Needs Assessments for Charitable Hospitals; Requirement of a Section 4959 Excise Tax Return and Time for Filing the Return; Final Rule" Federal Register Vol. 79, No. 250 (December 31, 2014) p. 78978.
599 "Additional Requirements for Charitable Hospitals; Community Health Needs Assessments for Charitable Hospitals; Requirement of a Section 4959 Excise Tax Return and Time for Filing the Return; Final Rule" Federal Register Vol. 79, No. 250 (December 31, 2014) p. 78978.
600 "Patient Protection and Affordable Care Act" Pub. L. No. 111-148, § 9007, 124 Stat. 119, 857 (2010).
601 "Additional Requirements for Charitable Hospitals; Community Health Needs Assessments for Charitable Hospitals; Requirement of a Section 4959 Excise Tax Return and Time for Filing the Return; Final Rule" Federal Register Vol. 79, No. 250 (December 31, 2014) p. 78984-78985.
602 Ibid, p. 78983.
603 "Additional Requirements for Charitable Hospitals; Community Health Needs Assessments for Charitable Hospitals; Requirement of a Section 4959 Excise Tax Return and Time for Filing the Return; Final Rule" Federal Register Vol. 79, No. 250 (December 31, 2014) p. 78987.
604 Ibid, p. 78989.
605 Ibid, p. 78960.

(1) The error or omission was minor;
(2) The error or omission was inadvertent or due to reasonable cause; and
(3) The hospital corrects the omission or error promptly after discovery.[606]

With potentially $20 billion at stake, tax-exempt organizations must sufficiently portray their tax-exempt status to the IRS. To support this reporting, the IRS issued an updated version of Form 990, the return that charities and other tax-exempt organizations are required to file annually. The redesign of Form 990 is based on three guiding principles: *"(1) enhancing transparency; (2) promoting tax compliance; and, (3) minimizing the burden on the filing organization."*[607] The most significant changes to Form 990 include: (1) adding a summary page that provides "a snapshot of the organization's key financial, compensation, governance, and operational information;" (2) "requiring governance information, including the composition of the board and financial practices;" and (3) revising and adding "schedules that will focus reporting on certain areas of interest to the public and the IRS."[608] Further, Form 990 will be revised with the issuance of the 501(r) regulations for taxable years beginning after December 29, 2015.

IRS AUDITS AND COMPLIANCE WITH SECTION 409A

Beginning in February 2010 and renewed in May 2014, the Tax Exempt and Government Entities Division of the IRS called for random audits of tax-exempt organizations to ensure their compliance with section 409A. This section requires that, unless certain requirements are met, tax-exempt organizations include nonqualified deferred compensation in an individual's gross income for the tax year in which the deferred compensation is actually paid.[609] The IRS is seeking a thorough examination of all executive compensation and benefit arrangements, including executive retirement contracts and deferred compensation arrangements.[610] The increased enforcement comes amid a growing public outcry against excessive executive compensation arrangements in both for-profit and nonprofit companies. Similar to the new Form 990, the goal of the audits is to increase transparency and hold tax-exempt organizations accountable for the benefits they receive. Renewed 409A audits in May 2014 may be a sign that the IRS is developing streamlined audit techniques before the scope of the program is expanded.[611]

606 "Additional Requirements for Charitable Hospitals; Community Health Needs Assessments for Charitable Hospitals; Requirement of a Section 4959 Excise Tax Return and Time for Filing the Return; Final Rule" Federal Register Vol. 79, No. 250 (December 31, 2014) p. 78960-78961; "Creeping Normality: IRS Releases Final Regulations Under Section 501(r)" McDermott Will & Emery, January 15, 2015, http://www.mwe.com/files/Uploads/Documents/Pubs/Creeping-Normality.pdf (Accessed 2/21/15).

607 "Do Nonprofit Hospitals Provide Community Benefit? A Critique of the Standards for Proving Deservedness of Federal Tax Exemptions" By Laura Folkerts, The Journal of Corporation Law, Vol. 34, No. 2 (2009), p. 627; "Background Paper: Redesigned Draft Form 990" Internal Revenue Service, 2007, http://www.irs.gov/pub/irs-tege/form_990_cover_sheet.pdf (Accessed 02/09/10).

608 "Do Nonprofit Hospitals Provide Community Benefit? A Critique of the Standards for Proving Deservedness of Federal Tax Exemptions" By Laura Folkerts, The Journal of Corporation Law, Vol. 34, No. 2 (2009), p. 627; ; "Highlights of Redesigned Form 990" Internal Revenue Service, June 3, 2007, http://www.irs.gov/pub/irs-tege/highlightsform990redesign_ 061307.pdf (Accessed 3/5/15).

609 "Inclusion in Gross Income of Deferred Compensation under Nonqualified Deferred Compensation Plans" 26 U.S.C. § 409A(a)(1)(A)(i) (2013); "Application of Section 409A to Nonqualified Deferred Compensation Plans" Federal Register Vol. 72, No. 73 (April 17, 2007), p. 19234.

610 "Enforcement Efforts Take Aim at Executive Compensation of Tax-Exempt Health Care Entities" By Candace L. Quinn and Jeffrey D. Mamorsky, Health Law Reporter Vol. 18 No. 1640, December 17, 2009 https://www.bloomberglaw.com/print/X1VTN9R36Q80 (Accessed 3/5/15).

611 "Look Out Below"—409A Audits Starting" American Appraisal, 2014, http://www.american-appraisal.com/AA-Files/Library/PDF/409AAudits.pdf (Accessed 2/25/15).

If an exempt organization is found to not be in compliance with section 409A, then the IRS has the ability to impose: (1) additional payroll taxes and interest; (2) significant tax penalties on individuals for failure of nonqualified deferred compensation plans to meet the requirements of section 409A; and (3) substantial monetary sanctions if the IRS determines that the executive compensation arrangement constitutes an *excess benefit transaction*, which are those transactions "… in which an economic benefit is provided by an applicable tax-exempt organization, directly or indirectly, to or for the use of a disqualified person, and the value of the economic benefit provided by the organization exceeds the value of the consideration received by the organization."[612]

The 2014 effort is expected to examine the top 10 "*most highly compensated individuals*" within 50 companies across all industries over a twelve-month period.[613] If fringe benefits for executives in these exempt organizations were incorrectly treated as tax-free, they could result in additional taxes owed by both the recipient and the employer.[614]

OTHER TAX PROVISIONS

Individual Health Insurance Mandate

Arguably, one of the most publicized provisions of the ACA is the *individual mandate*, the requirement that U.S. citizens and legal residents maintain minimum amounts of health insurance coverage, i.e., *essential coverage*. *Essential coverage* includes: (1) government sponsored programs; (2) certain employer-sponsored programs; (3) insurance plans sold on the individual market; (4) grandfathered group health plans; and, (5) some other types of coverage.[615] Some individuals are excluded from this broad requirement, including: (1) members of a recognized religion who are conscientiously opposed to the requirement; (2) members of a healthcare-sharing ministry; (3) individuals not lawfully present in the U.S.; (4) incarcerated individuals; (5) individuals who cannot afford coverage; (6) taxpayers whose income is less than 100 percent of the federal poverty limit; and (7) members of Indian tribes.[616] To assist U.S. citizens in paying for health insurance premiums purchased through a state health benefit exchange, the ACA provides refundable *premium tax credit* for taxpayers whose income is 9.5 percent under the lowest cost plan.[617] Individuals who are not in compliance with the law, which went into effect on January 1, 2014, are subject to the greater of: (1) $95 per individual or (2) 1.0% of household income over the filing threshold.[618] For those without coverage in 2015, these penalties increase to: (1) $325 per individual or (2) 2.0 percent of household income over the filing threshold, respectively.[619]

612 "Intermediate Sanctions—Excess Benefit Transactions" Internal Revenue Service, August 28, 2014, http://www.irs.gov/Charities-&-Non-Profits/Charitable-Organizations/Intermediate-Sanctions-Excess-Benefit-Transactions (Accessed 03/05/15); "Enforcement Efforts Take Aim at Executive Compensation of Tax-Exempt Health Care Entities" By Candace L. Quinn and Jeffrey D. Mamorsky, 18 Health Law Reporter 1640, December 17, 2009 https://www.bloomberglaw.com/print/X1VTN9R36Q80 (Accessed 3/5/15).

613 "Initiative Gathers Section 409A Data for Compliance Check, IRS Official Says" By Mary Hughes, Bloomberg BNA, August 6, 2014, http://www.bna.com/initiative-gathers-section-b17179893402/ (Accessed 2/25/15), p. 1-2.

614 "Exempt Organizations: Employment Tax Audits of Exempt Hospitals Could Turn Up Other Issues Attorneys Warn" BNA's Health Law Reporter, Vol. 18, No. 1653, December 24, 2009, https://www.bloomberglaw.com/print/X1VTNHR36Q80 (Accessed 3/5/15).

615 "Patient Protection and Affordable Care Act" Pub. L. 111-148, § 1501, 124 Stat. 119, 242-249 (March 23, 2010).

616 "Patient Protection and Affordable Care Act" Pub. L. 111-148, § 1501, 124 Stat. 119, 246-248 (March 23, 2010).

617 "Patient Protection and Affordable Care Act" Pub. L. 111-148, § 1411, 124 Stat. 119, 224-231. (March 23, 2010). Of note, this section was amended to include Social Security benefits in the modified adjusted gross income in order to calculate the premium tax credit. "Three Percent Withholding Repeal and Job Creation Act" Pub. L. 112-56, § 401, 125 Stat. 711, 734 (November 21, 2011).

618 "The Fee You Pay if You Don't Have Health Coverage" Healthcare.gov, 2015, https://www.healthcare.gov/fees-exemptions/fee-for-not-being-covered/ (Accessed 3/6/15).

619 Ibid.

Tax-Exempt, Consumer-Operated Plan (CO-OP) Program

The ACA also established the *Consumer Operated and Oriented Plan (CO-OP) Program,* a new form of tax-exempt organization under I.R.C. § 501(c)(29)[620] that incentivizes tax-exempt health insurers to offer health plans in individual and small-group markets.[621] These plans will receive federal funding, provided that they satisfy the requirements of the I.R.C. § 501(c)(29) exemption as well as meet the ACA's *Consumer Operated and Oriented Plan (CO-OP) Program* requirements that:

(1) The organization provides *notice* to the Secretary of HHS that it is applying for § 501(c)(29) status;
(2) *Net profits will be inured only to health plan benefit members* (e.g., lower premiums, improve benefits, etc.), not to private individuals;
(3) It *does not propagandize or otherwise attempt to influence legislation*; and
(4) It *refrains from any participation* in, on behalf of, or in opposition to any *campaign or candidate for political office.*[622]

Failure of the exempt organization to meet the above criteria will result in a penalty mandating repayment of 110 percent of their loan or grant, plus interest.[623]

Provider Taxes

In response to recent laws, such as the 2009 *American Reinvestment and Recovery Act* (ARRA),[624] many states have passed *provider taxes* on healthcare providers in their state. The state may not tax providers more than 25 percent of its share of Medicaid expenditures and may not guarantee any return of that tax to providers.[625] As of 2014, 49 states and Washington, D.C. have some type of Medicaid related *provider tax.*[626] *Provider taxes* are funneled back to providers by way of increased Medicaid reimbursement rates, while states can retain the *federally matched funds*.[627]

Ad Valorem Tax and Personal Property Tax

In addition to *provider taxes*, healthcare providers may also be subject to personal property taxes and *ad valorem* taxes. An *ad valorem tax* is a tax that is generally determined to be a fixed or calculated proportion of the value of the property "as assessed or appraised on a regular basis."[628] Frequently assessed by state and local authorities, *ad valorem taxes* generally pertain to *real*

620 "Patient Protection and Affordable Care Act" Pub. L. 111-148, § 1322, 124 Stat. 119, 187-192 (March 23, 2010).
621 Ibid.
622 "CO–OP Health Insurance Issuers" 26 U.S.C. § 501(c)(29) (2011).
623 "Patient Protection and Affordable Care Act" Pub. L. 111-148, § 1322, 124 Stat. 119, 188 (March 23, 2010).
624 "Health Care Provider and Industry Taxes/Fees" National Conference of State Legislatures, July 2012, http://www.ncsl.org/issues-research/health/health-provider-and-industry-state-taxes-and-fees.aspx (Accessed 9/8/12); "American Recovery and Reinvestment Act" Pub. L. No. 111-5, § 5001, 123 Stat. 115, 496 (February 17, 2009).
625 "Prohibition on use of voluntary contributions, and limitation on use of provider-specific taxes to obtain Federal financial participation under Medicaid" 42 U.S.C. § 1396b(w)(2010).
626 "Health Provider and Industry State Taxes and Fees" National Conference of State Legislatures, July 10, 2014, http://www.ncsl.org/research/health/health-provider-and-industry-state-taxes-and-fees.aspx#2914_guidance (Accessed 3/6/15).
627 "Health Care Provider and Industry Taxes/Fees" National Conference of State Legislatures, July 2012, http://www.ncsl.org/issues-research/health/health-provider-and-industry-state-taxes-and-fees.aspx (Accessed 9/8/12).
628 "State and Local Taxation" 71 Am. Jur. 2d, § 18 (2012).

property and sales, but are also applicable to *imported goods*. For imported goods, the ACA includes a provision that "any manufacturer or importer with gross receipts from branded prescription drug sales" must pay an annual fee for any drugs—whose sales did not exceed $5 million in a calendar year—that were submitted for *U.S. Food and Drug Administration* (FDA) approval (excluding orphan drugs), and any biological products submitted for licensing under the *Public Health Service Act*.[629]

Excise, Sales, and Use Taxes

Effective January 1, 2018, the ACA created a 40 percent *excise tax* against employees with *high-cost health coverage*, i.e., an employer-sponsored health insurance plan that provides the employee *excess benefit* above certain thresholds.[630] These thresholds include the following: (1) for employees possessing self-only coverage, the product of $10,200 and the health cost adjustment percentage for such employees and (2) for employees possessing any other type coverage, the product of $27,500 and the health cost adjustment percentage for such employees.[631] Additionally, the ACA includes an *excise tax* on *medical devices*, effective January 1, 2013, in which the device *manufacturer, producer, or importer* must pay a tax equivalent to 2.3 percent of the *sale price of the medical device*.[632]

OTHER FEDERAL REGULATIONS

OCCUPATIONAL SAFETY AND HEALTH ACT (OSHA)

The *Occupational Safety and Health Act* of 1970 (OSHA) established standards for occupational health and safety, and it requires states to enact legislation implementing standards and procedures developed by the Department of Labor.[633] OSHA promulgated regulations include those designed to protect health care employees from blood borne diseases, latex allergies, needle sticks, tuberculosis, patient violence, ionizing radiation, and anesthetic gasses that leak into the surrounding room during medical procedures, among others.[634]

CLINICAL LABORATORY IMPROVEMENT ACT (CLIA)

Congress passed the *Clinical Laboratory Improvement Act* (CLIA) and its subsequent amendments in order to improve the accuracy, reliability, and timeliness of test results.[635] The

629 "Patient Protection and Affordable Care Act" Pub. L. 111-148, § 9008, 124 Stat. 119, 859-862 (March 23, 2010).
630 "Patient Protection and Affordable Care Act" Pub. L. 111-148, §§ 9001, 10901, 124 Stat. 119, 847-853, 1015-1016 (March 23, 2010), as amended by "Health Care and Education Reconciliation Act" Pub. L. 111-152, § 1401, 124 Stat. 1029, 1059-1060 (March 30, 2010).
631 Ibid.
632 "Patient Protection and Affordable Care Act" Pub. L. 111-148, §§ 9009, 10904, 124 Stat. 119, 862-865, 1016-1017 (March 23, 2010), as amended by "Health Care and Education Reconciliation Act, Sec.1405" Pub. L. 111-152, § 1405, 124 Stat. 1029, 1064-1065 (March 30, 2010).
633 "Problems in Health Care Law: Challenges for the 21st Century" By John E. Steiner, Jr., Tenth Edition, Burlington, MA: Jones and Bartlett Publishers, 2014, p. 108.
634 "Problems in Health Care Law: Challenges for the 21st Century" By John E. Steiner, Jr., Tenth Edition, Burlington, MA: Jones and Bartlett Publishers, 2014, p. 108; "Radon in the Workplace, The OSHA Ionizing Radiation Regulations" By Robert K. Lewis, Bureau of Radiation Protection, 2004, http://www.aarst.org/proceedings/2004/2004_07_Radon_in_the_Workplace_The_OSHA_Ionizing_Radiation.pdf (Accessed 10/13/2009).
635 "Clinical Laboratory Improvement Amendments" Medicare Learning Network, Centers for Medicare & Medicaid Services, July 2014, http://www.cms.gov/Outreach-and-Education/Medicare-Learning-Network-MLN/MLNProducts/downloads/CLIABrochure.pdf (Accessed 3/5/15), p. 1.

act requires laboratories to regulate all laboratory testing performed on humans, except the testing performed for research purposes.[636] CMS assumes the responsibility for overseeing the CLIA program.[637] CLIA requires that healthcare providers who perform laboratory testing on specimens derived from humans in order to gain information for the diagnosis, prevention, or treatment of disease or the assessment of health to abide by federally established quality standards in order to operate these services.[638]

UNITED STATES NUCLEAR REGULATORY COMMISSION (NRC)

The United States *Nuclear Regulatory Commission* (NRC) is an independent agency created by Congress in 1974.[639] The goal of the agency is to ensure the safe use of radioactive material for civilian purposes through a combination of regulatory requirements, licensing, safety oversight, operational evaluation, and support activities.[640] Under section 274 of the *Atomic Energy Act of 1954*, the NRC is authorized to delegate its authority to oversee certain licensees to state regulatory commissions, or agreement states.[641] An agreement state then has the authority to regulate the use of nuclear material by certain licensees. To date, the NRC has entered into agreements with thirty-seven states.[642]

The NRC or the agreement state regulates the medical use of radioactive material through the licensing of medical facilities and physicians, inspection of facilities, and enforcement of regulations and procedures. The types of medical use regulated by the NRC and the agreement state include the production of radiation from imaging devices used by hospitals, physicians, dental offices, and podiatry offices; the use of nuclear material to deliver pain reliving or therapeutic doses to parts of the body; and medical research involving the use of nuclear material in human subjects.[643]

EMERGENCY MEDICAL TREATMENT AND ACTIVE LABOR ACT (EMTALA)

The *Emergency Medical Treatment and Labor Act* (EMTALA), enacted in 1986 by the *Consolidated Omnibus Budget Reconciliation Act of 1985,* requires covered hospitals to provide an "*appropriate medical screening examination*" to any patient presented to the hospital's emergency department.[644] "*Participating hospitals*" under EMTALA are hospitals that participate in the Medicare program and have an emergency room, leaving some hospitals outside the purview of the statute.[645] Patients who suffer harm as a "*direct result*" of a hospital's

636 "Clinical Laboratory Improvement Amendments: Overview" Centers for Medicare & Medicaid Services, http://www.cms.hhs.gov/clia/ (Accessed 09/01/09).
637 Ibid.
638 "Clinical Laboratory Improvement Amendments" Medicare Learning Network, Centers for Medicare & Medicaid Services, July 2014, http://www.cms.gov/Outreach-and-Education/Medicare-Learning-Network-MLN/MLNProducts/downloads/CLIABrochure.pdf (Accessed 3/5/15), p. 1.
639 "About NRC" United States Nuclear Regulatory Commission, January 14, 2015, http://www.nrc.gov/about-nrc.html (Accessed 3/05/15).
640 "Medical, Industrial, and Academic Uses of Nuclear Material" United States Nuclear Regulatory Commission, February 10, 2015, http://www.nrc.gov/materials/medical.html (Accessed 3/5/15).
641 "Governing Legislation" United States Nuclear Regulatory Commission, September 30, 2014, http://www.nrc.gov/about-nrc/governing-laws.html#top (Accessed 3/5/15).
642 "Agreement State Program" United States Nuclear Regulatory Commission, April 10, 2013, http://www.nrc.gov/about-nrc/state-tribal/agreement-states.html (Accessed 3/5/15).
643 "Medical Uses of Nuclear Material" United States Nuclear Regulatory Commission, November 12, 2014, http://www.nrc.gov/materials/miau/med-use.html (Accessed 3/5/15).
644 "Medical Screening Requirement" 42 U.S.C. § 1395dd(a) (2013).
645 "Definitions" 42 U.S.C. § 1395dd(e)(2) (2013).).

violation of EMTALA are authorized to bring a claim against the hospital, but patients lack a private right of action under EMTALA against the specific treating physician.[646] Additionally, EMTALA provides for civil penalties against the hospital.[647]

As noted above, EMTALA does not require hospitals to have an emergency department; however, some specialty hospitals are required by state licensure laws to have emergency departments.[648]

TORT REFORM

Malpractice, defined as "an instance of negligence or incompetence on the part of a professional,"[649] has always been a risk inherent in the practice of medicine. Specifically, *medical malpractice* is defined as "a doctor's failure to exercise the degree of care and skill that a physician or surgeon of the same medical specialty would use under similar circumstances."[650] The U.S. tort system allows patients who are injured or wronged in some way to sue the wrongdoer, or *tortfeasor*. The medical malpractice system was designed to operate as a quality control measure, creating an incentive for prevention of medical errors and reducing accident producing behavior by awarding damages, "money claimed by or ordered to be paid to a person as compensation for loss or injury,"[651] to plaintiffs who have been harmed by the error.[652] The result is that the wrongdoer is essentially held accountable for his or her actions, the injured party is able to recover for damages incurred as a result of the tort, and the public is provided with a means to incentivize physicians and hospitals to improve the quality of their care.[653]

Damages for medical malpractice are monetary and are typically awarded for (1) economic losses; (2) non-economic losses; and/or (3) punitive losses. *Economic damages* compensate victims for actual monetary losses, such as medical expenses, lost wages, and rehabilitation costs, while non-economic damages compensate victims for losses that are not traditionally measured in monetary terms, including pain and suffering, disfigurement, and loss of companionship.[654] In addition, to punish the defendant's conduct and deter future wrongdoers, punitive damages may be awarded in cases where the defendant has acted in a reckless or deceitful manner.[655]

As advancements in research and technology have advanced medical practice, the ability to diagnose and treat patients has led to an increased volume of medical assessments and procedures performed. Unfortunately, increases in the volume of procedures performed often

646 "Personal Harm" 42 U.S.C. § 1395dd(d)(2)(A) (2013).
647 "Civil Money Penalties" 42 U.S.C. § 1395cc(d)(1)(A)-(B) (2013).
648 "Specialty Hospitals: Focused Factories or Cream Skimmers?" By Kelly Devers, Linda R. Brewster, and Paul B. Ginsburg, Center for Studying Health System Change, Issue Brief No. 62 (April 2003), http://www.hschange.com/CONTENT/552/ (Accessed 5/10/10).
649 "Malpractice" Black's Law Dictionary, 9th ed., West Publishing Co., 2009.
650 "Medical Malpractice" Black's Law Dictionary 9th ed., West Publishing Co., 2009.
651 "Damages" Black's Law Dictionary 9th ed., West Publishing Co., 2009
652 "Health Law: Cases, Materials, and Problems" By Barry R. Furrow, et al., 7th Edition, St. Paul, MN: West Publishing Company, 2013, p. 508.
653 "Justice for the Injured: Defending the Civil Justice System from the Corporate 'Tort Reform' Movement." Multinational Monitor, (March 2003), p. 23-26.
654 "Addressing the Medical Malpractice Insurance Crisis" National Governors Association Center for Best Practices, December 5, 2002, p. 5.
655 "Tort Law and Alternatives: Cases and Materials" By Marc A. Franklin, Robert L. Rabin, and Michael D. Green, 9th ed., New York, NY Foundation Press, 2011, p. 750.

increase both the risk of harm to patients and the exposure to liability for physicians.[656] With the growth of ACOs contributing to an increase in managed care, concerns about physician volume and associated medical errors are prominent. Today, most healthcare services are delivered through an institution, group practice, or hospital system. While there are many advantages to providing care this way, some managed care mechanisms—such as diminishing physician autonomy, requiring physicians to see a certain amount of patients, and limiting the amount of time physicians spend with patients—may contribute to medical errors, which are one of the foundations of a medical malpractice claim. The result of these increased risks, medical errors, and disgruntled patients has produced an environment that is ripe for malpractice litigation.[657]

State Tort Reform

The malpractice *crisis* of the 2000s resulted in a patchwork of state political and legal actions meant to limit problems such as preventable medical errors and/or jury verdicts. While actions taken by the public and its political representatives addressed certain issues at the heart of this malpractice *crisis*, i.e., excessive verdicts and the validation of expert witness testimony, actions taken in response to the *crisis* of the early 2000s did not effectively decrease medical errors nationally, nor were they uniform nationally. As a result, this jumble left medical liability insurers, doctors, and patients to grapple with the effects of patchwork solutions; reconciling this patchwork continues to date.

States commonly worked to resolve the tort reform *crisis* by enacting a cap on payments for non-economic damages, including pain and suffering, loss of consortium, and emotional distress. In 1975, California first modeled this approach by passing the *Medical Injury Compensation Reform Act* (MICRA), which enacted a cap of $250,000 for awards based on non-economic damages.[658] After the passage of MICRA, other states followed California's lead in enacting similar legislation. Similarly, states passed laws creating punitive damage caps and other limitations sought to limit the "prospect of receiving a big 'bonus'" that may prolong cases that otherwise would be settled.[659] However, the number of states with active caps on noneconomic and/or punitive damages has decreased slightly over the past 15 years. From 2002 to 2013, the number of states with active caps specifically for noneconomic damages decreased slightly from 30 to 27,[660] reflecting the actions of state supreme courts invalidating such caps.[661] Similarly, within the same time frame, the number of states with active caps specifically targeted at punitive damages decreased from 20 to 19.[662]

656 "Overview of Medical Errors and Adverse Events" By Maité Garrouste-Orgeas et al., Annals of Intensive Care, Vol. 2, No. 2, 2012, p. 6.
657 "Health Law: Cases, Materials, and Problems" By Barry R. Furrow et al., 7th Edition St. Paul, MN: West Publishing Company, 2013, p. 506-507.
658 "Damages for Wrongs" Cal. Civ. Code § 3333.2 (1975); "Voters Turn Down Proposition 46 to Lift Medical Malpractice Cap, Require Drug Tests for Doctors" CBS San Francisco, November 4, 2014, http://sanfrancisco.cbslocal.com/2014/11/04/proposition46doctorsdrugtestsresults/ (Accessed 12/10/14).
659 "Liability System" Insurance Information Institute, September 2014, http://www.iii.org/issue-update/liability-system (Accessed 10/31/14), p. 4.
660 "Health Care: Medical Malpractice Tort Reform (Statutes)" Thomson Reuters, September 2013.
661 Various state supreme courts have invalidated relevant state statutes that imposed caps on noneconomic damages. For example, see McCall v. U.S., No. SC11-1148 (Fla. Mar. 13, 2014); "Health Care: Medical Malpractice Tort Reform (Statutes)" Thomson Reuters, September 2013.
662 "Health Care: Medical Malpractice Tort Reform (Statutes)" Thomson Reuters, September 2013.

Federal Tort Reform

Though medical malpractice law has traditionally been regulated at the state level, the federal government has taken an interest in tort reform. A 2002 HHS report alleged that the legal system was to blame for rising medical malpractice premiums, citing California's noneconomic damages cap as a model for national tort reform.[663] While there have been efforts at federal tort reform, a federal cap on damages has yet to be signed into law. The most recent effort to cap damages at the federal level, the *Help Efficient, Accessible, Low-Cost, Timely Healthcare Act of 2009*, was introduced before the House of Representatives in February 2009.[664] This bill is a new attempt to pass a federal cap on noneconomic damages in medical malpractice suits, which has been a continuing congressional goal since the same bill was first introduced in the House in 2002.[665] Similar bills have repeatedly passed in the House; however, no version of the bill has yet to be passed in the United States Senate.[666]

Proponents of tort reform have historically pushed for caps on punitive damage awards.[667] However, more viable reform proposals include shifting tribunals (for example, from judicial to administrative panels) or creating federal safe harbors for physicians who practice in accordance with credible comparative-effectiveness research.[668] Additionally, insurance companies are experimenting with disclosure and offer programs in which providers offer compensation to patients immediately upon disclosure of a negative outcome, reducing the number of malpractice lawsuits.[669]

PHYSICIAN PAYMENTS SUNSHINE ACT

When the ACA was passed, it included the *Physician Payments Sunshine Act* as part of its initiative to promote transparency in the healthcare industry.[670] In October 2014, CMS issued its final rule regarding the *Sunshine Act*, which required the establishment of a transparency program, now known as the *Open Payments* Program, to monitor and report on payments or other "*transfers of value*" by manufacturers and applicable group purchasing organizations to healthcare providers.[671] The program is voluntary for physicians to register, but mandatory for manufacturers of medical devices and drugs, although all data is reported regardless of the registration status of the physician.[672] The published financial data, which is updated at least

663 "Confronting the New Health Care Crisis: Improving Health Care Quality and Lowering Costs By Fixing Our Medical Liability System" Department of Health and Human Services, (July 24, 2002), p. 1.
664 "Help Efficient, Accessible, Low-Cost, Timely Healthcare (HEALTH) Act of 2009" H.R. 1086 (February 13, 2009).
665 "Help Efficient, Accessible, Low-Cost, Timely Healthcare (HEALTH) Act of 2002" H.R. 4600 (April 25, 2002).
666 "Bill Text Versions 112th Congress (2011-2012) H.R.5" The Library of Congress, 2015, http://thomas.loc.gov/cgi-bin/query/z?c112:H.R.5: (Accessed 3/6/15); "Bill Text Versions 107th Congress (2001-2002) H.R. 4600" The Library of Congress, 2015, http://thomas.loc.gov/cgi-bin/query/z?c107:H.R.4600: (Accessed 3/6/15).
667 "Beyond MICRA: New Ideas for Liability Reform" American College of Physicians, Annals of Internal Medicine, Vol. 122, No. 6 (1995), p. 466-67; "The Role of Medical Liability Reform in Federal Health Care Reform" By Michelle M. Mello, and Troyen V. Brennan, New England Journal of Medicine, Vol. 361, No. 1 (July 2, 2009), p. 1.
668 "The Role of Medical Liability Reform in Federal Health Care Reform" By Michelle M. Mello and Troyen V. Brennan, New England Journal of Medicine, Vol. 361, No. 1 (July 2, 2009), p. 3.
669 Ibid, p. 2-3.
670 "Patient Protection and Affordable Care Act" Pub. L. 111-148, § 6002, 124 Stat. 119, 571 (March 23, 2010).
671 "Open Payments (Physician Payments Sunshine Act) Fact Sheet" Centers for Medicare & Medicaid Services, 2013, http://www.cms.gov/Regulations-and-Guidance/Legislation/National-Physician-Payment-Transparency-Program/Downloads/Physician-fact-sheet.pdf (Accessed 2/25/15), p. 1.
672 "Open Payments (Physician Payments Sunshine Act) Fact Sheet" Centers for Medicare & Medicaid Services, 2013, http://www.cms.gov/Regulations-and-Guidance/Legislation/National-Physician-Payment-Transparency-Program/Downloads/Physician-fact-sheet.pdf (Accessed 2/25/15), p. 1.

once annually by CMS, is accessible by anyone after such data is submitted by manufacturers and aggregated by CMS.[673] In 2015, CMS released additional changes that will go into effect for the 2016 program year, with reporting to CMS in 2017.[674] These changes include:

(1) Deletion of the definition of "*covered device,*" because specific device definitions are already included in the Open Payments Rule;
(2) Deletion of the provision excluding compensation (both indirect and direct) provided to physician speakers at continuing education events;
(3) Requirement that the marketed name and therapeutic area, or product category of the related covered drugs, devices, biological, or medical supplies, be reported unless the payment or other transfer of value is not related to a particular covered or non-covered drug, device, biological or medical supply; and
(4) Requirement that stocks, stock options, or any other ownership interest be reported as distinct categories.[675]

CONCLUSION

> "Perhaps this complex, hybrid regulatory structure has emerged because it fits America's temperament. It may, in fact, be the only kind with which the country would be truly comfortable. The decentralization and complexity of health care regulation are distinctively American in the interplay of layers of government, different agencies within each level, and private forces. It is a system of checks and balances that prevents any single regulatory authority from becoming too influential and that encourages diversity in programs and approaches. There is almost a 'marketplace' of regulation, with a competitive harness that disciplines government policy in a similar manner to the discipline of a private market for goods and services. The system in unquestionably less efficient than one that is more centralized, but perhaps the inefficiency has its advantages. It may even enhance overall regulatory effectiveness."[676]—Robert I. Field

In his 1982 book, *The Social Transformation of American Medicine,* Paul Starr asserted that the *once sovereign medical profession* (at the turn of the twentieth century) was relatively free from the shackles of government regulation relating to the profession's control over its organization; standard of practice; and the markets in which it operated. However, recently, with the rise of the "*corporatization of medicine*," physician control has been gradually eroded by "[e]mployers and the government becom[ing] critical intermediaries in the system because of their financial role," who are "using their power to reorient the system."[677]

673 Ibid, p. 5.
674 "Law and Policy: CMS Implements Final Rule Changes for Open Payments" Centers for Medicare & Medicaid Services, 2014 http://www.cms.gov/OpenPayments/About/Law-and-Policy.html (Accessed 2/25/15).
675 Ibid.
676 "Health Care Regulation in America: Complexity, Confrontation, and Compromise" By Robert I. Field, New York, NY: Oxford University Press, 2007, p. 241-242.
677 "The Social Transformation of American Medicine" By Paul Starr, New York, NY: Basic Books, Inc., 1982, p. 445.

As a result of the *corporatization* of the U.S. healthcare delivery system, as well as the increasing consolidation stemming from healthcare reform efforts, the potential exists for healthcare entities to become subject to substantial penalties arising from the their entrance into transactions and arrangements that may subsequently be found to be legally impermissible. In considering any potential transactions, providers should take note of this heightened regulatory environment and work closely and with competent healthcare legal counsel and certified valuation professionals to ensure that prospective transactions and arrangements are in compliance with current laws, as well as satisfy applicable regulatory thresholds. A determination that a transaction has met the requisite tax, corporate, organizational, licensure, and certification requirements may only be the first steps. Providers may feel more comfortable with also obtaining a certified opinion prepared in compliance with professional standards by an independent credential valuation professional (under the advice of legal counsel) and supported by adequate documentation as to whether each of the proposed elements of the transaction are both at *Fair Market Value* and *commercially reasonable*, so as to establish a risk adverse, defensible position that the transactional arrangement can withstand regulatory scrutiny.

Key Sources

Key Source	Description	Citation	Website
The Library of Congress: THOMAS	Provides up-to-date copies of pending legislation in the United States Congress.	"About Thomas" The Library of Congress: THOMAS, http://thomas.loc.gov/home/abt_thom.html, (Accessed 4/1/15).	https://www.congress.gov
The Joint Commission	Provides information on accreditation and certification standards for more than 17,000 healthcare organizations and programs. Joint Commission accreditation and certification is recognized nationwide as a symbol of quality that reflects an organization's commitment to meeting certain performance standards.	"About the Joint Commission" The Joint Commission, http://www.jointcommission.org/about_us/about_the_joint_commission_main.aspx (Accessed 4/1/15).	www.jointcommission.org
National Committee for Quality Assurance	Provides standards of accreditation and certification to various types of healthcare entities, as well as performance measures, and recognizes providers that consistently provide high-quality care in order to provide consumers with information on provider quality.	"About NCQA" The National Committee for Quality Assurance, www.ncqa.org/tabid/675/Default.aspx (Accessed 4/1/15).	www.ncqa.org
United States Department of Health And Human Services (HHS) Office of Inspector General	The Office of the Inspector General of the HHS oversees all HHS programs in order to protect the integrity of the programs and the health and welfare of beneficiaries.	"Office of the Inspector General" U.S. Department of Health and Human Services, http://oig.hhs.gov (Accessed 4/1/15).	http://oig.hhs.gov
Centers for Medicare and Medicaid Services (CMS)	The CMS administers the Medicare, Medicaid, and CHIP programs. The CMS website contains important information for beneficiaries of these programs, as well as for guidelines for providers.	"Guidelines for Ensuring the Quality of Information Disseminated to the Public: E. Centers for Medicare & Medicaid Services" Department of Health and Human Services, http://aspe.hhs.gov/infoquality/Guidelines/CMS-9-20.shtml (Accessed 4/1/15).	www.cms.hhs.gov

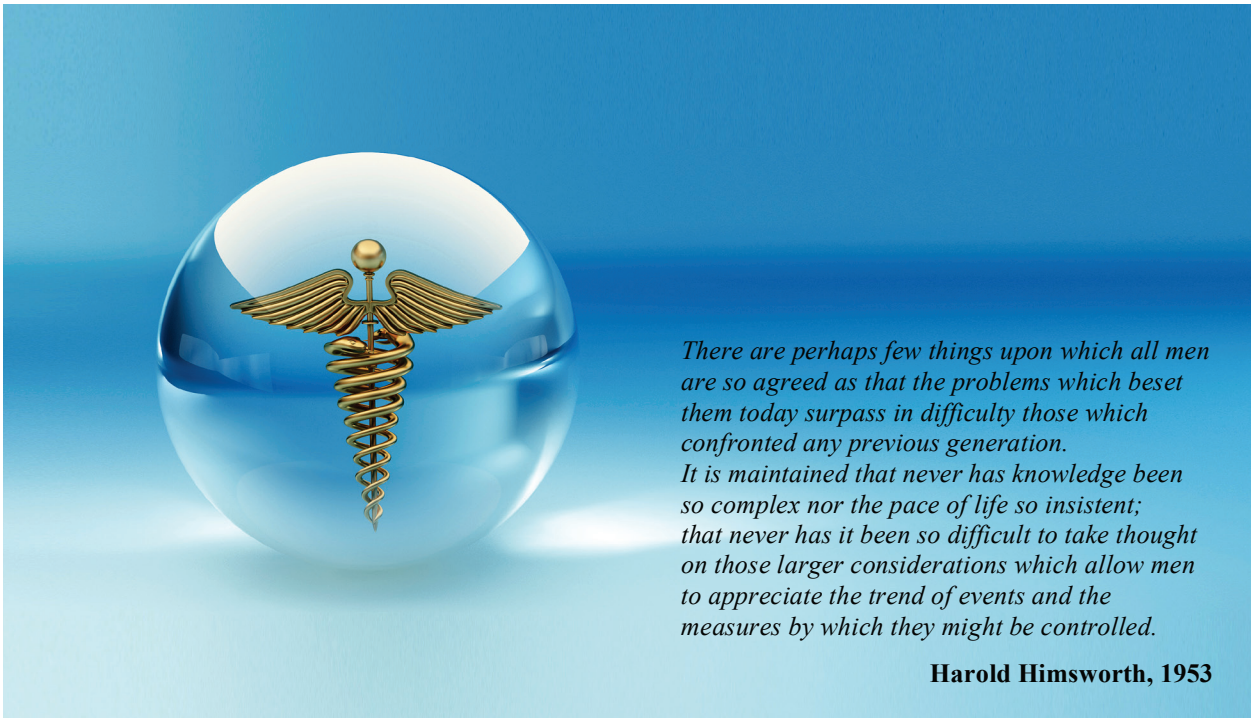
Associations

Type of Association	Professional Association	Description	Citation	Contact Information
National	American Health Lawyers Association (AHLA)	The AHLA website (Health Lawyers) "provides resources to address the issues facing its active members who practice in law firms, government, in-house settings and academia and who represent the entire spectrum of the health industry: physicians, hospitals and health systems, health maintenance organizations, health insurers, life sciences, managed care companies, nursing facilities, home care providers, and consumers."	"About AHLA: Our Mission," www.healthlawyers.org/About/WhoWeAre/Pages/default.aspx (Accessed 4/1/15).	American Health Lawyers Association 1025 Connecticut Avenue, NW Suite 600 Washington, DC 20036 Phone: 202-833-1100 Fax: 202-833-1105 E-mail: n/a www.healthlawyers.org/Pages/Default.aspx
National	American Bar Association (ABA): Health Law Section	ABA provides resources dedicated specifically to health lawyers. Provides access to all legal issues related to health and allows lawyers to connect with the latest legal developments in public health, federal healthcare regulations, managed care, Medicare, or healthcare fraud, as seen from a national perspective. Publishes The Health Lawyer and Health eSource.	"Health Law Section" American Bar Association, http://www.americanbar.org/groups/health_law.html (Accessed 4/1/15).	Health Law Section American Bar Association 321 N. Clark St. Chicago, IL 60654 Phone: n/a Fax: 312-988-5814 E-mail: healthlaw@abanet.org http://www.americanbar.org
National	American Medical Association (AMA)	Founded in 1847, the AMA's mission is to promote the art and science of medicine and the betterment of public health and provides a variety of data and resources to the healthcare community.	"About AMA," American Medical Association, www.ama-assn.org/ama/pub/about-ama.shtml (accessed December 4, 2009).	American Medical Association 515 N. State Street Chicago, IL 60654 Phone: 800-621-8335 Fax: n/a E-mail: n/a www.ama-assn.org
National	American Osteopathic Association	The AOA is the main board certifying entity for osteopathic physicians and is the accrediting body for every osteopathic healthcare facility and medical college. It strives to promote the practice of osteopathic medicine by ensuring quality in education, research, and the delivery of healthcare services.	"About the AOA" American Osteopathic Association, www.osteopathic.org/index.cfm?PageID=aoa_main, (accessed June 30, 2009).	American Osteopathic Association Main Headquarters 142 East Ontario Street Chicago, IL 60611 Phone: 312-202-8000 / 800-621-1773 Fax: 312-202-8200 E-mail: info@osteotech.org www.osteopathic.org
National	American Hospital Association (AHA)	Founded in 1898, the AHA provides education for healthcare leaders and is a source of information on healthcare issues and trends and is comprised of close to 5,000 hospitals, healthcare systems, networks, other providers of care, and 37,000 individual members.	"About the American Hospital Association" American Hospital Association, http://www.aha.org/about/index.shtml (accessed December 4, 2009).	American Hospital Association One North Franklin Chicago, IL 60606 Phone: 312-422-3000 Fax: n/a E-mail: n/a www.aha.org

Type of Association	Professional Association	Description	Citation	Contact Information
National	Ambulatory Surgery Center Association (ASC Association)	A membership and advocacy organization that provides advocacy support and assistance for ASCs across the nation on a state and federal level.	"ASC Association," By Ambulatory Surgery Center Association, http://ascassociation.org/about/association (accessed December 4, 2009).	Ambulatory Surgery Center Association 1012 Cameron Street Alexandria, VA 22314 Phone: 703-836-8808 Fax: 703-549-0976 E-mail: ASC@ascassociation.org www.ascassociation.org
National	American Health Planning Association (AHPA)	"A non-profit public interest organization committed to health policies and practices that promote equal access health care at a reasonable cost."	"About AHPA: Who We Are," By American Health Planning Association, www.ahpanet.org/about_ahpa1.html (accessed December 4, 2009).	American Health Planning Association 7245 Arlington Boulevard, Suite 300 Falls Church, VA 22042 Phone: 703-573-3103 Fax: n/a E-mail: info@ahpanet.org www.ahpanet.org

Chapter 4

Impact of Competitive Forces



KEY TERMS
Cherry-pick or Cream-skim
Economic Demand
Economic Supply
Monopsony
Purple Pill

Key Concept	Definition	Citation	Concept Mentioned on Page #
Normal Markets versus Healthcare Markets	Competition in healthcare is unique from competition in other sectors because traditional theories of economic forces do not always govern the choices made.	n/a	309
Three-Legged Stool Model of Healthcare	Cost, quality, and access are each considered distinct elements of healthcare administration.	"Why Competition Law Matters to Health Care Quality," by William M. Sage, David A. Hyman, and Warren Greenberg, Health Affairs, Vol. 22, No. 2 (March/April 2003), p. 35–36.	293
Emergency Medical Treatment and Labor Act	Hospital emergency departments are required to provide care under certain circumstances, even to patients who are uninsured and unable to pay for that care.	"Examination and Treatment for Emergency Medical Conditions and Women in Labor" 42 U.S.C. § 1395dd (2011).	293
Most Favored Nation Status	A provider contractually agrees to not charge an insurance company any more than it charges any other customer.	"Improving Health Care: A Dose of Competition: Chapter 6, Competition Law: Insurers," A Report by the Federal Trade Commission and Department of Justice, July 2004, p. 20.	294
Trend Toward Physician Ownership	Physicians have become owners and investors in surgical facilities, such as ambulatory surgery centers, and specialty hospitals that compete with the same general hospitals to which the physicians traditionally have referred patients.	"Hospital-Physician Relations: Cooperation, Competition, or Separation?" by Robert A. Berenson, Paul B. Ginsburg, and Jessica H. May, Health Affairs, Web Exclusive, (Dec. 5, 2006), p. w33-34.	298-301
Effect of Declining Patient Volumes	Hospitals began offering additional services and entering into the practice of providing insurance and primary care services, taking on a powerful role as both provider and insurer through integrated delivery systems. In addition, hospitals began to merge with each other so that they could leverage their consolidated bargaining power against private insurers.	"Competition in Health Care: It's Evolution Over the Past Decade," by Paul B. Ginsburg, Health Affairs, Vol. 24, No. 6, Nov/Dec 2005, p. 1513–14.	297
Conflict of Interest Credentialing	The limiting or terminating physician-investors' privileges and medical staff membership.	"Banning Physician Self-Referral is an Important Step Toward Health Reform," by Rich Umbdenstock and Chip Kahn. HA News Now, www.ahanews.com/ahanews_app/jsp/display.jsp?dcrpath=AHANEWS/AHANewsArticle/data/AHA_News_090720_Physician&domain=AHANEWS (accessed November 9, 2009).	300
Michael Porter's Five Competitive Forces	(1) The threat of new market entrants. (2) The bargaining power of suppliers. (3) Threats from substitute products or services. (4) The bargaining power of buyers. (5) Rivalry among existing firms.	"Competitive Strategy: Techniques for Analyzing Industries and Competitors," by Michael E. Porter, The Free Press, 1980, p. 4.	310-19
Strategies to Out-Perform Competitors or Maintain a Market Position Against Competition	Porter's three generic strategies are (1) overall cost leadership, (2) differentiation, and (3) market niche or segmentation.	"On Competition" By Michael E. Porter, Boston, MA: Harvard Business School Publishing, 2008, p. 53.	312
McCarran-Ferguson Act	Limits federal scrutiny of insurers and places states in primary control of antitrust enforcement.	"McCarran-Ferguson Act" 15 U.S.C 1011 et seq. March 9, 1945.	318

OVERVIEW

Competition in healthcare is unique from competition in other sectors because traditional theories of economic forces do not always govern the choices made by professional practice enterprises within the healthcare industry. Unlike other markets, in which competition is viewed positively as a necessary element of capitalism, competition in the healthcare sector frequently is considered to be resistant to the universal availability and accessibility of quality care.

Although traditional notions of *economic supply* and *demand,* and the inherent concept of competition, have gained influence over healthcare professional practice enterprises in recent years, these factors historically were subjugated to a normative argument in favor of the mission-centered provision of services regardless of cost. This has led to the perception that healthcare demand is supply-driven and operates within an inelastic pricing mechanism, the circumstances of which will be discussed in detail later in this chapter.

The relationship between price and quality of care generally has been defined by providers rather than patients, meaning consumers (that is, patients) were less equipped to make informed healthcare purchase decisions than they were in other markets. However, recent pressure for transparency in the healthcare industry has led to the disclosure of reimbursement rates by insurers, which may lead to a more consumer-driven healthcare system in the future.[1] Further, the intensive regulation of medical professionals, new technologies and treatments, and evolving drug therapies may delay or disable the development of substitutes and, therefore, stymie innovation, which is one of the fundamental drivers of quality improvement and the underlying dynamic of an organization's ability to compete.

In addition to the impact of regulation on the delivery of healthcare services, the government's role as the single largest payor for healthcare services exerts enormous pressure on providers to reduce costs.[2] The impact of these changes has not been limited to Medicare and Medicaid fees; it is also reflected in reimbursement policies of other third-party payors.[3] This pre-eminent influence on, and pervasive dominance of, government over the healthcare industry presents a significant and essentially unique differential between healthcare and other industries.

Finally, the past two decades have seen the accelerated transformation of U.S. healthcare professions into a service industry enterprise, whereby many believe that professional health services have been unitized, protocolized, and homogenized in order to facilitate their *sale*, as if they were any other market commodity (e.g., frozen orange juice, soy beans, or pork bellies). These changes have accelerated the *corporatization* of medicine as demonstrated by the increase in for-profit healthcare in hospitals, outpatient technical component providers (e.g., *independent diagnostic testing facilities* [IDTFs] and *ambulatory surgery centers* [ASCs]), and large for-profit health insurance payors.

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1 "Blue Cross North Carolina's Price Tool Could Shake Up Medical Industry" By John Murawski and Ann Doss Helms, Kaiser Health News, February 4, 2015, http://kaiserhealthnews.org/news/blue-cross-north-carolinas-price-tool-could-shake-up-medical-industry/ (Accessed 3/28/15).

2 Discussed in Chapter 3: Regulatory Environment.

3 "Bargaining in the Shadow of a Giant: Medicare's Influence on Private Payment Systems" by Jeffrey Clemens and Joshua D. Gottlieb, National Bureau of Economic Research, October 2013, p. 3.

These issues, in part, moved healthcare to the forefront of consumer and political discourse, which led to the passage of the 2010 *Patient Protection and Affordable Care Act (ACA)*. Some other persistent issues that may have factored into the passage of the ACA include:

(1) Rapid rise in healthcare costs;[4]
(2) Socioeconomic disparities in both access to and quality of healthcare;[5] and
(3) Perceived threats of budget deficits and national debt related to the cost of care for a *baby boomer* generation now becoming eligible for Medicare.[6]

Various provisions of the ACA seek to address these concerns, including the development of new *emerging healthcare organizations* (EHOs) and healthcare delivery models, e.g., *accountable care organizations* (ACOs) and *patient centered medical homes* (PCMHs), which aim to improve quality while reducing cost by providing for better communication and collaboration among providers along the patient's continuum of care. Other ACA provisions that have affected competition in the healthcare industry include those establishing *health insurance exchanges* (HIEs) and various *value-based purchasing (VBP)* initiatives.[7]

ECONOMICS OF HEALTHCARE

While the growth rate in healthcare costs has begun to level off, it has been growing over the past few decades at a proportionally greater rate compared to the rise in cost of other goods and services in the U.S. economy.[8] The percentage of the U.S. *gross domestic product* (GDP) devoted to healthcare services has grown from 5.3% in 1960 to 17.2% in 2012, and it is projected to be 19.3% by 2023.[9] Although many causes exist for this gap between growth in healthcare spending and growth in GDP, note that the impact of the economic recession, which started in 2008, had a greater negative impact on GDP than it did on healthcare spending, though the growth rate of the latter did decline slightly.[10]

4 "Trends in Health Care Cost Growth and the Role of the Affordable Care Act" Executive Office of the President of the United States, November 2013, https://www.whitehouse.gov/sites/default/files/docs/healthcostreport_final_noembargo_v2.pdf (Accessed 3/31/15), p. 1.
5 "Focus on Health Care Disparities" The Henry J. Kaiser Family Foundation, December 2012, https://kaiserfamilyfoundation.files.wordpress.com/2012/11/8396-disparities-in-health-and-health-care-five-key-questions-and-answers.pdf (Accessed 3/31/15), p. 1.
6 "The Boomer Challenge" By Paul Barr, Hospitals & Health Networks, January 14, 2014, http://www.hhnmag.com/display/HHN-news-article.dhtml?dcrPath=/templatedata/HF_Common/NewsArticle/data/HHN/Magazine/2014/Jan/cover-story-baby-boomers (Accessed 3/31/15).
7 "Patient Protection and Affordable Care Act" Pub. L. 111-148, §§ 1311 et seq., 3001 et seq., 214 Stat. 119, 173, 353 (March 23, 2010).
8 "Health Spending Projections Through 2018: Recession Effects Add Uncertainty to the Outlook" By Andrea Sisko et al., Health Affairs, Vol. 28, No.2, Web Exclusive, (February 24, 2009), http://content.healthaffairs.org/cgi/content/abstract/hlthaff.28.2.w346 (Accessed 05/21/10), p. w346.
9 "National Health Expenditure Projections: 2013-2023" Centers for Medicare and Medicaid Services, http://www.cms.gov/Research-Statistics-Data-and-Systems/Statistics-Trends-and-Reports/NationalHealthExpendData/Downloads/Proj2013.pdf (Accessed 3/25/15); "Three Decades of Government-Financed Health Care in the United States" By Patrick Fleenor, Tax Foundation, August 1994, http://www.taxfoundation.org/files/bd006ece1a4b8166023dbc913175b7b7.pdf (Accessed 11/11/09).
10 "Health Spending Projections Through 2018: Recession Effects Add Uncertainty to the Outlook" By Andrea Sisko et al., Health Affairs, Vol. 28, No.2, Web Exclusive, (February 24, 2009), http://content.healthaffairs.org/cgi/content/abstract/hlthaff.28.2.w346 (Accessed 05/21/10), p. w349.

> The percentage of the *gross domestic product* (GDP) devoted to healthcare services has grown from 5.3% in 1965 to almost 18% at the time of publication, and is projected to almost reach 20% by 2023.
>
> ***Patrick Fleenor, August 1994, Centers for Medicare and Medicaid Services.***

Some economists have cited the aging population as the reason for the increase in healthcare's share of the GDP. Other voices have asserted that greed among *health maintenance organizations* (HMO), pharmaceutical companies, hospitals, and medical providers, such as doctors and nurses, is responsible.[11] In reality, there is no single force driving the increase in healthcare costs, but rather a combination of forces that have led to such a dramatic rise in costs that the U.S. now spends more per capita than any other country on its healthcare.[12]

Documented and significant differences exist in productivity growth between the healthcare sector of the economy and the economy as a whole. Healthcare services have experienced significantly lower productivity growth rates than other industry sectors for three main reasons. First, healthcare services are inherently resistant to automation, so innovation (in the form of technological advancement) has not made the same impact on healthcare productivity as it has on productivity in other industries. The manufacturing assembly line robot increases assembly line productivity by accelerating the process and reducing labor input. In contrast, most medical technology is still applied in a labor-intensive process, that is, patients are cared for one at a time, and diseased or ill patients cannot be disposed of as routine work product error like automated factories can cost-effectively reject a percentage of defective items. Healthcare providers cannot (and, most would agree, should not) try to operate as factories, because each patient is unique and disease is widely variable. This makes providers unable to adapt to the productivity gains and efficiency derived from mass production techniques.[13]

Second, unlike other labor-intensive industries, healthcare is local in nature and cannot be imported. Despite the technological advances described previously, healthcare services are mainly provided by skilled workers within the local market. Within that market, providers compete locally[14] and may be compensated at higher levels than those implied by national statistics.

Third, healthcare consumers believe that quality of service is correlated with the amount of labor expended in its provision, in contrast to mass production, in which the number of man-hours per unit is not an important predictor of product quality.[15]

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11 "Why U.S. Health Care is So Expensive and So Pathetic" By Kent Sepkowitz, The Daily Beast, June 18, 2014, http://www.thedailybeast.com/articles/2014/06/18/why-u-s-health-care-is-so-expensive-and-so-pathetic.html (Accessed 3/31/15); "Tangible and Unseen Health-Care Costs" By Dionne Searcey and Jacob Goldstein, The Wall Street Journal, September 3, 2009, http://online.wsj.com/article/SB125193312967181349.html (Accessed 1/6/10); "The High Concentration of U.S. Health Care Expenditures" By Mark W. Stanton, Research in Action, Vol. 19, June 2006, http://www.ahrq.gov/research/ria19/expendria.htm (Accessed 01/05/10); "Why Are Healthcare Costs So High?" Planet Money Blog, November 11, 2008, http://www.npr.org/blogs/money/2008/11/why_are_healthcare_costs_so_high.html (Accessed 1/6/10).

12 "Seven Factors Driving Up Your Health Care Costs" By Julie Appleby, Kaiser Health News, October 24, 2012, http://kaiserhealthnews.org/news/health-care-costs/ (Accessed 3/25/15); "Main Indicators: /capita, US$ purchasing power parity—total expenditrues" Organisation for Economic Co-Operation and Develoment, April 1, 2015, http://stats.oecd.org/index.aspx?DataSetCode=HEALTH_STAT (Accessed 4/1/15).

13 "Do Health Care Costs Matter?" By William J. Baumol, The New Republic, November 22, 1993, p. 17.

14 "A Checkup on Health Care Markets" By Patricia E. Powers, MPPA and Michael W. Painter, MD, Robert Wood Johnson Foundation, 2007, p. 2; "The Effect of Health Care Cost Growth on the U.S. Economy" By Neeraj Sood, Arkadipta Ghosh, and Jose J. Escarse, U.S. Department of Health and Human Services, September 2007, p. 6, 9, 15, 22.

15 "Do Health Care Costs Matter?" By William J. Baumol, The New Republic, November 22, 1993, p. 17.

Since healthcare productivity tends to grow at a slower rate than other industries, the higher *relative* costs for healthcare services pose a serious consequence, even though higher costs are an unavoidable and indelible part of a developed economy. For example, as technological advancements increased efficiency and productivity in the computer manufacturing industry, computer industry labor wages also increased. However, the *total cost* per produced computer declined. But in healthcare, wherein technological advancements do not (currently) have the same impact on the rate of growth of productivity, wage increases that would be consistent with other sectors of the economy would be problematic, i.e., the cost per unit of healthcare produced grows, resulting in healthcare's share of the U.S. GDP increasing relative to other industry sectors, which have experienced greater productivity (see above).

Despite both the slow productivity growth and the continually rising percentage of healthcare as a part of U.S. GDP, Baumol noted that growth in other areas of the economy may be utilized to offset the relative cost growth experienced in the healthcare sector, to wit:

> "…productivity growth in the entire economy means we can afford more of everything. In an economy in which productivity is growing in almost every sector and declining in none … consumers can have more of every good and service; they simply have to transfer gains from the sector that's becoming more productive into the sector that's only becoming a little more productive."[16]

Consequently, Baumol posited that if U.S. society deems health to be important, then its employers and governments must be willing to implement policies that share productivity gains in other sectors with healthcare providers. Enterprises cannot accrue increasing profits and governments cannot take escalating taxes from an expanding, technologically efficient economy and expect healthcare services to survive at acceptable levels of quality and access. This economic theory has been implemented through various ACA provisions and other policies that impact the supply of, and demand for, healthcare delivery services.

SUPPLY AND DEMAND IN HEALTHCARE

Historically, healthcare was considered a *special* economic market, in which quality of care traditionally trumped general economic notions of the consumer-driven model of supply and demand. Competition law, which considers quality as only one element of a good or service, inherently conflicts with the traditional perspectives of providers who see quality as "an irreducible minimum standard, to be determined by physicians without reference to cost."[17] Prior to the mid–twentieth century, healthcare was dominated by these providers who justified anticompetitive behavior under the guise of quality control. In the mid- to late-twentieth century, however, the scrutiny of competition in healthcare increased to address such behavior among providers and, as such, competition laws have begun to regulate the healthcare sector as an economic market more directly.[18]

16 "Do Health Care Costs Matter?" By William J. Baumol, The New Republic, Nov. 22, 1993, p. 18.
17 "Why Competition Law Matters to Health Care Quality" By William M. Sage, David A. Hyman, and Warren Greenberg, Health Affairs, Vol. 22, No. 2, (March/April 2003), p. 39.
18 Ibid, p. 34-35.

> Prior to the mid–twentieth century, healthcare was dominated by these providers that justified anticompetitive behavior under the guise of quality control.
>
> ***William M. Sage, David A. Hyman, and Warren Greenberg, March/April 2003.***

Additionally, competition law now addresses the traditional notion of the *three-legged stool* model of healthcare, under which *cost*, *quality*, and *access* are considered distinct elements of healthcare administration. As the impact of competition law on healthcare policy has grown, these three "legs" have demonstrated their interconnectedness, with price being viewed as having a direct impact on quality of care. Competition laws have been used to combat the practice of increasing prices above competitive levels, as well as to prevent providers from excising certain competitors from the market in the pursuit of "*higher quality of care*".[19]

Also unique to the healthcare sector is the widespread notion of providing services irrespective of the client's (i.e., the patient's) ability to pay. Under laws such as the *Emergency Medical Treatment and Labor Act* (EMTALA), hospital emergency departments are required to provide care under certain circumstances, even to patients who are uninsured and unable to pay for services rendered.[20] Additionally, the power of Medicare and Medicaid, as the largest payors for healthcare services, forces providers to operate at a loss for many services because those programs typically reimburse providers only for a fraction of the amount the services cost. As these payors provide more than 50% of a hospital's revenue, the general relationship between cost and price found in other markets is not commonly followed in the healthcare sector.[21]

> Medicare and Medicaid provide more than 50% of a hospital's revenue.
>
> ***Hospital Accounts Receivable Analysis, HARA Report, December 1, 2014.***

Also, competition in healthcare does not divide neatly between supply and demand, further contributing to the complexity that distinguishes competition within the healthcare market from other industry sectors. Ultimately, the major players on the supply side of the healthcare industry are powerful private insurance companies and large hospital systems. Despite the fact that providers actually *supply* services to treat patients, insurance companies are able to limit access to these healthcare services through the use of provider networks, e.g., *health maintenance organizations* (HMO) and *preferred provider organizations* (PPO). Hospital and physician providers, on the other hand, are incentivized to keep costs low and maximize utilization of those services that have the highest reimbursement yield.[22] HMOs and PPOs have sought to combine the role of insurance companies, utilization review organizations, and healthcare providers to offer prepaid medical plans to subscribers. *Primary care physicians* practicing within an HMO or PPO are considered to be a *gatekeeper* who restricts access to, and utilization of, services in order to contain costs.

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19 See Chapter 3: Regulatory Environment; "Why Competition Law Matters to Health Care Quality" By William M. Sage, David A. Hyman, and Warren Greenberg, Health Affairs, Vol. 22, No. 2, (March/April 2003), p. 35-36.

20 "Could U.S. Hospitals Go The Way Of U.S. Airlines?" By Stuart H. Altman, David Shactman, and Efrat Eilat, Health Affairs, Vol. 25, No. 1 (January/February 2006), p. 11-12; "Emergency Medical Treatment and Labor Act" 42 U.S.C 1395dd, January 5, 2009 p. 2534-2541.

21 "Medicare, Managed Care, and Other Sources of Revenue" By Hospital Accounts Receivable Analysis, HARA Report, Third Quarter (December 1, 2014) http://eds.a.ebscohost.com/eds/pdfviewer/pdfviewer?sid=1c177128-4a31-4a50-99cf-d210bc9ee0db%40sessionmgr4001&vid=7&hid=4210 (Accessed 3/25/15), p. 22.

22 "Redefining Competition in Health Care," By Michael E. Porter and Elizabeth Olmsted Teisberg, Harvard Business Review, June 2004, p 3.

To date, cost containment has continued to affect the way in which healthcare services are delivered, and current reform efforts seek to further tie reimbursement to both cost and quality metrics. For example, public and private payors have implemented *bundled payment initiatives* into provider reimbursement models, which initiatives aim to "…align the incentives for both hospitals and physicians, leading to better quality and greater efficiency in the care that is delivered."[23] Narrow networks have also been a tool used in cost containment, wherein networks only offer a select group of covered physicians and services at a lower price than plans with greater coverage in order to reduce costs for the insurer and the consumer.[24]

Payors operate as both *suppliers* and *consumers* of healthcare services by supplying insurance and paying for the services provided, deferring the direct payment of those costs from the patient.[25] As *suppliers* and *consumers*, large insurance companies have been able to benefit from *monopsony* (i.e., one buyer many sellers) power in the U.S., allowing them to demand *Most Favored Nation* provisions in their provider contracts (i.e., the provider contractually charges the insurance company the same as, or less than, any other customer).[26] This provision has allowed insurance companies to prevent the entry of new competitors[27] and, in combination with multiple insurance company mergers, has led to a highly concentrated U.S. health insurance market that reimburses providers at lower rates, resulting in a significant fiscal burden on physician groups and small hospitals, driving them out of business or forcing them to join large health systems.[28]

Conversely, private payors have asserted that, due to increasing leverage on the part of large hospitals and health systems, they are often unable to contain rate increases, which in turn are passed along to insurance beneficiaries in the form of premium increases.[29] Despite the potential to raise premiums, much of the healthcare industry consolidation will likely avoid scrutiny under antitrust regulations, as the majority of mergers occur over broad geographic areas and do not result in excessive market concentration as it has been defined by the *Federal Trade Commission* (FTC) and *Department of Justice* (DOJ).[30] Myriad factors beyond *mergers and acquisitions* can aid in increasing hospitals' market power,[31] such as a hospital's brand recognition or its ability to provide a specialized service, which may confer significant leverage in negotiations with private payors.[32] Additionally, the ability of multi-hospital systems to negotiate a single contract on behalf of all of its facilities allows systems to bargain for higher reimbursement rates.[33]

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23 See Chapter 2: Reimbursement Environment for further discussion regarding bundled payments; "Press Release to Announce Sites for the CMS ACE Program" Centers for Medicare and Medicaid Services, January 6, 2009, p. 1.

24 "Narrow Provider Networks in New Health Plans: Balancing Affordability with Access to Quality Care" By Sabrina Corlette, et al., Report for The Center of Health Insurance Reforms and the Urban Institute, May 2014, Robert Wood Johnson Foundation, p. 1.

25 "Improving Health Care: A Dose of Competition" Federal Trade Commission and The Department of Justice, July 2004, Executive Summary, p. 4-5.

26 "Improving Health Care: A Dose of Competition" A Report by the Federal Trade Commission and Department of Justice, July 2004, Chapter 6, p. 20.

27 "The Next Antitrust Agenda: The American Antitrust Institute's Transition Report on Competition Policy to the 44th President of the United States," By The American Antitrust Institute, Albert A. Foer, Ed., Vandeplas Publishing (2008), p.323.

28 "Statement of the American Medical Association to the Subcommittee on Health Committee on Ways and Means United States House of Representatives, RE: Health Care Industry Consolidation," American Medical Association, September 9, 2011.

29 "Key Findings from HSC's 2010 Site Visits: Health Care Markets Weather Economic Downturn, Brace for Health Reform" By Laurie E. Felland, Joy M. Grossman, and Ha T. Tu, Center for Studying Health System Change Issue Brief, No. 135 (May 2011), p. 3; "Rising Hospital Employment of Physicians: Better Quality, Higher Costs?" By Ann S. O'Malley, Amelia M. Bond, and Robert A. Berenson, Center for Studying Health System Change Issue Brief, No. 136 (August 2011), p. 3-4.

30 "Antitrust Guidelines for Collaborations Among Competitors" Federal Trade Commission and Department of Justice, April 2000, p.6.

31 "The Growing Power of Some Providers to Win Steep Payment Increases from Insurers Suggest Policy Remedies May Be Needed" By Robert A. Berenson et al., Health Affairs, Vol. 31 No. 5 (May 2012), p. 975-976.

32 Ibid, p. 975.

33 Ibid, p. 975-976.

Community hospitals have an increasing difficulty in cost shifting and cross-subsidizing cost-ineffective services due to competition from specialty providers.[34] Decreasing reimbursement yields, which have restricted hospitals' revenue streams, as well as difficulties in accessing capital to support the provision of money-losing services are among the reasons that smaller hospital systems are consolidating with larger, for-profit systems.[35] By merging with larger health systems, smaller hospitals may be able to maintain sustainable margins by increasing efficiency and lowering costs, and more easily address their capital requirements. Additionally, mergers may aid *larger health systems* in reducing costs through *economies of scale*, *care coordination*, and *consolidation*.[36] The acquisition of other hospitals and physician group practices confers significant leverage to the purchasing hospitals when they negotiate rates with private payors.[37]

Within the current hospital growth trend, hospitals have developed a method for securing revenue that may result in provider supply disparities. In what has been called the "*geographic expansion race*," U.S. hospitals have begun implementing new strategies to expand their market presence and compete for valuable insured patients.[38] In a study of 12 healthcare markets, the *Center for Studying Health System Change* observed facility growth in large metropolitan areas, analyzing the different expansion strategies employed and the resulting market composition.[39] Though the study acknowledged that it is likely too early to predict the impact that the geographic expansion of hospitals will have on *access*, *quality*, and *costs*, other healthcare industry commentators have both praised and sharply criticized this new trend for its anticipated effects.[40]

In order to target well-insured patients during geographic expansion, hospitals are increasingly employing one or more expansion strategies, including:

(1) Acquiring existing full-service hospitals or constructing new ones;
(2) Building ambulatory care facilities;
(3) Building freestanding emergency departments;
(4) Strengthening relationships with emergency medical transport systems; and/or
(5) Operating their own emergency medical transport systems.[41]

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34 "Could U.S. Hospitals Go The Way Of U.S. Airlines?" By Stuart H. Altman, David Shactman, and Efrat Eilat, Health Affairs, Vol. 25, No. 1, (Jan/Feb 2006), p. 11-12.

35 "Competition in Health Care: It's Evolution Over the Past Decade," by Paul B. Ginsburg, Health Affairs, Vol.24, No. 6, Nov/Dec 2005, p. 1521.

36 "3 Reasons Why Not-For Profits Hospitals Are Merging" By James Ellis and Aaron Razavi, Healthcare Finance News, August 16, 2011, http://www.healthcarefinancenews.com/blog/3-reasons-why-not-profits-hospitals-are-merging,. (Accessed 7/9/2012); "Take a look at how market forces will impact healthcare" By Gene O'Dell, Hospitals & Health Networks, September 9, 2014, http://www.hhnmag.com/display/HHN-news-article.dhtml?dcrPath=/templatedata/HF_Common/NewsArticle/data/HHN/Magazine/2014/Sep/gate-aha-environment-scan-2015 (Accessed 4/1/15).

37 See the Provider Consolidation section; "Key Findings from HSC's 2010 Site Visits: Health Care Markets Weather Economic Downturn, Brace for Health Reform" By Laurie E. Felland, Joy M. Grossman, and Ha T. Tu, Center for Studying Health System Change Issue Brief, No. 135 (May 2011), p. 3.

38 "Hospitals' Geographic Expansion in Quest of Well-Insured Patients: Will the Outcome be Better Care, More Cost, or Both?" By Emily R. Carrier et al., Health Affairs, Vol. 31, No. 4 (April 2012), p. 827.

39 "Key Findings from HSC's 2010 Site Visits: Health Care Markets Weather Economic Downturn, Brace for Health Reform" By Laurie E. Felland, Joy M. Grossman, and Ha T. Tu, Center for Studying Health System Change Issue Brief, No. 135 (May 2011), p. 2.

40 "Hospitals' Geographic Expansion in Quest of Well-Insured Patients: Will the Outcome be Better Care, More Cost, or Both?" By Emily R. Carrier et al., Health Affairs, Vol. 31, No. 4 (April 2012), p. 831, 832.

41 Ibid.

Though hospitals offer both efficiency and quality justifications for these expansion strategies, others in the healthcare industry assert that these strategies have the potential to raise costs, diminish the quality of care, and eliminate access to care for some patients.[42]

A growing trend in consumer-driven healthcare is increased rate transparency by providers and insurers.[43] Because of greater transparency, consumers have more opportunities to determine a health plan that fits their financial needs. With this knowledge, some consumers enduring the repercussions of high insurance premiums have chosen to switch to more consumer-driven healthcare insurance by contributing to a health saving account (HSA) from which to pay their medical expenses, then supplementing the HSA with high-deductible health plans (HDHP) to cover catastrophic conditions.[44] Another recent trend is narrow networks, which were developed in an effort to offer low-cost health plans to consumers.[45] While narrow networks offer lower-cost options to consumers, they may be too restrictive for many consumers because of the limited choice of providers offered under these plans.[46] There are also some potential problems for states with any willing provider laws who also offer narrow networks.[47] If a state requires insurers to accept all providers that meet certain requirements, the concern is that these insurers will not be able to reduce costs for consumers, thus interfering with the structure of narrow networks.[48] These concerns aside, this shift to *consumer-driven healthcare* has changed the demand environment of the healthcare industry such that providers are now dealing directly with patients who are starting to more closely scrutinize the procedures and services they purchase.[49] By making these purchasing decisions directly rather than relying on an insurance provider to pay most of the cost of treatment, the ability of healthcare consumers to affect demand in the healthcare market has increased, and the demand side of this sector is finally beginning, in some capacity, to mimic that of other industries.[50]

IMPACT OF GOVERNMENT REGULATION

Healthcare enterprises are subject to extensive regulatory control at both the state and federal levels of government. Some of the most significant regulations address the financial relationships between providers[51] State and federal fraud and abuse laws have profoundly affected the provision of healthcare services in the U.S. because they, in part, prohibit particular financial

42 Ibid, p. 828, 833.
43 "Blue Cross North Carolina's Price Tool Could Shake Up Medical Industry" By John Murawski and Ann Doss Helms, Kaiser Health News, February 4, 2015, http://kaiserhealthnews.org/news/blue-cross-north-carolinas-price-tool-could-shake-up-medical-industry/ (Accessed 3/28/15).
44 For more information about HSAs, see Chapter 2 Reimbursement Environment; "Health Savings Accounts (HSAs)" U.S. Department of Treasury, February 13, 2015, http://www.treasury.gov/resource-center/faqs/Taxes/Pages/Health-Savings-Accounts.aspx (Accessed 3/25/15).
45 "Providers, Advocates Seek Tougher Rules on Network Advocacy" By Paul Demko, Posted on Modern Healthcare, November 20, 2014, http://www.modernhealthcare.com/article/20141120/NEWS/311209971/providers-advocates-seek-tougher-rules-on-network-adequacy?CSReferrer=accessControl-modernhealthcare-metered (Accessed 3/28/15).
46 "Narrow Provider Networks in New Health Plans: Balancing Affordability with Access to Quality Care" By Sabrina Corlette, et al., Report for The Center of Health Insurance Reforms and the Urban Institute, May 2014, Robert Wood Johnson Foundation, p. 1.
47 Ibid, p. 5.
48 Ibid, p. 5.
49 "Defined Contribution: From Managed Care to Patient-Managed Care" By E. Haavi Morreim, Cato Journal, Vol. 22, No. 1 (Spring/Summer 2002), p. 112.
50 "All About HSAs" U.S. Treasury Department, July 22, 2007, http://www.treas.gov/offices/public-affairs/hsa/pdf/all-about-HSAs_072208.pdf (Accessed 07/01/09), p. 2; "Defined Contribution: From Managed Care to Patient-Managed Care" By E. Haavi Morreim, Cato Journal, Vol. 22, No. 1 (Spring/Summer 2002), p. 112.
51 See Chapter 3: Regulatory Environment.

relationships between healthcare providers. Proponents of these laws contend that practitioner medical judgment is influenced by financial relationships with referral sources.[52] However, substantial regulation has the capacity to limit free market competition in the healthcare industry.[53] Additionally, the influence of the government as both a *regulator* and *purchaser* of healthcare services may distort provider responses to patient demand, restrict access to care, and reduce potential rewards resulting from medical innovation.[54]

SUPPLY: COOPERATION AND COMPETITION BETWEEN HOSPITALS AND PHYSICIANS

Historically, physicians and hospitals each provided distinct services to patients, with physicians providing physician services and hospitals providing surgical facilities and other related services to patients referred to the hospital in which the physicians enjoyed staff privileges.[55] Under this symbiotic dynamic, there was relatively little to no competition between physicians and hospitals.[56] However, this trend has begun to shift as physicians have become owners and investors in surgical facilities such as ASCs and specialty hospitals that compete with the same general hospitals to which the physicians traditionally have referred patients. Additionally, the willingness of physicians to volunteer for responsibilities within a hospital has declined significantly in recent years, marking another shift toward a more competitive and adversarial relationship between physicians and hospitals.[57]

Hospitals

During the 1990s, the focus of managed care on the role of primary care physicians as *gatekeepers* resulted in declined patient volumes for hospitals.[58] Due in part to these reduced patient volumes, hospitals began offering additional services and entering into the practice of providing insurance and primary care services, taking on a powerful role as both *provider* and *insurer* through *integrated delivery systems*.[59] Declining patient volumes also prompted hospitals to merge with each other so that they could leverage their consolidated bargaining power against private insurers, in addition to competition from specialty providers.[60] As time progressed, concerns regarding access to capital have led to continued hospital consolidation,[61] such that smaller, typically nonprofit, hospitals are faced with the grim choice of going bankrupt or joining

52 "Health Care Fraud and Abuse: Practical Perspectives" Edited by Linda A. Baumann, Washington, DC: American Bar Association, 2002, p. 48.
53 "Improving Health Care: A Dose of Competition" Federal Trade Commission and The Department of Justice, July 2004, Executive Summary, p. 4-5.
54 Ibid, p. 5; For more information related to government regulation of the healthcare industry, see Chapter 3: Regulatory Environment.
55 "Hospital-Physician Relations: Cooperation, Competition, or Separation?" By Robert A. Berenson, Paul B. Ginsburg, and Jessica H. May, (December 5, 2006), p. w31; "The Effect of Physician-Owned Surgicenters On Hospital Outpatient Surgery" By William J. Lynk and Carina S. Longley, Health Affairs, Vol. 21, No. 4 (July/August 2002), p. 215.
56 "Hospital-Physician Relations: Cooperation, Competition, or Separation?" By Robert A. Berenson, Paul B. Ginsburg, and Jessica H. May, (December 5, 2006), p. w31.
57 Ibid, p. w34; For more detail related to the organizational structure of healthcare services in the current market, see Chapter 5 of Consulting with Professional Practices.
58 "Competition in Health Care: It's Evolution Over the Past Decade" By Paul B. Ginsburg, Health Affairs, Vol. 24, No. 6, November/December 2005, p. 1514.
59 Ibid, p. 1513-1514.
60 Ibid, p. 1514.
61 Ibid, p. 1521.

larger, for-profit hospital systems to survive and reduce costs through *economies of scale* and other methods, as mentioned in the earlier Supply and Demand in Healthcare section.

Physician-Owned Healthcare Facilities

Physician-owned hospitals have long prompted debate due to their potential for ethical violations related to physician referrals and the perception that these hospitals often *cherry-pick* and *cream-skim* the most profitable patients and procedures.[62] Despite contentions that the profits of general hospitals have been negatively impacted as specialty hospitals have selectively siphoned off more profitable services such as surgical and specialty procedures (e.g., orthopedic surgery, cardiac services), there is no conclusive evidence to support this assertion.[63] Further, physician-owned hospital proponents cite statistics indicating that patients often receive higher quality care and are more satisfied with their care at physician-owned hospitals.[64] Supporters have asserted that action against physician ownership is counter-productive to the aims of healthcare reform, i.e., to limit care facilities at the same time health insurance coverage is expanded to improve access to care for a greater percentage of the U.S. population.[65]

Further, physicians who provide outpatient services receive only the physician fee component reimbursement rate under the *Medicare Physician Fee Schedule* (MPFS).[66] Conversely, when procedures are performed in a *hospital outpatient department* (HOPD), hospitals (in the absence of bundled payments) receive both the *physician fee* (with which they reimburse their doctors) and the *facility fee* reimbursed under the OPPS rate.[67] Although the payment differential between HOPDs and ASCs is mostly standardized, the payment differential between services provided in HOPDs or ASCs and services provided in physicians' offices varies considerably by both payor and service.[68]

Campaign Against Physician Ownership

As the physician ownership of hospitals and other healthcare facilities has increased, so has the legislation restricting it. Incessant legislative and regulatory efforts have been undertaken at both the federal and state levels due in large part to massive lobbying initiatives by oligopoly hospitals (and their trade associations) to reverse the trend of physician investment in *ancillary services and technical component* (ASTC) revenue stream enterprises, e.g., ASCs, IDTFs, surgical/specialty hospitals, physical therapy, etc. These measures have served to relegate independent physicians in private practice to receiving only professional fee component revenues

62 "Physician-owned hospitals: Endangered species?" By Chris Silva, American Medical News, June 28, 2010, http://www.ama-assn.org/amednews/2010/06/28/gvsa06028.htm. (Accessed 7/10/12).

63 "Market Impact of Specialty Hospitals: A Study of the Profitability of General Short-Term Acute Care Hospitals Post Market Entry of Specialty Hospitals" By Robert James Cimasi, Anne P. Sharamitaro, Lance A. Hayes , and Rachel L. Seiler, Journal of Health Care Finance, Vol. 35, No. 2, Winter 2008, p. 1.

64 "The Future of Physician-owned Hospitals" By James Ellis and Aaron Razavi, Healthcare Finance News, March 14, 2012. http://www.healthcarefinancenews.com/blog/future-physician-owned-hospitals. (Accessed 7/10/2012).

65 "Physician-Owned Hospitals Racing To Meet Health Law Deadline" By Christopher Weaver, Kaiser Health News, October 28, 2010. http://www.kaiserhealthnews.org/stories/2012/october/28/physician-owned-hopitals.aspx, (Accessed 7/10/12).

66 "Medicare Payment Differentials Across Ambulatory Settings" By Barbara O. Wynn et al., July 2008, http://www.rand.org/pubs/working_papers/2008/RAND_WR602.sum.pdf (Accessed 09/24/09).

67 "Ambulatory Surgical Centers Payment System" MedPAC Payment Basics, October 2008, http://www.medpac.gov/documents/MedPAC_Payment_Basics_08_ASC.pdf (Accessed 09/24/09), p. 1.

68 "Medicare Payment Differentials Across Ambulatory Settings" By Barbara O. Wynn et al., July 2008, http://www.rand.org/pubs/working_papers/2008/RAND_WR602.sum.pdf (Accessed 09/24/09); For more information on Medicare reimbursement see Chapter 2: Reimbursement Environment.

or to accept employee status under the substantial control of hospital systems or large corporate players.

The Stark Law prohibits physicians from referring their patients to facilities in which they have a financial interest.[69] Historically, physicians were able to refer patients through the *whole hospital* exception. This exception allowed physicians to perform certain services despite their financial interest(s) as long as that financial interest was invested in the hospital generally and not in a particular subdivision.[70] Elimination of the Stark *whole hospital exception* was first introduced in Section 651 of the 2007 U.S. House of Representatives Bill 3162 entitled, *The Children's Health and Medicare Protection Act of 2007* (CHAMP). Although Section 651 of CHAMP was never signed into law, Section 6001 of the ACA bans future physician-owned hospitals from forming and, additionally, limits the expansion of existing facilities, effectively eliminating the use of the *whole hospital exception* for any healthcare facility established after 2010.[71]

Additional legislative actions against physician ownership include:

(1) The November 20, 2007 New Jersey court holding in *Health Net of New Jersey, Inc. v. Wayne Surgical Center, LLC*, that physicians who refer their patients to an ASC in which they have an ownership interest violates the *1989 Codey Act* prohibitions against self-referral;[72]
(2) Stark III updates prohibiting "*under arrangements*" and "*per click*" leasing ventures; [73]
(3) Various state tax acts (applicable only to ASCs, IDTFs, and cancer treatment centers), whereby physicians subsidize care provided in hospitals; and
(4) CMS's 2008 restrictions whereby IDTFs are no longer allowed to share practice locations, operations, and diagnostic testing equipment with other Medicare-enrolled providers, including leasing and subleasing agreements.[74]

Exclusionary Boycotts

In response to the threat from specialty hospitals, many community hospitals have also fought back in ways that may be perceived as being in violation of antitrust laws. In situations when specialty hospitals are owned in whole or in part by physicians with privileges on the medical staff of a general acute care hospital and when the specialty hospital competes with the general hospital either on an inpatient or outpatient basis, many general hospitals have engaged in activities that attempt to shut the physician-owned healthcare enterprise out of the market. Some of these practices include refusing to assist or cooperate with the enterprise, pressuring other members of the medical staff or community physicians to not do business with the specialty

69 "The Future of Physician-owned Hospitals" By James Ellis and Aaron Razavi, Healthcare Finance News, March 14, 2012. http://www.healthcarefinancenews.com/blog/future-physician-owned -hospitals. (Accessed 7/10/2012).
70 bid.
71 "Physician-Owned Hospitals Fire Back at Obamacare Restrictions" By Kenneth Artz, Heartlander, http://news.heartland.org/print/29036, (Accessed 7/10/2012).
72 "New Jersey Court Sends Blow to Doctor-Owned Facilities, By: Amy Lynn Sorrel, AMANews, American Medical Association January 14, 2008; "Garcia v Health Net of New Jersey, Inc." 2009 WL 3849685 (November 17, 2009).
73 "Potential Impact of 2008 Medicare Physician Fee Schedule Proposed Rules on Imaging Arrangements," By Thomas W. Greeson and Health M. Zimmerman, Reed Smith LLP, Health Lawyers Weekly, available at http://www.reedsmith.com/_db/_documents/ Potential_Impact_of_2008_Medicare_Physician_Fee_Schedule.pdf (Accessed 9/25/07).
74 "2008 Physician Fee Schedule Regulations Include Anti-Markup and IDTF Rule Change" McDermott Newsletters, McDermott Will & Emery, November 16, 2007.

hospital, pressuring payors to exclude specialty hospitals from their networks, and limiting or terminating physician-investors' privileges and medical staff membership (conflict of interest credentialing).[75] In response to these practices, some physician-owned healthcare enterprises have initiated antitrust suits, claiming that general hospitals are engaging in illegal exclusionary boycotts.[76]

Although courts have typically favored general hospitals that have tried to combat *cream-skimming* by specialty hospitals, one notable case brought by Heartland Surgical Specialty Hospital, a Kansas City–area hospital, in 2005 demonstrates that courts will not always overlook anticompetitive behavior by hospitals. The specialty hospital filed an antitrust lawsuit alleging horizontal conspiracies between multiple health plans and multiple hospitals, as well as vertical conspiracies between the hospitals and payors directly, resulting in pressure on payors, as well as direct agreements with them, to exclude the specialty service hospital from their networks.[77] The eventual settlement in this case demonstrates that antitrust laws still protect against entities with market power from using that market power to pressure others (in this case, other hospitals and payors) into agreeing to exclude a competitor from the market.[78]

Physicians

Competition in the healthcare industry operates predominantly at the level of hospitals, health plans, and provider networks rather than at the level of healthcare delivery with an independent practitioner.[79] This has incentivized physicians to join together in one of many types of emerging healthcare models so that they may improve their positioning *vis-à-vis* third-party payors.[80] However, because physician manpower shortages are projected through the first quarter of this century, the independent practice of medicine may become less common.

Consolidation with Other Physicians

There has also been a noticeable shift in competition among physicians in recent years. Originally, many physicians operated as independent competitors, perhaps allied only with the hospital(s) to which they referred patients.[81] The more recent trend has been for physicians to join networks with other physicians and to clinically integrate their services in an effort to lower costs and improve quality.[82] Managed care and reforms associated with the ACA have placed

75 "Antitrust Implications of Competition Between Physician-Owned Facilities and General Hospitals: Competition or Exclusion?" By William E. Berlin, Esq., The Health Lawyer, Volume 20, No. 5 (June 2008), p. 4.
76 Ibid, p. 3-5.
77 Ibid, p. 5.
78 Ibid, p. 5; see Chapter 3: Regulatory Environment.
79 "The Healthcare Crisis: Competition Is the Problem and the Solution" By Zachary R. Paterick, Timothy E. Paterick, and Blake E. Waterhouse, Medical Practice Management, July/August 2009, p. 13.
80 See Chapter 6 of Consulting with Professional Practices.
81 "Unhealthy Trends: The Future of Physician Services" By Hoangmai H. Pham and Paul B. Ginsburg, Health Affairs, Vol. 26, No. 6 (November/December 2007), p. 1587, 1589, 1593.
82 "Clinical Integration Can Lead to Cost Reduction" By Jennifer Zaino, Healthcare Finance, November 18, 2014, http://www.healthcarefinancenews.com/news/clinical-integration-can-lead-cost-reduction (Accessed 3/31/15); "Industry Perspective: Frequently Asked Questions about Clinical Integration" Valence Health, http://valencehealth.com/uploads/files/Valence_Health_Industry_Perspective_What_is_Clinical_Integration.pdf (Accessed 3/31/15); "Lessons From Market Competition in Healthcare: Love Everyone, Trust No One & Paddle Your Own Canoe" By Robert James Cimasi, Health Capital Consultants: St. Louis, MO, March 29, 2000.

pressure on these organizations to reduce costs, maintain quality, and protect market share.[83] A key driver of physician integration has been the potential negotiating power it merits, namely for contracting with hospitals and *managed care organizations* (MCOs).[84] The *independent physician association* (IPA) may be an extremely popular model, with the advent of ACOs and favorable rulings regarding clinical integration.[85]

Manpower Shortage

In 1980, the *Graduate Medical Education National Advisory Committee* (GMENAC) projected a surplus of 70,000 physicians in the year 1990 and a surplus of 145,000 physicians by 2000, which led to the implementation of a cap on medical school enrollment to control supply of physicians to the market.[86] Due to tightly controlled managed care in the 1990s, the projections of a physician surplus in the next decade were reaffirmed and the number of graduates per year remained unchanged for nearly twenty-five years.[87] As the *Great Recession* hit in 2008, the physician workforce, like many other professions, experienced a shortage that is expected to continue through the next decade, reaching a possible shortage of up to 90,000 physicians by the year 2025.[88] The shortage can be attributed to both the increased demand resulting from the growing *baby boomer* population and the misaligned cap on medical school enrollment.

> The physician workforce shortage is expected to continue through the next decade, reaching a possible a shortage of 160,000 physicians by the year 2025.
>
> ***Jeff Goldsmith, Feb. 15, 2012.***

In its physician workforce assessment, despite a projected 14% increase in the demand for primary care physician services by 2020, the *U.S. Department of Health and Human Services* (HHS) noted that the primary care physician shortage is expected to continue.[89] HHS attributed a

83 "Has the ACA Triggerred a wave of Hospital Mergers" Advisory Company, Daily Briefing, September 30, 2013, http://www.advisory.com/Daily-Briefing/2013/09/30/Has-the-ACA-triggered-a-wave-of-hospital-mergers (Accessed 3/31/15) citing "Obamacare Side Effect: More Hospitals Expected to Merge Under Affordable Care Act" By Susan Livio, New Jersey Star-Ledger, September 26, 2013, http://www.nj.com/news/index.ssf/2013/09/obamacare_side_effect_more_hospitals_to_merge_under_affordable_care_act.html (Accessed 3/31/15); "Lessons From Market Competition in Healthcare: Love Everyone, Trust No One & Paddle Your Own Canoe" By Robert James Cimasi, Health Capital Consultants: St. Louis, MO, March 29, 2000.

84 "Industry Perspective: Best of Both Worlds—Physician Benefits of Joining Clinically Integrated Networks" By Lori Fox Ward, Valence Health, http://valencehealth.com/uploads/files/Valence_Health_Industry_Perspective_Best_of_Both_Worlds.pdf (Accessed 3/31/15); "Lessons From Market Competition in Healthcare: Love Everyone, Trust No One & Paddle Your Own Canoe" By Robert James Cimasi, Health Capital Consultants: St. Louis, MO, March 29, 2000.

85 "The Basics of Independent Practice Associations" By Martin merritt, Physicians Practice, November 18, 2012, http://www.physicianspractice.com/blog/basics-independent-practice-associations (Accessed 3/31/15); See generally "RE: Norman PHO Advisory Opinion" By Markus H. Meier, Federal Trade Commission, February 13, 2013, http://www.ftc.gov/sites/default/files/documents/advisory-opinions/norman-physician-hospital-organization/130213normanphoadvltr_0.pdf (Accessed 3/2/2015); For detail on each of these types of physician integration models, see Chapter 6 of Consulting with Professional Practices.

86 "The Physicians Workforce: Projections and Research into Current Issues Affecting Supply and Demand" By U.S. Department of Health and Human Services and Health Resources and Services Administration, December 2008, p. 3.

87 "Looming Shortage of Physicians Raises Concerns About Access to Care" By Mike Mitka, Journal of the American Medical Association, Vol. 297, No. 10 (March 14, 2007), http://jama.ama-assn.org/cgi/content/full/297/10/1045 (Accessed 10/26/09) p. 1045-1046; "The Complex Dynamics of the Physician Workforce: Projected Supply and Demand through 2025" By Michael J. Dill and Edward S. Salsberg, Center for Workforce Studies, Association of American Medical Colleges, November 2008, p. 12.

88 "The Complexities of Physician Supply and Demand: Projectinos from 2013 to 2025: Final Report" IHS, Inc., March 2015, https://www.aamc.org/download/426242/data/ihsreportdownload.pdf (Accessed 3/31/15), p. v.

89 "Projecting the Supply and Demand for Primary Care Practitioners Through 2020-In Brief" Bureau of Health Professions, Health Resources and Services Administration, U.S. Department of Health and Human Services, November 2013, http://bhpr.hrsa.gov/healthworkforce/supplydemand/usworkforce/primarycare/primarycarebrief.pdf (Accessed 3/25/15) p. 2.

significant portion of this growth in demand to specialties that care for elderly patients, e,g., cardiology and internal medicine.[90] Despite the growing need for primary care physicians, interest in the field from medical students remains low.[91] Lower incomes, less prestige, and difficult workloads are all listed as major factors in medical students' decision to enter specialties instead of primary care, and rural areas in particular are seen as nonviable locations for physician practices.[92] In addition to a declining supply of new primary care physicians, the existing workforce is anticipated to experience a significant shift over the next two decades as the baby boomer population of physicians is likely to retire in the near-term, with many of the soon to be retirees being primary care physicians.[93] Combined with an aging population and healthcare reform's significant expansion in access to care, the strain on the physician workforce is rapidly becoming untenable.

Primary care is one of the practice areas suffering most from the physician shortage, which likely can be attributed to the gap in pay between primary care physicians and specialists.[94] Further exacerbating this particular shortage is the focus of medical schools on advanced specialization arising from low reimbursement rates for *academic medical centers* (AMCs). As a result, AMCs are forced to rely on higher reimbursement rates for training by subspecialists, leading to a focus on subspecialties.[95] Additionally, many surgeons have specialized so much that they do not feel qualified to provide emergency services, with some surgeons only providing outpatient care.[96] Furthermore, today's physicians are seeking a greater work-life balance than those in the past, and this work-life balance only exacerbates the problem of physician shortage.[97] In the future, a greater emphasis on flexible hours may be the key to maintaining satisfaction for both patients and physicians.[98] The healthcare industry has begun to address anticipated primary care shortages by establishing new medical schools and residency programs, some of which specifically promote a primary care focus. In 2006, the *Association of American Medical Colleges* (AAMC) set a goal to increase medical school enrollment 30% by 2015 (based on 2002 enrollment statistics).[99] Current studies suggest the enrollment goal was almost met, as medical schools saw a 29.5% increase in enrollment, 85 spots shy of the targeted 30% goal.[100] The projected growth in medical school enrollment is anticipated to be attributed to *current* (two-

90 "The Physicians Workforce: Projections and Research into Current Issues Affecting Supply and Demand" By U.S. Department of Health and Human Services and Health Resources and Services Administration, December 2008, p. iv, 59.

91 "Why is There a Shortage of Primary Care Doctors?" Association of American Medical Colleges, https://www.aamc.org/linkableblob/70310-6/data/primarycarefs-data.pdf (Accessed 6/30/12).

92 "Why is There a Shortage of Primary Care Doctors?" Association of American Medical Colleges, https://www.aamc.org/linkableblob/70310-6/data/primarycarefs-data.pdf (Accessed 6/30/12); "Rural Research Focus: Rural Physician Shortages" By George E. Wright et al., Health Resources and Services Administration, ftp://ftp.hrsa.gov/ruralhealth/RRF-RHHA.pdf (Accessed 6/30/12).

93 "Why is There a Shortage of Primary Care Doctors?" Association of American Medical Colleges, https://www.aamc.org/linkableblob/70310-6/data/primarycarefs-data.pdf (Accessed 6/30/12). "The Future of Medical Practice: Creating Options for Practicing Physicians to Control Their Professional Destiny" By Jeff Goldsmith, The Physicians Foundation, Feb. 15, 2012, http://www.physiciansfoundation.org/uploads/default/Physicians_Foundation_Future_of_Medical_Practices.pdf (Accessed 3/25/15) p. 48-50.

94 "Match Day: High-Paid Specialties Still IN, Primary Care Still Out" By Jacob Goldstein, Wall Street Journal Blogs, (March 19, 2009), http://blogs.wsj.com/health/2009/03/19/match-day-high-paid-specialties-still-in-primary-care-still-out/ (Accessed 03/27/09).

95 "Fewer Medical Students Choose Family Medicine in 2009 Match" By Barbara Bein, American Academy of Family Physicians, March 19, 2009, http://www.aafp.org/online/en/home/publications/news/news-now/resident-student-focus/20090319match.html (Accessed 3/27/09).

96 "Statement on the Surgical Workforce" American College of Surgeons, Bulletin of the American College of Surgeons, Vol. 92, No. 8, (August 2007), Accessed at http://www.facs.org/fellows_info/statements/st-57.html (Accessed 5/10/10).

97 See Chapter 6: Healthcare Reform; "Wanting It All: A New Generation of Doctors Places Higher Value on Work-Life Balance" By Eve Glicksman, AAMC Reporter, May 2013, https://www.aamc.org/newsroom/reporter/336402/work-life.html (Accessed 3/28/15).

98 Ibid.

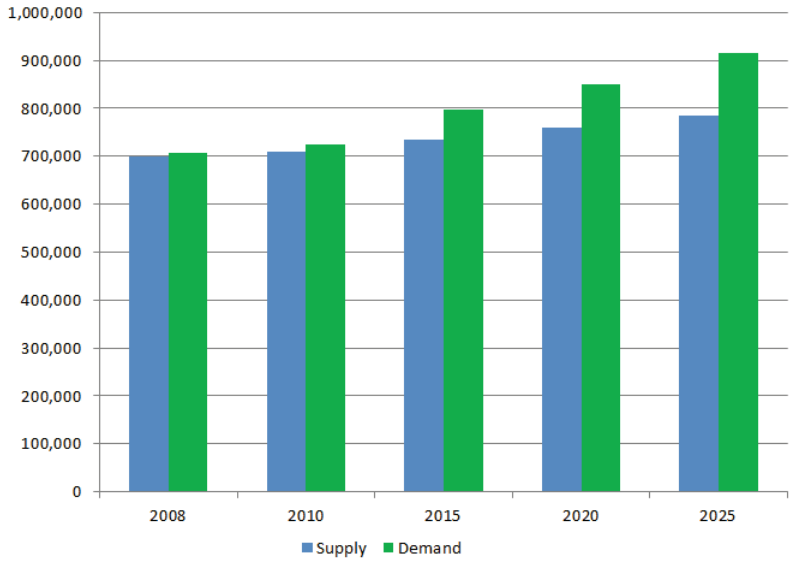
99 "Results of the 2011 Medical School Enrollment Survey" Association of American Medical College, Center for Workforce Studies, May 2012, p. 4.

100 "Results of the 2013 Medical School Enrollment Survey" Association of American Medical Colleges, Center for Workforce Studies, March 2014, https://members.aamc.org/eweb/upload/13-239%20Enrollment%20Survey%20201310.pdf (Accessed 3/25/15), p. 3.

thirds) as well as *new* (one-third) medical schools.[101] In response to the pending shortage and the AAMC goal, 16 institutions were granted some form of accreditation as of March 2014,[102] a stark contrast to the period between 1980 and 1990, where *no* new medical schools were established (due to the GMENAC report).[103] While academic institutions may be motivated by the prestige a medical school affiliation may lend to both the university and the surrounding community,[104] the establishment of new sources of physicians may also positively impact the physician manpower shortage. In addition to the development of new medical schools, some existing facilities have established broader primary care programs in rural communities to address access to care and physician shortage issues, e.g., the *University of Kansas School of Medicine* north-central campus rural program and the *Columbia University College of Physicians and Surgeons* Columbia-Basset rural program, both established in 2011.[105]

The historical and projected increase in the perceived physician shortage is illustrated below in Figure 4-1.

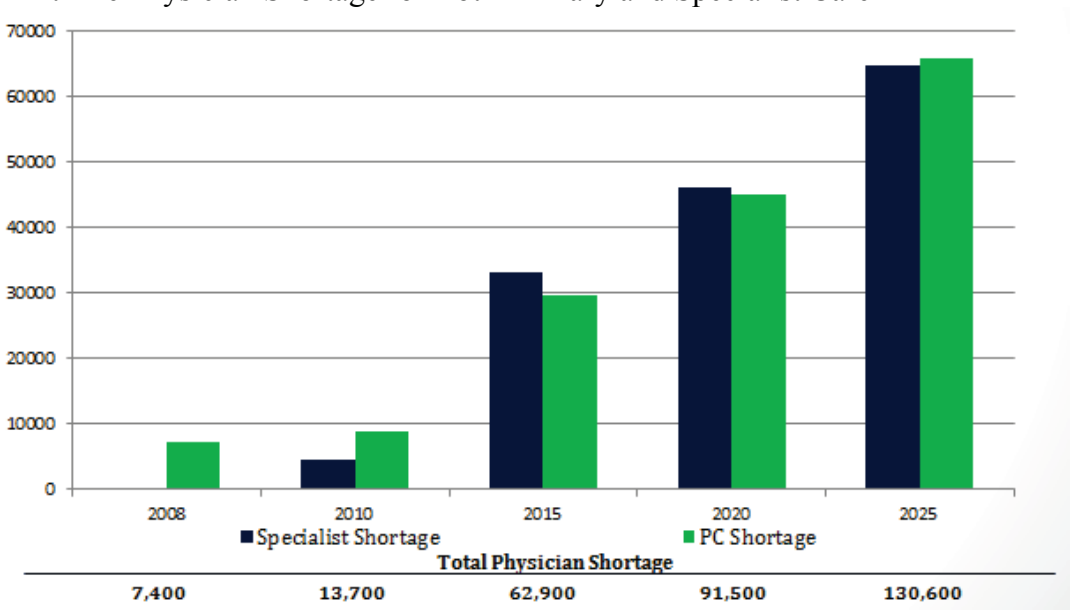
Figure 4-1: Physician Supply and Demand[106]



The physician manpower shortage is not projected to be restricted to primary care. A comparison between the perceived physician shortage for both primary and specialist care is illustrated below in Figure 4-2.

101 "Results of the 2013 Medical School Enrollment Survey" Association of American Medical Colleges, Center for Workforce Studies, March 2014, https://members.aamc.org/eweb/upload/13-239%20Enrollment%20Survey%20201310.pdf (Accessed 3/25/15), p. 3.
102 For standards to become a medical school see "Functions and Structure of a Medical School" Liaison Committee on Medical Education, http://www.lcme.org/publications/2015-16-functions-and-structure-march-2014.doc (Accessed 3/28/15).
103 "New Medical Schools in the United States" By Michael E. Whitcomb, New England Journal of Medicine, Vol. 362, No. 14, April 8, 2010, p. 1255-56.
104 Ibid, p. 1258.
105 "More Medical Schools Boost Primary Care Doctors Through Small-Town Campuses" By Gina Shaw, AAMC Reporter, Association of American Medical Colleges, July 2012, https://www.aamc.org/newsroom/reporter/july2012/297208/small-town.html (Accessed 8/14/2012).
106 "Physician Shortages to Worsen Without Increases in Residency Training" Association of American Medical College, 2010, https://www.aamc.org/download/286592/data/physicianshortage.pdf (Accessed 8/2/2012).

Figure 4-2: The Physician Shortage for Both Primary and Specialist Care[107]



These projections and subsequent concerns regarding patient access to care have prompted several initiatives, including: (1) increased funding incentives for primary care students (contained within the ACA); (2) increased incentives for physician movement to rural and underserved areas (contained within the ACA); and (3) less restrictive scope of practice laws for midlevel providers (i.e., various state laws allowing the unsupervised practice of medicine by *physician assistants, nurse practitioners,* and *certified registered nurses*).

The current and impending physician manpower shortage paired with declining reimbursement rates has fueled physician demand for manpower relief. To meet this demand, the healthcare workforce continues to diversify, with versatility no longer limited to the horizontal expansion of specialty and subspecialty areas of medical expertise. Rather, current trends have solicited a vertical expansion in the role of the non-physician workforce to provide services that support, supplement, and parallel physician services. Midlevel providers are afforded a significant level of autonomy within their scope of practice, which authorizes them to act not only incident-to, but also in lieu of, physicians under certain conditions, and for the provision of previously determined services.[108] The degree of practice autonomy typically differs from state to state and for each type of midlevel provider.[109] In the next few years, the midlevel provider population is expected to continue to grow in both scope and volume. From 1987 to 1997 alone, the number of patients treated by non-physician providers grew to 1.4 times the original amount.[110] According to a 2009 Office of Inspector General (OIG) report, 51% of Medicare-billed physician services

107 "Physician Shortages to Worsen Without Increases in Residency Training" Association of American Medical College, 2010, https://www.aamc.org/download/286592/data/physicianshortage.pdf (Accessed 8/2/2012).

108 "Interprofessional Healthcare: A Common Taxonomy to Assist with Understanding," by Alice B. Aiken, PT, PhD and Mary Ann McColl, PhD, Journal of Allied Health, Volume 38, Number 3 (Fall 2009), p. e-94.

109 "Health and Health Care 2010: the Forecast, The Challenge", by the Institute for the Future and the Robert Wood Johnson Foundation, Princeton, NJ: Jossey-Bass, 2003, p. 108; "Report of the Council on Medical Service: Ratio of Physician to Physician Extenders", presented by Kay K. Hanley, December 1998, p. 1; For a further discussion of midlevel providers, see Chapter 8 of Consulting with Professional Practices.

110 "Trends in Care by Nonphysician Clinicians in the United States" By Benjamin G. Druss et al., The New England Journal of Medicine, Vol. 348, No. 2, 2003, p. 134.

that exceed a 24-hour workday were actually performed by qualified non-physician practitioners (i.e., midlevel providers which may have been performing "*incident to*" services).[111] Further, the services provided by non-physician clinicians (both qualified and non-qualified) over a three-month period totaled approximately $85 million in Medicare claims.[112]

DEMAND: THIRD-PARTY PAYORS AND CONSUMER-DRIVEN HEALTHCARE

Although Chapter 2, *Reimbursement Environment*, provides an extensive discussion of third-party payor reimbursement, it is important to understand the significant power of third-party payors as purchasers of healthcare services. Insurers essentially hold all the cards when dealing with both providers and patient-consumers. Although there will always be a significant amount of patient demand, how that demand affects the market is affected by the existence of an intermediary between supplier and consumer that takes most of the purchasing burden off the consumer and, as a result, eliminates traditional demand forces that work in other markets to keep prices at reasonable levels.

Insurance and Managed Care

With regard to demand, as noted in the FTC's and DOJ's 2004 report entitled, "Improving Health Care: A Dose of Competition," the presence of third-party payors in the healthcare industry may be capable of distorting the traditional supply and demand model by shifting the risks associated with ill health from patient (consumer) to a third party that pays for the management of those risks.[113] By shifting that risk, consumers are insulated from the cost of the services needed to manage their health and, therefore, do not make entirely informed choices when balancing costs and benefits, resulting in an imperfect demand curve.[114] Conversely, insurance companies bear the costs associated with healthcare services, but generally do not capture the full benefits, which may further discredit the application of a traditional supply and demand model to the healthcare competitive market.[115]

Health insurance has previously affected the healthcare marketplace by offering misaligned incentives to physicians who are reimbursed by third-party payors at levels that do not reflect quality of care, but rather focus mainly on the procedural volumes.[116] As a result, physicians were neither rewarded nor punished based on the quality of their work.[117] This insulated physicians from traditional competitive forces that force low-performing participants out of other markets.[118] However, recent changes encourage providers to place quality over quantity in regards to patient treatment. Previous payment systems rewarded physicians for the number of procedures performed, thus encouraging overuse and overspending, but the new system of value-

111 "Prevalence and Qualifications of Nonphysicians Who Performed Medicare Physician Services" Office of the Inspector General, August 2009, p. 8.
112 Ibid.
113 "Improving Health Care: A Dose of Competition" Federal Trade Commission and The Department of Justice, July 2004, Executive Summary, p. 5.
114 Ibid.
115 Ibid.
116 Ibid.
117 Ibid.
118 Ibid.

based purchasing scores physician performance with quality considerations to determine payment for services.[119]

MCOs, such as HMOs and PPOs, also can distort the traditional competitive marketplace model by integrating the financing and delivery of healthcare services under the administration of one organization.[120] MCOs may be attractive to consumers because they offer lower premiums, deductibles, and co-payments than traditional third-party payors.[121] However, MCOs also take many choices out of a patient's hands by creating restricted networks of providers from which the insured must choose in order to obtain those lower prices.[122] One way of reducing the cost of care employed by MCOs is to contract with select physicians who agree to lower costs in order to be admitted to the MCO's provider network. In this way, MCOs force price competition between providers, which allows them to negotiate volume discounts with providers, something that would not be possible for individual consumers to do on their own.[123] This same approach is used by narrow networks that contract with a select number of physicians to keep costs low for consumers and the network itself.[124]

However, when the popularity of more restrictive forms of managed care began to wane at the end of the twentieth century, flexibility began to re-emerge in managed care, which has re-introduced traditional supply and demand back into the health industry. As the popularity of *point-of-service* (POS), PPOs, and *pay-for-performance* (P4P) plans has grown, patients have been able to once again take a more active role as *consumers* in the healthcare marketplace.[125] POS plans mandate that patients use a primary care gatekeeper, but allow patients to use out-of-plan specialty physicians for some services; PPOs allow patients to choose out-of-plan providers listed as preferred providers without the need for a gatekeeper.[126]

MCOs are beginning to push their way into smaller markets, offering broader provider networks in the process. In recent years, there has been a shift in the consolidation of healthcare entities. Historically, mergers were motivated by financial necessity, wherein they had to merge to survive, but new mergers are often motivated by strategy, [127] meaning that entities are finding it more important to merge to increase their market share of a field or spread costs. Many states

119 "Hospital Value-Based Purchasing" Centers for Medicare and Medicaid Services, http://www.medicare.gov/hospitalcompare/Data/hospital-vbp.html?AspxAutoDetectCookieSupport=1 (Accessed 3/28/15); See Chapter 2: Reimbursement Environment.
120 "Improving Health Care: A Dose of Competition" Federal Trade Commission and The Department of Justice, July 2004, Executive Summary, p. 11.
121 Ibid.
122 Ibid.
123 Ibid.
124 "Providers, Advocates, Seek Tougher Rules on Network Adequacy" By Paul Demko, Posted on Modern Healthcare, http://www.modernhealthcare.com/article/20141120/NEWS/311209971/providers-advocates-seek-tougher-rules-on-network-adequacy?CSReferrer=accessControl-modernhealthcare-metered (Accessed 3/28/15).
125 "Improving Health Care: A Dose of Competition" Federal Trade Commission and The Department of Justice, July 2004, Executive Summary, p. 12.
126 Ibid.
127 "Mergers and Acquisitions in the Health Care Industry Hit Highest Volume Since 2007"Managed Care Outlook, Vol. 26, No. 24, December 15, 2013, p. 6.

have approximately three insurers that insure more than half of the individual, small, and large group markets.[128]

The state *health insurance exchange* (HIE) provision of the ACA (which became effective in 2014) is designed to have a significant impact on competition between private payors by providing patients with an online portal on which to compare various options for coverage. Although these exchanges were under contention by many states, the U.S. Supreme Court's decision upholding the constitutionality of the ACA, and specifically the *individual mandate* provision, has insured that these managed competition marketplaces will be fully implemented in 2014.[129] At this time, 13 states and the District of Columbia have established state-based exchanges, three states have established federally-supported marketplaces, and seven have established state-partnership marketplaces,[130] while the remaining twenty-seven state exchanges are run by the federal government.[131] The validity of these federally-run state exchanges has come under scrutiny recently in the case of *King v. Burwell*; however, on June 25, 2015, the Supreme Court upheld the legality of health insurance subsidies for these exchanges.[132]

Public Payors

Prior to 1983, Medicare and most private insurers reimbursed providers on a *fee-for-service* (FFS) basis, which paid hospitals and physicians based on the cost and the number of services they provided.[133] Beginning in 1983, however, CMS adopted the hospital *Inpatient Prospective Payment System* (IPPS) as a means of combating rising costs associated with FFS.[134] The IPPS reimbursed hospitals based on the DRG of the patient's diagnosis at the time he or she was discharged, which reflected the average cost of treating patients in that DRG.[135] By reimbursing hospitals at this fixed amount, the IPPS introduced a more competitive, market-like environment for hospital reimbursement and encouraged hospitals to reduce costs so that procedures remained profitable.[136] Similarly, the hospital *Outpatient Prospective Payment System* (OPPS) was implemented in 2000 to accomplish the same competitive environment for outpatient procedures by reimbursing hospitals based on a number of *Ambulatory Payment Classifications* (APCs).[137] In the past few years, public payors have placed a greater emphasis on quality of services, with payment structures reflecting that change. This has been particularly emphasized with the value-

128 "Market Share and Enrollment of Largest Three Insurers—Individual Market" The Henry J. Kaiser Family Foundation, 2013, http://kff.org/other/state-indicator/market-share-and-enrollment-of-largest-three-insurers-individual-market/ (Accessed 4/1/15); "Market Share and Enrollment of Largest Three Insurers—Small Group Market" The Henry J. Kaiser Family Foundation, 2013, http://kff.org/other/state-indicator/market-share-and-enrollment-of-largest-three-insurers-small-group-market/ (Accessed 4/1/15); "Market Share and Enrollment of Largest Three Insurers—Large Group Market" The Henry J. Kaiser Family Foundation, 2013, http://kff.org/other/state-indicator/market-share-and-enrollment-of-largest-three-insurers-large-group-market/ (Accessed 4/1/15).

129 "After ACA Ruling, HHS Moves Ahead with Insurance Exchanges" by Jennifer Lubell, American Medical Association, July 6, 2012, (Accessed 7/9/2012).

130 "State Health Insurance Marketplace Types 2015" Kaiser Family Foundation, November 2014, http://kff.org/health-reform/state-indicator/state-health-insurance-marketplace-types/ (Accessed 3/25/15);"Establishing Health Insurance Exchanges: An Overview of State Efforts" Kaiser Family Foundation, Publication #8213, August 2012, p. 1.

131 State Health Insurance Marketplace Types 2015" Kaiser Family Foundation, November 2014, http://kff.org/health-reform/state-indicator/state-health-insurance-marketplace-types/ (Accessed 3/25/15).

132 See chapter 6 Healthcare Reform; "King et al. v. Burwell, Secretary of Health and Human Services, et al" No. 14-114 (U.S. June 25, 2015), Slip Opinion, p. 4, 21.

133 "Improving Health Care: A Dose of Competition" Federal Trade Commission and The Department of Justice, July 2004, Executive Summary, p. 8.

134 Ibid, p. 9.

135 Ibid, p. 9.

136 Ibid, p. 9.

137 Ibid, p. 9.

based purchasing program, healthcare-associated infection reduction efforts, and hospital readmission and reduction programs.[138]

Consumer-Driven Healthcare

Third-party payors deflect a substantial portion of the true cost of services away from the consumer (i.e., the patient).[139] However, the rise of *consumer-driven healthcare* (CDHC) indicates that healthcare markets may be shifting away from the traditional model and that the market distortion which arises out of the third-party payor system may be beginning to dissolve.[140] A significant competitive trend in health insurance is the rise of individual, high-premium insurance plans coupled with HSAs as well as narrow network plans to accommodate low-income consumers or employers looking to limit healthcare costs.[141]

> However, the rise of Consumer-Driven Healthcare (CDHC) shows that healthcare markets may be shifting away from the traditional model and that the market distortion which arises out of the third-party payor system may be beginning to dissolve.
>
> ***Stuart H. Altman, David Shactman, and Efrat Eilat, Jan/Feb 2006.***

CDHC is a growing trend based on neoclassical economic theory and studies that have shown that insured individuals with higher deductibles tend to purchase less healthcare services than insured individuals with low deductibles.[142] CDHC advocates the idea that consumers who pay for services directly are more likely to compare price to quality and demand higher-quality care, a theory which supports the use of HSAs coupled with HDHPs.[143] Generally, HSAs are personalized accounts into which an individual (and possibly an individual's employer) contributes. The individual then may withdraw funds to cover healthcare expenses.[144] HSAs put the purchasing power directly into the hands of the patient, who may use the tax-free funds to cover basic qualified medical expenses, including preventive care and over-the-counter drugs.[145] HDHPs are then used in the traditional insurance context to pay the costs associated with catastrophic events like trauma and chronic disease.[146] Proponents of CDHC encourage the implementation of narrow networks to create small provider networks at a lower cost for

138 "Linking Quality to Payment" Centers for Medicare and Medicaid Services, http://www.medicare.gov/hospitalcompare/linking-quality-to-payment.html (Accessed 3/28/15); See Chapter 2: Reimbursement Environment.

139 "Healthy Competition: What's Holding Back Healthcare and How to Free It" By Michael F. Cannon and Michael D. Tanner, Cato Institute, 2007, p. 46-47; "Improving Health Care: A Dose of Competition" Federal Trade Commission and The Department of Justice, July 2004, Executive Summary, p. 5.

140 See Chapter 2: Reimbursement Environment.

141 "Could U.S. Hospitals Go The Way Of U.S. Airlines?" By Stuart H. Altman, David Shactman, and Efrat Eilat, Health Affairs, Vol. 25, No. 1 (January/February 2006), p. 16; "2014 Employer Health Benefit Survey" Kaiser Family Foundation, September 10, 2014, http://kff.org/report-section/ehbs-2014-summary-of-findings/ (Accessed 3/25/15).

142 "Is Health Insurance a Bad Idea? The Consumer-Driven Perspective" By Timothy Stoltzfus Jost, Connecticut Insurance Law Journal, Vol. 14 (Spring 2008), p. 378-379; "The Health Insurance Experiment: A Classic RAND Study Speaks to the Current Health Care Reform Debate" RAND Health, http://www.rand.org/pubs/research_briefs/2006/RAND_RB9174.pdf (Accessed 10/27/09), p. 2.

143 "Is Health Insurance a Bad Idea? The Consumer-Driven Perspective" By Timothy Stoltzfus Jost, Connecticut Insurance Law Journal, Vol. 14 (Spring 2008), p. 379-80.

144 "All About HSAs" U.S. Treasury Department, July 22, 2007, http://www.treas.gov/offices/public-affairs/hsa/pdf/all-about-HSAs_072208.pdf (Accessed 07/01/09), p. 2.

145 Ibid.

146 "Is Health Insurance a Bad Idea? The Consumer-Driven Perspective" By Timothy Stoltzfus Jost, Connecticut Insurance Law Journal, Vol. 14 (Spring 2008), p. 380.

consumers.[147] These narrow networks are capable of great success if regulations can be implemented to ensure that the provider plans are not so small as to be inefficient for consumers.[148] The idea is that consumers with narrow networks will have essential providers included in their network but with little provider-variety and a potential lack of provider-specialization.[149]

Although proponents of CDHC argue that the use of HSAs and HDHPs will promote better analysis of cost and quality at the point of service,[150] skeptics argue that there is not enough evidence to demonstrate that CDHC leads to better informed choices based on quality.[151] Nonetheless, CDHC plans have the capacity to alter the traditional healthcare marketplace, which has become accustomed to the third-party payor system. The mere existence of CDHPs may alter the healthcare industry landscape to look more like markets in other industries in which consumers make purchasing decisions and more carefully scrutinize what they receive for their money. Additionally, by making consumers more aware of the actual cost of procedures, this trend may affect the ability of hospitals to cross-subsidize for costly care.[152]

BARRIERS TO FREE MARKET COMPETITION IN HEALTHCARE DELIVERY

Perfectly competitive markets exist only in economic theory. In reality, industries and markets have varying constraints on competition. The healthcare industry has often been characterized as unique in its numerous significant barriers to free market competition. Much of the inhibition from market controls on price and quality result from factors that can be expressed in three general categories:

(1) The nature of health creates an unpredictable, urgent, and infinite level of demand;
(2) The ubiquitous involvement of insurance, both private and governmental, as an intermediary in the purchase of healthcare services interferes with consumer motivations and consequently their choice of providers and services; and
(3) The difficulties in measuring healthcare quality and beneficial outcomes (both of *quantifying* and *qualifying* outcomes data) and the lack of information related to the relative costs of healthcare providers and services also inhibits consumer selection, further removing incentives to providers to increase quality and lower costs.

More specific examples of barriers to competition in healthcare delivery are provided below, in Table 4-1.

147 "Narrow Provider Networks in New Health Plans: Balancing Affordability with Access to Quality Care" By Sabrina Corlette, et al., Report for The Center of Health Insurance Reforms and the Urban Institute, May 2014, Robert Wood Johnson Foundation, p. 1.
148 Ibid.
149 "Narrow Provider Networks in New Health Plans: Balancing Affordability with Access to Quality Care" By Sabrina Corlette, et al., Report for The Center of Health Insurance Reforms and the Urban Institute, May 2014, Robert Wood Johnson Foundation, p. 1, 3.
150 "Is Health Insurance a Bad Idea? The Consumer-Driven Perspective" By Timothy Stoltzfus Jost, Connecticut Insurance Law Journal, Vol. 14 (Spring 2008), p. 379-80.
151 Ibid, p. 383.
152 "Could U.S. Hospitals Go The Way Of U.S. Airlines?" By Stuart H. Altman, David Shactman, and Efrat Eilat, Health Affairs, Vol. 25, No. 1 (January/February 2006), p. 17.

Table 4-1: Barriers to Competition in Healthcare

Patients	Patients Do Not Purchase Services Directly from Providers
	Patients Do Not Compare Prices Between Providers
Payors	The Government is the Largest Purchaser of Healthcare
	Private Purchasers Often Lack Market Power
Providers	Many Providers Have Monopoly or Near Monopoly Power (Yet Antitrust Laws Prevent Some Potentially Beneficial Integration)
	Providers Are Rewarded for Increasing Costs
	Capital Investments Are Overly Subsidized
	Certificate of Need, Regulation, and Licensing Laws are an Entry Barrier to Competing and Substitute Providers and Services
	Exit Barriers Protect Low Quality Providers
Patients, Purchasers, and Providers Lack Information	

DIFFICULTIES IN MEASURING QUALITY AND OUTCOMES

As discussed above, the difficulties in measuring healthcare quality and beneficial outcomes and the lack of information related to the relative costs of healthcare providers and services inhibits consumer selection. However, as transparency initiatives and *electronic health record* (EHR) technologies become more common, the difficulties associated with measuring quality and outcomes may diminish. More significantly, the current spread of *VBP initiatives*, which tie reimbursement to quality metrics, will likely incentivize providers to utilize those *health information technologies* (HIT) more so than the mere existence of HIT. CMS is funding many of these incentives through the *Hospital VBP* program, which makes distributions to hospitals for inpatient acute care services based upon quality performance measurements.[153] The hospital VBP program continues to undergo changes as CMS determines the best ways to allocate payments and measure quality of services. In August 2014, CMS announced the 2015 IPPS Final Rule, which includes new policies specifically for 2017 and 2018-2020.[154]

THE APPLICATION OF PORTER'S FIVE FORCES TO HOSPITALS AND PHYSICIAN GROUPS

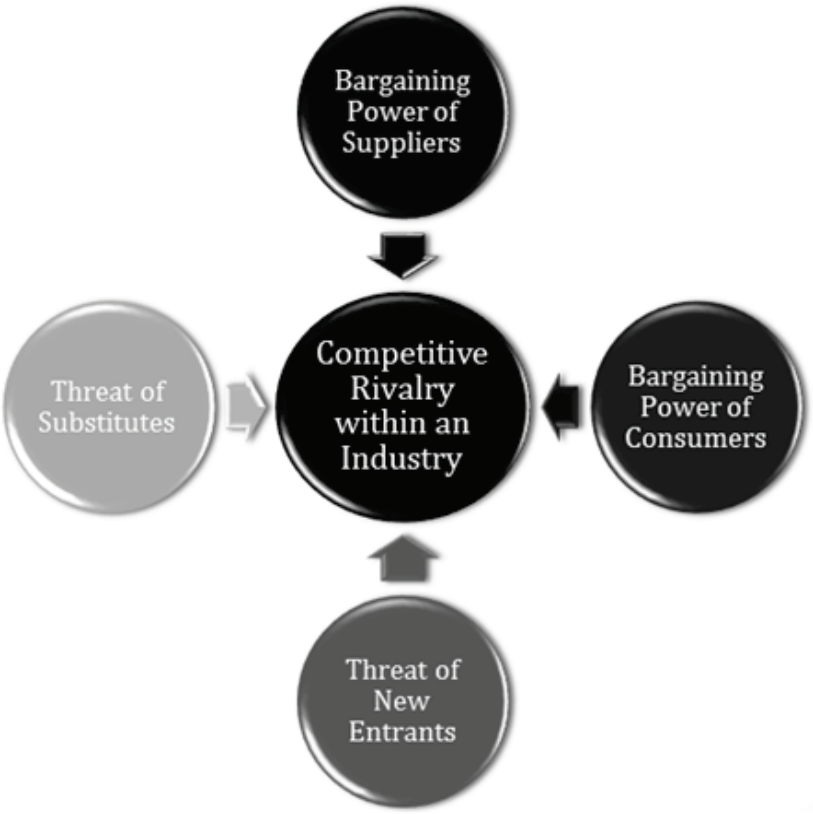
Michael Porter, a Harvard Business School professor, is considered by many to be one of the leading international authorities on competitive strategy and international competitiveness. Porter asserts that all businesses must respond to *five competitive forces*: (1) the threat of new market entrants; (2) the bargaining power of suppliers; (3) threats from substitute products or services;

153 "Hospital Value-Based Purchasing" Centers for Medicare and Medicaid Services, December 18, 2014 https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/hospital-value-based-purchasing/index.html?redirect=/hospital-value-based-purchasing/ (Accessed 3/26/15).

154 "Hospital Value-Based Purchasing" Centers for Medicare and Medicaid Services, December 18, 2014 https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/hospital-value-based-purchasing/index.html?redirect=/hospital-value-based-purchasing/ (Accessed 3/26/15); "Medicare Program; Hospital Inpatient Prospective Payment Systems for Acute Care Hospitals and the Long-Term Care Hospital Prospective Payment System and Fiscal Year 2015 Rates; Quality Reporting Requirements for Specific Providers; Reasonable Compensation Equivalents for Physician Services in Excluded Hospitals and Certain Teaching Hospitals; Provider Administrative Appeals and Judicial Review; Enforcement Provisions for Organ Transplant Centers; and Electronic Health Record (EHR) Incentive Program; Final Rule" Federal Register Vol. 79, No. 163 (August 22, 2014) p. 49864, 50048, 50055-87; A further discussion of value-based reimbursement can be found in Chapter 2: Reimbursement Environment.

(4) the bargaining power of buyers; and (5) rivalry among existing firms.[155] A visual depiction of the five fundamental forces of competition is set forth in Figure 4-3, below. When attempting to understand competitors and select competitive strategies, a review of these five forces may be useful to understand the underlying fundamentals of competition.[156]

Exhibit 4-3: Porter's Five Forces[157]



Healthcare often is described as being different from other industries for a number of reasons including the:

(1) Large role of governmental regulation and reimbursement;
(2) Seemingly limitless demand for healthcare;
(3) Necessity of having local providers;
(4) Absence of *normal* consumer motivation due to the use of *third party payors*; and
(5) Difficulties in quantifying health and the quality and costs of care.

However, these differences may be found individually in other industries and, increasingly, the barriers to competition in healthcare are under pressure to be removed, diminished, or altered

155 "Competitive Strategy: Techniques for Analyzing Industries and Competitors" By Michael E. Porter, New York, New York: The Free Press, 1980, p. 4.
156 "Competitive Strategy: Techniques for Analyzing Industries and Competitors" By Michael E. Porter, New York, New York: The Free Press, 1980, p. 4.
157 Ibid.

because of rising costs. Therefore, Porter's five forces model may well be applicable to healthcare just like any other industry.[158] Porter has further explored the value of his model as a process or framework for use when examining competition in healthcare.[159]

Because Porter's model applies to a company operating within a given industry, it is necessary to define "*healthcare industry*," which contains numerous subsets interacting with each other including, among others, hospitals, nursing homes, medical practices, home health agencies, sub-acute providers, ASCs, and urgent care centers. The totality of these facilities and providers, along with the administrators, equipment suppliers, pharmaceutical companies, and other support and managerial providers may be considered for this exercise in definition, because they share the common goal of maximizing human health. While this is not an easily quantifiable outcome, it can be viewed as the common denominator among all the factions in the healthcare industry, and advances are being made in the sciences of quality and outcomes research.

A hospital that does not acknowledge the local independent family medical practice or cardiology group as working in the same industry as a competitor (as well as a customer) may have missed the point. There is a complex relationship between the various subsets of the healthcare industry and any competitive evaluation should assess this relationship from several different perspectives.

Porter recommends three generic strategies to out-perform competitors or maintain a market position against competition: (1) overall cost leadership; (2) differentiation; and (3) market niche or segmentation.[160] Each of these is a strategy that has a different set of ethical considerations related to its application by healthcare providers in a care and treatment environment.

Threat of New Market Entrants

Historically, many hospitals and physicians believed that there was a low risk (or even no risk) of new market competitors due to the entry barriers in their segments of the industry. Healthcare has been viewed as a localized industry because providers must personally administer services to their patients. In the current healthcare environment, however, new entrants do not necessarily compete within their local market. Advances in technology and communication, as well as the ability to recruit providers nationally, are changing some aspects of the direct physician–patient relationship, such that this emphasis on localized competitive markets is no longer universal or absolute.[161]

Overall, the threat from new market entrants may be related to the size of the financial return in that particular segment of the industry. Traditionally, healthcare has differed from many industries because financial return does not always drive the decision process. The goals of *education*, *charity*, and *community service* make some healthcare business decisions appear economically or financially irrational. The interest(s) held by society in the consolidation and

158 "Making Competition in Health Care Work" By Elizabeth Olmsted Teisberg et al., Harvard Business Review, July/August, 1994, http://hardvardbusinessonline.hbsp.harvard.edu/hbsp/hbr/articles/article.jsp?artilcleID=9440, (Accessed 09/11/08), p. 140.

159 Ibid.

160 "On Competition" By Michael E. Porter, Boston, MA: Harvard Business School Publishing, 2008, p. 53; See generally "Making Competition in Health Care Work" By Elizabeth Olmsted Teisberg et al., Harvard Business Review, July/August, 1994, http://hardvardbusinessonline.hbsp.harvard.edu/hbsp/hbr/articles/article.jsp?artilcleID=9440 (Accessed 09/11/08).

161 See Chapter 5: Technological Development.

creation of new market entrants is a *positive social externality*. The value a new entrant conveys to society can be defined as the perceived future benefits that the entrant will contribute to the U.S. population, or a sub-population. When identifying and establishing the scope of a *positive social externality* within a large external group, the appropriate selection of defined measures of comparison (e.g., benchmarking health outcomes against industry norms and historical trends) that must be in place to quantify the value added by such entrants is especially important. Benchmarks for patient populations before and after its creation on a national and/or regional level are useful in determining the existence of statistically significant evidence of improved population health outcomes, which can be utilized as an indication of a new market entrant's *societal value*.

Boutique and Concierge Medicine

Concierge, or *boutique*, medical practices began in 1996 in Seattle and are now in several major metropolitan areas. Concierge medical practices are concentrated principally on the East and West coasts, with most practices focused on providing primary care services.[162] Concierge medicine is basically a return to old fashioned medicine, in which physicians limit their client base and devote more time to each patient.[163] Patients usually can see their physician within a day of requesting an appointment, and most have twenty-four-hour access to their physician by cell phone. Concierge medical practices typically charge patients an annual retainer fee, which provides for guaranteed, around-the-clock access to standard healthcare services, as well as an increased access to personalized physician care.[164] Physicians, tired of working long hours, not having enough time with their patients, and dealing with overbooked caseloads, are turning to concierge medicine as a way of balancing their work and their life and providing quality care for their patients.[165] Patients who have physicians in this type of practice appreciate the perks received in exchange for a yearly fee—similar to annual membership dues. These fees can range anywhere from $60 to $15,000 per year depending on a variety of factors such as patient age, benefits received, residence location, and type of practice.[166] Amenities vary by practice, but some include more time with the physician (e.g., a thirty-minute office visit), increased access to physicians, newsletters or condition-specific information sent by e-mail, wellness planning, and house calls.[167]

Although concierge medicine may provide many benefits for patients, including more, and in some cases nearly unlimited, access to their physicians, it has been met with some scrutiny. Some say that this type of medicine is elitist—that it is available only to wealthy patients who can pay the annual fees.[168] However, many concierge clinics appeal to middle-income people who are willing to pay for the immediacy of physician services, and many charge low rates in

162 "Physician Services: Concierge Care Characteristics and Considerations for Medicare (GAO-05-929)" By the U.S. Government Accountability Office, For Congressional Committees, August 2005, p. 3.
163 For more information, see Chapter 2: Reimbursement Environment and Chapters 7 and 8 of Consulting with Professional Practices.
164 "Impact of Concierge Care on Healthcare and Clinical Practice" By Anthony J. Linz, DO et al., Journal of the American Osteopathic Association, Vol. 105, No. 11 (November 2005), p. 515.
165 Ibid.
166 "Physician Services: Concierge Care Characteristics and Considerations for Medicare (GAO-05-929)" By the U.S. Government Accountability Office, For Congressional Committees, August 2005, p. 4.
167 "The Three Faces of Retainer Care" By Frank Pasquale, Yale Journal of Health Policy, Law, and Ethics , Vol. 7, No. 1 (March 3, 2013) http://digitalcommons.law.yale.edu/cgi/viewcontent.cgi?article=1142&context=yjhple (Accessed 3/26/15), p. 60-61.
168 Ibid, p. 40.

exchange for cash.[169] Concierge medicine can be a substitute for traditional insurance, but patients typically keep their traditional health insurance to pay for any tests or scans ordered by the concierge physician.[170] Medicare beneficiaries cannot be charged more than 115% of the rate for services,[171] and many politicians have said that the annual fee requirement is significantly greater than the Medicare rate and, consequently, is illegal billing.

Certificate of Need

A *Certificate of Need* (CON) program is one in which government determines where, when, and how capital expenditures will be made for public healthcare facilities and major equipment.[172] By their very nature, CON programs are anticompetitive, a principle that serves as, *de minimis*, part of the rationale for the inception of state CON programs, in response to concern that market forces were not adequate to prevent providers from overinvesting in equipment and facilities and, as a result, driving up the cost of healthcare.[173] Various shifts in the healthcare industry in the years since CON legislation was introduced have fueled disputes against the implementation of CON programs in order to avoid excess capacity.[174]

A central argument against CON regulatory policy is that intervention disrupts the natural market forces and is significantly anticompetitive. As a result, CON often serves as a barrier to new market entrants and has been viewed by many healthcare economists as a strong disincentive to the introduction of potentially advantageous innovations and technologies. As stated by Elizabeth Teisberg and Michael Porter, in any industry:

> "…the underlying dynamic is the same: competition compels companies to deliver increasing value to customers. The fundamental driver of this continuous quality improvement and cost reduction is innovation. Without incentives to sustain innovation in [healthcare], short-term cost savings will soon be overwhelmed by the desire to widen access to care, the growing health needs of an aging population, and the unwillingness of Americans to settle for anything less than the best treatments available. Inevitably, the failure to promote innovation will lead to lower quality or more rationing of care—two results viewed as equally undesirable results."[175]

This assertion resembles the continuing consensus among health economic analysts that competition between providers drives patient quality of care and beneficial outcomes and acts as

169 "Pros and Cons of Concierge Medicine" By Jen Wieczner, The Wall Street Journal, November 10, 2013, http://www.wsj.com/articles/SB10001424052702303471004579165470633112630 (Accessed 3/26/15).

170 "Physician Services: Concierge Care Characteristics and Considerations for Medicare" By the United States Government Accountability Office, August 2005, p. 3; "Pros and Cons of Concierge Medicine" By Jen Wieczner, The Wall Street Journal, November 10, 2013, http://www.wsj.com/articles/SB10001424052702303471004579165470633112630 (Accessed 3/26/15).

171 "Physician Services: Concierge Care Characteristics and Considerations for Medicare (GAO-05-929)" By the U.S. Government Accountability Office, For Congressional Committees, August 2005, p. 6; "The Public Health and Welfare" 42 U.S.C. § 1395w-4(g)(2)(c) (2006).

172 "Certificate of Need: State Health Laws and Programs" National Conference of State Legislature, April 30, 2009, http://www.ncsl.org/IssuesResearch/Health/CONCertificateofNeedStateLaws/tabid/14373/Default.aspx (Accessed 01/13/10).

173 "Monopoly is Not the Answer" By Clark C. Havighurst, Health Affairs, Web Exclusive (August 9, 2005), http://content.healthaffairs.org/cgi/content/full/hlthaff.w5.373/DC1 (Accessed 05/21/10), p. W5-373-374

174 "Improving Health Care: A Dose of Competition" Federal Trade Commission and the Department of Justice, July 2004, Chapter 8, p. 2,5, 6; See Chapter 3: Regulatory Environment.

175 "Making Competition in Health Care Work" By Elizabeth Olmsted Teisberg et al., Harvard Business Review, July/August, 1994, http://hardvardbusinessonline.hbsp.harvard.edu/hbsp/hbr/articles/article.jsp?artilcleID=9440..., (Accessed 09/11/08) (emphasis added).

a force for cost efficiency. Hospitals in more competitive markets have exhibited lower levels of spending on average than hospitals found in less competitive markets.[176] Healthy competition appears to offer both patients and payors a means of economic leverage by creating choices for consumers and raising quality standards as providers compete for patient loyalty. When patient choice is diminished, decisions about access, quality, and beneficial outcomes become the sole purview of oligopoly market players that, as decision makers acting in the absence of healthy competition, are free to ignore patient demands and needs.[177]

The implementations of CON legislation in competitive markets have been perceived as a notable shift from CON's original purpose of supporting competition by preventing overinvestment in healthcare facilities.[178] Most notably, proponents of CON programs argue that CON legislation may prevent healthcare markets from becoming oversaturated with ASCs and other specialty hospitals; this is a position that has helped community hospitals use the regulatory environment in their campaign against physician-owned healthcare facilities.[179]

Rise of Urgent Care Walk-In Clinics

Urgent care centers have become increasingly more popular in the U.S. with up to 9,000 facilities already in existence that serve between 71 and 160 million people each year.[180] Acute care patients, tired of the progressively longer waits for appointments with primary care physicians or for emergency room services, are attracted to the convenience of urgent care centers (e.g., the extended hours and the availability of walk-in appointments).[181] With the supply of primary care physicians dwindling combined with many family physicians declining to accept new Medicare FFS patients and fewer emergency departments nationally, urgent care utilization will likely continue to rise.[182] In fact, a survey of 326 urgent care centers in 2013 found that 88% of centers expected to see an increase in patients and/or expansion of the location.[183]

Medical Tourism

Another competitive force in the healthcare industry is the growing incidence of *medical tourism*, which is the practice of patients traveling to countries, such as India, Thailand, or any number of other countries, to receive medical procedures at a fraction of what they may cost in

176 "Health Policy Reform: Competition and Controls" By J. Zwanziger, G. Melnick G, A. Bamezai, & R. Helms, ed., Washington, DC: American Enterprise Institute Press, 1993, p. 241-58.
177 See the Supply and Demand in Healthcare section and the Consumer Driven Healthcare section earlier in this chapter.
178 "Monopoly is Not the Answer" By Clark C. Havighurst, Health Affairs, Web Exclusive (August 9, 2005), http://content.healthaffairs.org/cgi/content/full/hlthaff.w5.373/DC1 (Accessed 05/21/10), p. W5-373.
179 "Specialty Versus Community Hospitals: What Role for the Law?" By Sujit Choudhry, et al., Health Affairs, Web Exclusive (August 9, 2005), http://content.healthaffairs.org/cgi/content/full/hlthaff.w5.361/DC1 (Accessed 5/21/10), p. w5-367.
180 "The Case for Urgent Care" Urgent Care Association of America, September 1, 2011, http://c.ymcdn.com/sites/www.ucaoa.org/resource/resmgr/Files/WhitePaperTheCaseforUrgentCa.pdf (Accessed 3/26/15) p. 1, 2.
181 Ibid, p. 1.
182 "Urgent Care Centers in the U.S.: Findings from a National Survey" By Robin M. Weinick, et. al., BMC Health Services Research, Vol. 79 (2009), p. 6.
183 "Benchmarking Survey Headlines Summary" Urgent Care Association of America, http://c.ymcdn.com/sites/www.ucaoa.org/resource/resmgr/Benchmarking/UCAOA-BenchmarkSurvey_Infogr.pdf (Accessed 3/26/15).

the U.S.[184] By avoiding the structural, regulatory, and legal barriers that are present in the U.S., foreign hospitals may be more free to innovate in ways that potentially can decrease the cost of many procedures.[185] Generally, these procedures are performed by skilled physicians who may have been trained in the U.S. and who may employ the latest technology with a risk of infection and mortality no higher than in the U.S.[186] According to the CDC, 750,000 U.S. residents utilize foreign medical tourism each year, often because of the lower costs associated with treatment.[187] This trend demonstrates the reach of globalization on the healthcare industry and, as with globalization in other sectors, it could mean that new competition for domestic suppliers is worldwide.

The Bargaining Power of Buyers

Most healthcare services are paid for by insurance, whether private or governmental. Most private health insurance is purchased through employers that, to a great degree, make most of the buying decisions. Employer coalitions have emerged, but most command leverage on price rather than quality or value. This often leaves healthcare providers as the only advocates for consumers (i.e., patients). Corporate buyers have asserted substantial, if disproportionate, influence over healthcare companies, but not always in the best interests of the consumers or the community at large.

Recently, payors have begun to shift toward P4P plans that assess certain performance outcomes and offer financial incentives to providers that attain them.[188] P4P programs have been shown to improve quality of care[189] and, by offering financial incentives to providers, P4P also will allow consumers to recognize the quality of care when making choices for provision of services.[190]

These traditional means of procuring insurance changed dramatically in 2014 with the advent of state health insurance exchanges and the small business health options program (SHOP) exchanges, both of which are mandated under the ACA.[191] The ACA provision requiring the provision of *minimal essential health benefits* and restricting the payor's ability to reject coverage based on *preexisting conditions* has further decreased the bargaining power of buyers and has placed more decision power with patients. To ease the burden on small businesses with 25 or fewer full time employees, the ACA implemented a federal tax credit, which, depending on need, will offset up to half of insurance premiums.[192] To qualify for the credits, a small employer

184 "Could U.S. Hospitals Go The Way Of U.S. Airlines?" By Stuart H. Altman, David Shactman, and Efrat Eilat, Health Affairs, Vol. 25, No. 1 (January/February 2006), p. 18; "2014 Yellow Book: Chapter 2 The Pre-Travel Consultation: Medical Tourism" By C. Virginia Lee and Victor Balaban, Centers for Disease Control and Prevention,August 1, 2013, http://wwwnc.cdc.gov/travel/yellowbook/2014/chapter-2-the-pre-travel-consultation/medical-tourism (Accessed 3/26/15).

185 "Innovation Abroad" Health Affairs, Vol. 27, No. 5, (September/October 2008), p. 1259.

186 "Lessons From India In Organizational Innovation: A Tale of Two Heart Hospitals" By Barak D. Richman et al., Health Affairs, Vol. 27, No. 5 (September/October 2008), p. 1261.

187 "Medical Tourism" Centers for Disease Control and Prevention, February 23, 2015, http://www.cdc.gov/features/medicaltourism/ (Accessed 3/26/15).

188 See Chapter 2: Reimbursement Environment.

189 "Hospital Quality Improving, Cost, Mortality Rate Trends Declining for Participants in Medicare Pay-For-Performance Project" Premier Inc., Press Release (January 31, 2008), http://premierinc.com/about/news/08-jan/performance-pays-2.jsp (Accessed 04/25/08).; "Patient outcomes and evidence-based medicine in a preferred provider organization setting: a six-year evaluation of a physician pay-for-performance program" By Amanda S. Gilmore, et al., Health Services Research, (December 2007), http://findarticles.com/p/articles/mi_m4149/is_6_42/ai_n21157693/print (Accessed 4/21/08).

190 "Improving Health Care: A Dose of Competition" Federal Trade Commission and The Department of Justice, July 2004, Chapter 1, p. 8.

191 "Patient Protection and Affordable Care Act" Pub. L. 111-148, § 1311(b), 124 Stat. 119, 173 (March 23, 2010).

192 "Patient Protection and Affordable Care Act" Pub. L. 111-148 (March 23, 2010), p. 102.

must pay at least half of each employee's premium.[193] As of 2012, up to four million companies were deemed eligible for this tax credit.[194]

The bargaining power of buyers, particularly insurance companies, is also subject to increasing scrutiny under the ACA, specifically regarding new limitations on the medical loss ratio (MLR). On December 2, 2011, HHS issued a final rule regarding the MLR, creating a significant change in industry oversight by considering insurance broker and agent fees as *administrative costs* for purposes of a MLR calculation[195] (i.e., that portion of insurance premium revenues spent on items other than clinical services, quality improvement, and other non-administrative activities[196]). The MLR final rule requires insurance companies to spend 80% of insurance premiums on medical care and healthcare quality improvement in the *individual* and *small group markets* and 85% of premiums on these components in the *large group markets*, *exclusive of* administrative costs.[197] Beginning in 2011, insurance companies were required to annually report their MLR data to HHS in an effort to allow consumers to evaluate available health plans based on the value they provide. Beginning in 2012, private payors who failed to meet MLR requirements are required to provide their customers with rebates.[198] The final rule allows the Secretary of HHS, through *The Center for Consumer Information and Insurance Oversight* (CCIIO), to adjust the MLR standard in states where it is determined that meeting the 80% MLR standard might destabilize the individual market.[199] To date, 17 states have applied for an adjustment to the MLR standard, but only Maine has received a constant adjustment (maintained at 65%).[200] However, CCIIMO has allowed various models of leniency regarding the MLR standard for those approved, including gradual adjustments[201] and temporary adjustments.[202]

Insurance companies are the main opponents of the MLR rebate, maybe in part because they were required to issue $332 million in rebates to 6.8 million consumers based on their 2013 performance.[203] Concern specifically surrounds the inclusion of insurance broker and agent fees in administrative costs, with the insurance industry asserting that these activities are necessary services for consumers that will be hindered by the regulations. While the insurance industry claims that the MLR rule will create a "desperate economic situation," consumer groups support

193 "Small Business Health Care Tax Credit for Small Employers" Internal Revenue Service, January, 15, 2015, http://www.irs.gov/uac/Small-Business-Health-Care-Tax-Credit-for-Small-Employers (Accessed 3/27/15).

194 "Why Health Care Tax Credit Eludes Many Small Business" By Robb Mandelbaum, New York Times, Sept. 25, 2012, http://boss.blogs.nytimes.com/2012/09/25/why-the-health-care-tax-credit-eludes-many-small-businesses/?_r=0 (Accessed 3/27/15).

195 "Medical Loss Ratio Requirements under the Patient Protection and Affordable Care Act" Federal Register, Vol. 76 No. 235, (December 2, 2011), p. 76574-76594.

196 "Medical Loss Ratio" Center for Consumer Information and Insurance Oversight, http://cciio.cms.gov/programs/marketreforms/mlr/index.html (Accessed 1/4/2012).

197 "Medical Loss Ratio: Getting Your Money's Worth on Health Insurance" Center for Consumer Information and Insurance Oversight, http://cciio.cms.gov/resources/factsheets/mlrfinalrule.html (Accessed 12/13/2011).

198 Ibid.

199 "Patient Protection and Affordable Care Act" Pub. L. 111-148, § 2718, 124 Stat. 119, 886 (March 23, 2010).

200 "Medical Loss Ratio Requirement Under the Patient Protection and Affordable Care Act (ACA): Issues for Congress" By Suzanne M. Kirchhoff, Congressional Research Service, August 26, 2014, https://fas.o http://www.irs.gov/uac/Small-Business-Health-Care-Tax-Credit-for-Small-Employers rg/sgp/crs/misc/R42735.pdf (Accessed 3/27/15), p. 14.

201 "Re: State of New Hampshire's Request for Adjustment to Medical Loss Ratio Standard" By Steven B. Larsen, Letter to Roger A. Sevigny, State of New Hampshire Insurance Departmetn, May 13, 2011, http://www.cms.gov/CCIIO/Programs-and-Initiatives/Health-Insurance-Market-Reforms/Downloads/nh_mlr_adj_decletter.pdf (Accessed 3/31/15), p. 2; For other examples, see generally "State Requests for MLR Adjustment" Center for Consumer Information & Insurance Oversight, http://www.cms.gov/CCIIO/Programs-and-Initiatives/Health-Insurance-Market-Reforms/state_mlr_adj_requests.html (Accessed 3/31/15).

202 Ibid.

203 "Medical Loss Ratio Requirement Under the Patient Protection and Affordable Care Act (ACA): Issues for Congress" By Suzanne M. Kirchhoff, Congressional Research Service, August 26, 2014, https://fas.org/sgp/crs/misc/R42735.pdf (Accessed 3/27/15) p. 2; "Consumers Benefitted from 80/20 Rule in 2013" Department of Health and Human Services, July 22, 2014, http://www.cms.gov/CCIIO/Resources/Forms-Reports-and-Other-Resources/Downloads/Final-MLR-Report_07-22-2014.pdf (Accessed 3/27/15).

including insurance broker and agent fees in administrative costs, touting the rule as "a great victory for consumers … maintain[ing] the integrity of incredibly important consumer protections that hold the insurance industry accountable."[204]

Power of the Insurance Lobby

The rise of antitrust law in the healthcare marketplace has indirectly led to the courts supporting the preferences of insurance companies. As agents for the consumers protected under the laws (i.e., patients), insurance companies have emerged as the dominant force in articulating competitive preferences for price and quality. Courts have deemed insurance providers to be the best voice for the needs of consumer patients and, therefore, have overlooked the traditional competitive transgressions of insurance companies (i.e., selective contracts with health professionals or onerous contractual requirements on network providers).[205]

Further adding to the power of the industry, insurance companies as an industry sector have enjoyed an exemption from federal antitrust laws since 1945. The *McCarran-Ferguson Act* limits federal scrutiny of insurers and places states in primary control of antitrust enforcement.[206] State legislation is preserved in the bill, but whether states are powerful enough to prevent insurance companies from engaging in price fixing, bid rigging, market allocations, deterring competition, and impairing consumers has been questioned.[207]

Power of Medicare and Other Public Payors

The government is the largest third-party payor in the U.S. Through programs like Medicare, Medicaid, and TRICARE, it exerts one of the most influential competitive forces in the health insurance industry. As the largest national purchaser of health services, the government exerts influence over not only the public delivery of health services, but also over the private sector.[208] Many private insurers negotiate their own arrangements with providers, but some private third-party payors base their arrangements on the Medicare payment systems or use those systems as a starting point for negotiations with providers.[209]

Medicare's influence on competition in certain sectors is limited, however. Under the MMA, the secretary of HHS is prohibited from negotiating drug prices with pharmaceutical manufacturers under Medicare Part D, a prohibition which also inhibits free market competition in healthcare.[210] Instead, negotiations are undertaken by private insurers and *Pharmacy Benefit*

204 "MLR Final Rule Keeps Broker Fees as Administrative Costs" By Margaret Dick Tockness, HealthLeaders Media, December 5, 2011, http://www.healthleadersmedia.com/print/HEP-273901/MLR-Final-Rule-Keeps-Broker-Fees-as-Administrative-Costs (Accessed 1/4/2012).

205 "Why Competition Law Matters to Health Care Quality" By William M. Sage, David A. Hyman, and Warren Greenberg, Health Affairs, Vol. 22, No. 2, (March/April 2003), p. 38.

206 "McCarran-Ferguson Act" 15 U.S.C 1011, March 9, 1945.

207 "House Panel Approves Bill Curbing Insurers' Antitrust Exemption" By David M. Herszenhorn, New York Times, October 21, 2009. *As of March 27, 2015, the MacCarren-Ferguson Act has not been repealed, but attempts have been made. "McCarran-Ferguson Act's Antitrust Exemption Dodges Another Attempt at Repeal" By James Burns and Williams Mullen, TAGLaw, 2015, http://www.taglaw.com/index.php?option=com_content&id=1656:mccarran-ferguson-acts-antitrust-exemption-dodges-another-attempt-at-repeal&Itemid=100074 (Accessed 3/27/15).

208 "The Next Antitrust Agenda: The American Antitrust Institute's Transition Report on Competition Policy to the 44th President of the United States" By Albert A. Foer, Ed., Vandeplas Publishing (2008), p. 344.

209 "How Medicare Shapes the US Health Sector" By Jeffrey Clemens, Economics in Action, Issue 10 (May 14, 2014) http://economics.ucsd.edu/economicsinaction/issue-10/headline.php (Accessed 3/27/15).

210 "The Medicare Prescription Drug Benefit Fact Sheet" The Henry J. Kaiser Family Foundation, September 19, 2014, http://kff.org/medicare/fact-sheet/the-medicare-prescription-drug-benefit-fact-sheet/ (Accessed 3/27/15) p. 9.

Managers (PBMs) that then offer prices they obtain through those negotiations to Medicare beneficiaries.[211] Under this system, the Medicare program is unable to use its power as what would be the largest purchaser of prescription drugs to bring the cost of such drugs down.[212] Proponents of the noninterference provision argue, however, that it prevents the federal government, which is motivated by taxpayers, voters, and Medicare beneficiaries alike, monopsony power to affect the price of prescription drugs, consequently stifling the ability of pharmaceutical companies to earn the profits that allow them to develop new drugs.[213]

Rivalry Among Existing Firms

Integrated physician organizations and other types of *emerging healthcare organizations* (EHOs) may be viewed as new market entrants or simply as a reorganization of existing providers in order to better compete. Provider organization and EHO volumes have grown significantly through integration, consolidation, and mergers, but in many ways their effectiveness as competitors is still uncertain. The collapse of PPMCs, or poor performance of hospital managed physician practices (including *physician-hospital organizations* [PHOs]), the failure of capitated groups and IPAs in California, and the previous trend toward divestiture of acquired practices would seem to indicate that some EHOs may not have been effective competitors. However, as a result of HHS Secretary Sylvia Burwell's January 2015 announcement that by 2016, HHS anticipates transitioning the majority of Medicare reimbursement from *volume-based* to *value-based* payments, EHOs such as ACOs and *clinically integrated networks* (CINs) may change the competitive dynamics in the healthcare industry.[214] Nonetheless, a strong argument could be made that the competitive forces that led to the formation of these integrated organizations still exist and that these initial failures have more to do with mismanagement and poor planning than the concept of physician integration itself.

Integration, affiliation, and collaboration among providers may, in some cases, be viewed as a means of circumventing competition unless the clinical benefits to patients can be demonstrated. Because the overarching mission of the healthcare delivery system is inherently human value-based, it is often deemed to be in conflict with the economic and financial goals of healthcare organizations, especially in the for-profit arena, as well as incompatible with the competitive forces that have been successful in other industries. These differences in basic values and the manifestation of these values between businesses in other industries, as well as the various existing organizations in healthcare, are deeply rooted and important to understand in assessing the impact of rivalry on the potential for competition to succeed in stimulating quality and efficiency.

211 "The Human Cost of Federal Price Negotiations: The Medicare Prescription Drug Benefit and Pharmaceutical Innovation" By Benjamin Zycher, Center for Medical Progress at the Manhattan Institute, November 2006, http://www.heartland.org/custom/semod_policybot/pdf/20365.pdf (Accessed 11/10/09), p. 1.

212 Ibid, p. 2.

213 Ibid, p. 3.

214 "Better, Smarter, Healthier: In historic announcement, HHS sets clear goals and timeline for shifting Medicare reimbursements from volume to value" U.S. Department of Health & Human Services, January 26, 2015, http://www.hhs.gov/news/press/2015pres/01/20150126a.html (Accessed 3/27/15).

ANTITRUST ISSUES

Antitrust law has traditionally been used to combat anticompetitive behavior arising from contractual- and/or payor-imposed barriers to competition (e.g., covenants not to compete, narrow networks), as well as against consolidations (either by collaboration or merger) by provider groups and health systems. However, around 2004 the FTC began paying special attention to antitrust enforcement in the pharmaceutical segment of the healthcare industry.[215] During that timeframe, antitrust jurisprudence began to experience a significantly increased level of judicial deference to professionalism in health market transactions which chilled the ability of federal antitrust authorities to bring effective enforcement actions against violators.[216] Additionally, federal enforcement agencies generally won cases against hospital mergers between the mid-1980s and the mid-1990s; those agencies lost all of the hospital merger cases brought in federal court between 1995 and 2001.[217] During this timeframe, courts tended to examine elements of antitrust decisions (such as a provider's market share and price) from a purely economic perspective and ignored other elements germane to healthcare, such as patients' personal and logistical considerations when choosing a provider.[218]

More recently, the DOJ and FTC have focused their efforts on evaluating the effect of horizontal consolidation of certain healthcare organizations (e.g., pharmaceutical giants, payors, outpatient clinics, and hospitals) to determine whether their respective market sectors experience a decrease in competition as a result.[219] The FTC and DOJ have also begun analyzing antitrust threats in vertical mergers, like the case of St. Luke's Health System and Saltzer Medical Group.[220]

Most research conducted to date suggests a potential correlation between hospital consolidation and higher prices for hospital services; the magnitude of price increase is estimated to range from three percent to nearly 50%.[221] While the impact of consolidation on quality of care is still a controversial topic, studies have shown that hospital consolidation may result in a reduced level of quality.[222] Surmising a sudden surge of hospital consolidation as a result of healthcare reform and continued technological growth, the FTC and DOJ may heighten the stringency of regulations and guidelines in order to ensure competitive veracity within the hospital sector.[223]

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215 "Improving Health Care: A Dose of Competition" Federal Trade Commission and the Department of Justice, White Paper, July 2004, Chapter 1, p. 35.

216 "Whither Antitrust? The Uncertain Future of Competition Law in Health Care" By Thomas L. Greaney, Health Affairs, Vol. 21, No. 2 (March/April 2002), p. 185-186.

217 Ibid, p. 186.

218 Ibid, p. 187.

219 "Commission Order Restores Competition Eliminated by Carilion Clinic's Acquisition of Two Outpatient Clinics" Federal Trade Commission, Press Release (October 7, 2009), http://www.ftc.gov/opa/2009/10/carilion.shtm (Accessed 11/11/09); "FTC Order Prevents Anticompetitive Effects from Pfizer's Acquisition of Wyeth" Federal Trade Commission, Press Release (October 14, 2009), http://www.ftc.gov/opa/2009/10/pfizer.shtm (Accessed 11/11/09); "FTC Order Restores Competition Lost Through Schering-Plough's Acquisition of Merck" Federal Trade Commission, Press Release, (October 29, 2009), http://www.ftc.gov/opa/2009/10/merck.shtm (Accessed 11/11/09).

220 See Chapter 3: Regulatory Environment.

221 "Medical Mergers Are Driving Up Health Costs" By Suzanne Delbanco, The Wall Street Journal, September 30, 2014, p.1 http://www.wsj.com/articles/suzanne-f-delbanco-medical-mergers-are-driving-up-health-costs-1412119178 (Accessed 3/27/15).

222 "Hospital Market Consolidation: Trends and Consequences" By William B. Vogt, PhD, National Institute for Health Care Management, November 2009; "How Has Hospital Consolidation Affected the Price and Quality of Hospital Care?" By Claudia H. Williams, William B. Vogt, Ph.D., and Robert Town, Ph.D., Robert Wood Johnson Foundation, Policy Brief No. 9, February 2006.

223 "Hospital Market Consolidation: Trends and Consequences" By William B. Vogt, PhD, National Institute for Health Care Management, November 2009.

Clinical Integration

One area of antitrust enforcement that did not suffer a significant decline in the beginning of the new millennium was the prosecution of collective actions by healthcare professionals that thwarted competition in violation of Section 1 of the Sherman Antitrust Act (which prohibits agreements between competitors in restraint of trade).[224] Commonly taking the form of IPAs and PHOs that wish to clinically integrate, these groups are generally found to be in violation of antitrust laws. In the wake of several FTC advisory opinions favorable toward clinical integration, it is likely that there may be a resurgence of IPAs and PHOs in the near future.

Clinical integration among provider networks has traditionally been scrutinized by the FTC as generally being anticompetitive and in violation of antitrust laws, in part because provider networks typically involve competing providers that agree to fix prices between them. Such practices are *per se* unlawful under antitrust law.[225] However, since the 2002 FTC Advisory Opinion for MedSouth,[226] the 2007 Advisory Opinion for the *Greater Rochester Independent Practice Association Inc.* (GRIPA),[227] and the 2013 Advisory Opinion for the Norman *Physician-Owned Hospital* (PHO),[228] it has become clear that clinical integration is not necessarily considered to be a *per se* violation of antitrust regulations. If the subject transaction is not deemed to be a *per se* violation, the FTC reviews joint contracting arrangements under a *rule of reason* analysis to determine whether the arrangement may lead to procompetitive outcomes. Clinical integration is beneficial in that it allows a network of competing providers to participate in both joint-pricing and risk sharing, thereby leading to improved efficiency that will benefit consumers.[229]

It is important to note, however, that the MedSouth and GRIPA opinions do not mean that *all* clinical integration programs will be subsequently approved by antitrust enforcement agencies. In fact, a 2005 FTC decision striking down a clinical integration program in Texas was affirmed by the Fifth Circuit Court of Appeals in 2008.[230] When analyzing any clinical integration scheme, the FTC first asks whether the proposed collaboration offers the potential for pro-consumer cost savings or qualitative improvements in the provision of healthcare services and then asks whether any price or other agreements exist among participants, in particular the terms on which they will deal with third-party payors, and if the terms are reasonably necessary to achieve those benefits.[231] If both questions are answered affirmatively, only then will the FTC consider the procompetitive and anticompetitive effects of the collaboration.[232] At that point, "as

224 "The Sherman Antitrust Act" Pub. L. No. 111-25, June 2, 2009.
225 "The Importance of Competition and Antitrust Enforcement to Lower-Cost, Higher-Quality Health Care" Prepared Statement of the Federal Trade Commission, July 16, 2009, p. 6.
226 "Advisory Opinion Related to the Proposal of MedSouth, Inc." By Jeffrey W. Brennan: Federal Trade Commission Bureau of Competition, Letter To John J. Miles: Law firm of Ober, Kaler, Grimes & Shriver (February 19, 2002), Accessed at http://www.ftc.gov/bc/adops/medsouth.shtm (Accessed 4/18/08).
227 "Greater Rochester Independent Practice Association, Inc., Advisory Opinion" By Markus H. Meier, Letter to Christi J. Braun and John J. Miles, Law firm of Ober, Kaler, Grimes & Shriver, September 17, 2007, Accessed at http://www.ftc.gov/bc/adops/gripa.pdf (Accessed 4/18/08).
228 "Letter from Markus H. Meier to Michael Joseph, Concerning Norman PHO's Proposal to Create a 'Clinically Integrate' Network" Prepared Statement of the Federal Trade Commission, February 13, 2013, p. 2.
229 "The Importance of Competition and Antitrust Enforcement to Lower-Cost, Higher-Quality Health Care" Prepared Statement of the Federal Trade Commission, July 16, 2009, p. 7.
230 "North Texas Specialty Physicians v FTC" Dkt. No. 9312, (July 18, 2005).
231 "The Importance of Competition and Antitrust Enforcement to Lower-Cost, Higher-Quality Health Care" Prepared Statement of the Federal Trade Commission, July 16, 2009, p. 8.
232 Ibid.

long as such collaborations cannot exercise market power, they are unlikely to raise significant antitrust concerns, precisely because they have the potential to benefit, not harm, consumers."[233]

It is important to note that the antitrust enforcement agencies support the procompetitive clinical integration of provider networks as a means of increasing efficiency and reducing costs, especially in a healthcare reform environment in which these objectives are two of the overall goals. Collaborations among providers often result in the implementation of efficiency-producing tools, such as *electronic health records*, as well as collaboration among clinicians to create guidelines, measure performance, and develop remedial measures and consequences for failure to meet those guidelines.[234]

Antitrust enforcement agencies will likely continue to carefully scrutinize healthcare mergers to ensure that no single entity gains enough market share such that patients are deprived of choices, and that the entity is able to increase prices to both patients and payors.[235]

HEALTHCARE REFORM AND ITS EFFECT ON COMPETITION

MANAGED COMPETITION

The dominant competition theory of 1990's healthcare reform was managed competition.[236] As proposed by Stanford University's Alain Enthoven, competing healthcare entities (particularly payors) should be monitored by a supervisory body that established equitable rules, created price-elastic demand, and avoided uncompensated risk selection[237]—not a far cry from current EHO structures, e.g. ACO/payor relationships.[238] This model was a combination of competitive and regulatory strategies that Enthoven suggested must strive to co-exist in the healthcare industry in order to achieve maximum value for both consumers and providers.[239] Several healthcare industry commentators viewed this compromise as springing from a "belief that health care is both a right and an obligation"—heralding the ACA's individual mandate, i.e., that people have a right to access, and an obligation to pay for, their share.[240] An illustration of the comparative features of the evolution of models of managed competition, from managed access to managed outcomes (i.e., VBP), is set forth in Figure 4-4, below.

233 The Importance of Competition and Antitrust Enforcement to Lower-Cost, Higher-Quality Health Care" Prepared Statement of the Federal Trade Commission, July 16, 2009, p. 8.
234 Ibid, p. 9.
235 Ibid, p. 12; See Chapter 3: Regulatory Environment for ACO Safety Zones and other agency considerations.
236 "The New American Compromise" By Ian Morrison, Trustee, Vol. 61, No. 8, September 2008, p. 32.
237 "The History and Principles of Managed Competition" By Alain C. Enthoven, Health Affairs, Vol. 12, no. suppl 1, 1993, p. 24, 30-35.
238 "Chasing Unicorns," By Ian Morrison, H&HN Weekly, January 3, 2011, http://www.hhnmag.com/hhnmag_app/jsp/articledisplay.jsp?dcrpath=HHNMAG/Article/data/01JAN2011/010411HHN_Weekly_Morrison&domain=HHNMAG (Accessed 3/29/2012).
239 "The History and Principles of Managed Competition" By Alain C. Enthoven, Health Affairs, Vol. 12, no. suppl 1, 1993, p. 25.
240 "The New American Compromise" By Ian Morrison, Trustee, Vol. 61, No. 8, September 2008, p. 32.

Figure 4-4: The Four Phases of Managed Competition

1st Generation	2nd Generation	3rd Generation	4th Generation
Managed Access	**Managed Benefits**	**Managed Care**	**Managed Outcomes**
• Emphasis on managing/restricting patient access • Administrative burdens (e.g., pre-certification, significant co-pays) • Reliance primarily on non-clinical reviewers • Physician totally outside system	• Emphasis on managing benefits • Pre-certification primary and treatment planning secondary • Cost containment emphasized over clinical management • Traditional treatment models employed • Physicians *"included,"* but their care delivery *"inspected"*	• Greater emphasis on treatment planning and quality management • Focus on most appropriate care in most appropriate setting • Patients managed through continuum of care • Clinical management of network; provider-care manager collegiality • Shift toward improving access and benefits to reduce costs	• Operational, clinical, and financial integration • Locally responsive delivery systems and services based on national standards and capabilities • Mutually beneficial partnerships with physician community • Effective use of technology to measure, report, and enhance quality and outcomes • Proof of value for patients • Full accountability for costs and quality

The regulatory safeguards in the healthcare industry related to competition go beyond specific laws monitoring the market size of various enterprises. As illustrated by the theory of managed competition, regulations monitoring what must be publically reported will also have an impact on the competitive nature of the healthcare industry.

REFORM OF THE INSURANCE AND PHARMACEUTICAL INDUSTRIES

Insurance Industry

Over the past year, transaction volume in the health insurance industry has increased, with this growth in merger and acquisition activity expected to continue into the near future.[241] These increased transaction volumes have resulted in a highly consolidated market and myriad consequences for consumers (e.g., higher costs, but also a potentially higher quality of care due to an increased continuum of care).[242] One reason for this consolidation is that there have only been two cases in the last decade in which the DOJ has required the restructuring of a merger agreement between two insurers.[243] The prevalence of these mergers without a strong enforcement of antitrust law permitted a variety of anticompetitive behavior by major insurers, resulting in higher costs (whether from higher premiums, deductibles, or co-pays) and compromised patient care.[244]

241 "Wall Street Ponders Plan Megamergers as M&A Spreads in Many Forms Across Sector (with Table: Top 10 Provider-Sponsored Health Plans, By Medical Membership)," Steve Davis, AIS Health Plan Week, March 23, 2015, http://aishealth.com/archive/nhpw032315-01 (Accessed 3/27/15).

242 "A Second Opinion: Rescuing America's Health Care: A Plan for Universal Coverage Serving Patients Over Profit" By Arnold S. Relman, New York, NY: PublicAffairs, 2007.

243 "The Next Antitrust Agenda: The American Antitrust Institute's Transition Report on Competition Policy to the 44th President of the United States" By Albert A. Foer, Ed., Vandeplas Publishing (2008), p. 323.

244 Ibid.

To reverse the insurer consolidation trend, healthcare reform proposals are likely to include provisions for identifying exclusionary conduct by insurers. As some critics blame the ability of insurers to consolidate (and the resulting monopoly/monopsony power enjoyed by large firms) on the federal antitrust exemption for insurance companies contained in the *McCarran-Ferguson Act*, industry commentators have suggested a modification or repeal of the exemption.[245] Although the act exempts all types of insurance providers, the application of the act to the healthcare industry has drawn particular criticism from the DOJ and lawmakers, both of which claim that the exemption has led to anticompetitive behavior that has resulted in higher healthcare costs to both providers and patients.[246] On the payor side, proponents of the act argue that states are capable of preventing anticompetitive behavior by private payors, so federal action is unnecessary.[247]

Pharmaceutical Industry

The constantly maturing PBM industry has grown as consumer use of pharmaceutical drugs has increased and insurers have worked pharmacy benefits into their plans.[248] Due to the extremely concentrated state of the PBM industry, careful attention should be paid to ensure fair competition in this industry as more and more healthcare spending is devoted to pharmaceuticals.[249] Specific competition concerns include the impact of factors such as PBM pricing, generic substitution, therapeutic interchange, and repackaging practices, in addition to industry practices such as PBM ownership of mail-order pharmacies.[250]

The PBM industry's expansion has received both positive and negative responses from the healthcare industry, which responses were memorialized in part in the FTC's approval of the April 2012 acquisition of Medco Health Solutions, Inc. by Express Scripts Inc. (which created one of the largest PBM companies in the U.S.).[251] The FTC approved the merger after eight months of investigation, noting that it was not an "easy decision," with one FTC Commissioner dissenting from the others, calling the transaction a "merger-to-duopoly."[252] Despite that Commissioner's dissent, the FTC's opinion notes that the PBM industry is only *moderately concentrated* (with at least ten significant competitors) and will remain competitive after the proposed merger.[253] Chairman Jon Leibowitz and Commissioners J. Thomas Rosch and Edith Ramirez concluded that, although the merger would result in higher market concentration, the market would remain highly competitive due to the presence of nine remaining firms and noted

245 "The McCarran-Ferguson Act" 15 U.S.C. § 1011 et seq. (2006); "Health Insurance Industry Antitrust Enforcement Act of 2012" H.R. 5838, 112th Congress, May 18, 2012; "Repeal McCarran_Ferguson—Before It's Too Late" By David A. Balto, The Hill, April 8, 2013, http://thehill.com/blogs/congress-blog/economy-a-budget/292405-repeal-mccarran-ferguson-before-its-too-late (Accessed 3/31/15).

246 "Health Insurance and Federal Antitrust Law: An Analysis of Recent Congressional Action" By Michael G. Cowie, The Antitrust Source (December 2009), http://www.americanbar.org/content/dam/aba/publishing/antitrust_source/Dec09_Cowie12_17f.authcheckdam.pdf, (Accessed 3/28/15), p. 4-6.

247 Ibid, p. 2, 6.

248 "Improving Health Care: A Dose of Competition" Federal Trade Commission and The Department of Justice, July 2004, Executive Summary, p. 20.

249 "The Importance of Competition and Antitrust Enforcement to Lower-Cost, Higher-Quality Health Care" Prepared Statement of the Federal Trade Commission, White Paper, July 16, 2009, p. 1-2.

250 "Improving Health Care: A Dose of Competition" Federal Trade Commission and The Department of Justice, July 2004, Chapter 7, p. 12; Executive Summary, p. 20.

251 "Statement of the Federal Trade Commission Concerning the Proposed Acquisition of Medco Health Solutions by Express Scripts, Inc.," FTC File No. 111-0210, April 2, 2012, https://www.ftc.gov/sites/default/files/documents/public_statements/statement-commission-concerning-proposed-acquisition-medco-health-solutions-express-scripts-inc./120402expressmedcostatement.pdf (Accessed 2/27/15) p. 1-2.

252 Ibid.

253 Ibid, p. 2.

that the merged company posed little risk of utilizing monopsony power because the PBM market does not incentivize coordinated interaction.[254]

It should be noted that previous reform efforts have addressed the possibility of removing the noninterference provision, which would result in granting the secretary of HHS the ability to negotiate directly with pharmaceutical companies.[255] In such an event, the market power of PBMs may cease to be a threat to healthcare competition.

COMMODITIZATION OF HEALTHCARE

Payment for healthcare services has evolved over the past few decades, starting with the implementation of Medicare in 1965 under an FFS paradigm, followed by the creation of the *prospective payment system* (PPS) for hospital and physician services through the 1980s and 1990s, to the current framework based on bundled payments that combines institutional and professional charges, or inpatient and post-discharge fees, into a single payment.[256] Beginning with the implementation of the PPS, whereby patients are classified into diagnostic related groups (DRGs) based on the average cost of services for a particular diagnosis, healthcare services are now bought and sold based on homogenous units of payment.[257] Even MedPAC's *Payment Basics* publications discuss Medicare reimbursement under the heading of "*the products that Medicare buys*."[258]

With the recent focus on bundling, hospitals are incentivized to provide the appropriate amount of care to make the procedure cost-effective, rather than the appropriate amount of care to treat the patient's condition.[259] Similar to how healthcare evolved under capitation systems, hospitals will receive payments based on a charge per episode of care methodology, which the hospitals will then distribute to physicians and other providers within the hospital who provided care for that patient.[260] The charge-per system focuses on the amount of money a hospital will receive for a given diagnosis and will incentivize providers to reduce services to save money as well as hospitals to hire physicians who are not as expensive (i.e., not as well qualified) so that the healthcare enterprise may retain as much of the payment as possible.[261]

Further evidence of the commoditization of the American healthcare system is reflected in the presence of a marketplace for *durable medical equipment* (DME), whereby DME manufacturers submit competing bids to Medicare based on the charge per unit, the lowest of which is then

254 Ibid, p. 6.
255 "Affordable Health Care for America Act" H.R. 3962, 111th Cong., § 1186 (October 29, 2009).
256 "Medicare Hospital Prospective Payment System: How DRG Rates Are Calculated and Updated" Office of Inspector General, Office of Evaluation and Inspections, Region IX, August 2001, p. 1, 5.
257 Ibid.
258 "Ambulatory Surgical Centers Payment System" MedPAC Payment Basics, October 2008, http://www.medpac.gov/documents/MedPAC_Payment_Basics_08_ASC.pdf (Accessed 09/24/09), p. 1.
259 "Payment Reform Options: Episode Payment is a Good Place to Start" By Robert E. Mechanic and Stuard H. Altman, Health Affairs, Web Exclusive (January 27, 2009), p. w262, w264, w265, w269.
260 "Are Bundled Payments the Answer?" By Elyas Bakhtiari, HealthLeaders Media, February 5, 2009, http://www.healthleadersmedia.com/content/227798/topic/WS_HLM2_PHY/Are-Bundled-Payments-the-Answer.html (Accessed 11/12/09).
261 "Payment Reform Options: Episode Payment is a Good Place to Start" By Robert E. Mechanic and Stuard H. Altman, Health Affairs, Vol. 228, No. 2 (January 27, 2009), Web Exclusive, http://content.healthaffairs.org/cgi/content/abstract/hlthaff.28.2.w262?ijkey=D/mPrZnyJkrDA&keytype=ref&siteid=healthaff (Accessed 5/21/10), p. w262, w264, w265, w269.

chosen to be the only Medicare provider of DME in ten different metropolitan areas.[262] The competitive bidding program was implemented in 2008, but an 18 month moratorium was enacted under MIPPA in response to pressure from DME suppliers that claimed that the program would lower quality of care and reduce access.[263] Re-launched on January 1, 2011,[264] the DME competitive bidding program demonstrates how competition has influenced the healthcare industry by turning healthcare into a commodity that can be freely bought and sold.

Although commoditization is an often criticized aspect of the healthcare industry, its development may be essential to the continued evolution of the healthcare industry. Mass retailers have been providing access to in-store health clinics and low-cost generic drugs to simplify the supply chain and increase volume in an attempt to save consumers money and improve patient care. The retail industry has become involved with the healthcare delivery system for a number of reasons, including: (1) customers' increased access to health information; (2) rising healthcare costs; (3) evidence-based medicine approaches; and (4) increased scope of practice considerations for midlevel providers (e.g., physician assistants and NPs).

Timothy P. Doty wrote about the commoditization of healthcare, to wit:

> "…[I]f health care is 'fungible,' then by implication the parts of health care are also interchangeable. Practically speaking, this also includes providers and patients as they are simply reduced to their identity and purpose within the confines of a business relationship. Just as the seller is interested only in providing that which the buyer needs (or desires) in so far as there is sufficient financial reward, the buyer is only concerned with obtaining the desired object (or service). Who they are makes no real difference. Commodification dictates that a physician is like any other, as long as they are matched with respect to specialty. He or she ceases to be the indispensable community caregiver, and instead becomes the link between company and profit, or shareholder and dividend. Patients, by the same token, are no longer seen as individuals with unique personalities and health care needs but as a source of revenue; they become 'covered lives' and a 'business asset whose value is inversely proportional to the cost of health care resources their care is predicted (statistically or otherwise) to consume.'"[265]

Provider Consolidation

In recent years there has also been a noticeable shift in competition among physicians. Historically, most physicians operated as independent competitors, allied only with the hospital(s) to which they referred patients.[266] The mid-1990s experienced a flurry of physician

262 "Durable Medical Equipment Competitive Bidding Program" Medicare.gov, http://www.medicare.gov/what-medicare-covers/part-b/durable-medical-equipment-bidding.html (Accessed 3/27/15).

263 "Medicare DME Bidding Program Set to Relaunch in 2010" By Chris Silva, American Medical News, May 4, 2009, http://www.amednews.com/article/20090504/government/305049980/7/ (Accessed 11/10/09); "Medicare Improvements for Patients and Providers Act of 2008" Public Law No. 110-275, § 122 STAT. 2547, Sec. 145 (July 15, 2008).

264 "Bidding Results from CMS's Durable Medical Equipment Competitive Bidding Program" US Government Accountability Office, November 2014, http://www.gao.gov/assets/670/666806.pdf (Accessed 3/27/15) p. 2.

265 "Health Care as a Commodity: The Consequences of Letting Business Run Healthcare," By Timothy P. Doty, March 2008 p.2.

266 "Unhealthy Trends: The Future of Physician Services," by Hoangmai H. Pham and Paul B. Ginsburg, Health Affairs, Volume 26, Number 6, (November/December 2007), p. 1587.

practice acquisitions by hospitals, health systems, and large integrated groups as MCOs (and HMOs) boomed. With the collapse of those managed care driven integration efforts, buyers of those acquisitions experienced significant financial losses, and many integrated systems divested physician practices;[267] several physicians even bought back elements of their previous practices.[268]

Although the managed care boom of the 1990s was short-lived, consolidation efforts have revitalized in recent years due to various legislative initiatives (e.g., ACOs, PCMHs); reimbursement cuts; increases in the cost to maintain independent practices; growing technological demands for reporting (i.e., ICD-10 conversion); restrictions on physician ownership; increased regulatory scrutiny; and shifting physician demographics and demands (e.g., a greater number of older physicians and an increased importance of physician work/life balance).

Provider consolidation (either through physician employment or mergers and joint ventures between healthcare organizations) has already impacted the competitive nature of the healthcare industry. Regulations designed to limit and monitor competition have been modified to facilitate ACA initiatives, i.e., Stark Law, anti-kickback statute, and antitrust law waivers for ACOs.[269] Hospital leverage has increased, especially in urban areas, as more physicians become hospital employees. Coordination of care efforts will force cooperation between primary care providers and specialists, which will likely require a new alignment of objectives between hospitals, physicians, and outpatient facilities. With the rapid sea change resulting from environmental and reform drivers, the once stable business landscape of U.S. healthcare delivery now presents an unpredictable environment of new provider configurations, strategies, and tactics to which the healthcare industry and the competitive forces that govern it must adapt.

Co-Management Arrangements

Physicians and hospitals are increasingly attempting to integrate in order to effectively respond to healthcare reforms (e.g., ACOs and PCMHs) and provide more coordinated care. One method of achieving this common goal is through *co-management arrangements*, which have re-emerged in recent years as an alternative care model.[270]

Under these new co-management models, a hospital may enter into a management agreement with an organization that is either jointly or completely owned by a physician to provide daily management services for the inpatient and/or outpatient components of a particular medical

267 "Back to the Future for Many Hospital-Physician Relationships: Where Do We Go From Here?" By Ronald L. Vance and Ronald B. Goodspeed, Journal of Ambulatory Care Management, Vol. 25, No. 4, 2002, p. 59; "Hospitals That Gobbled Up Physician Practices Feel Ill—High Costs and a Decline in Productivity Among Doctors Bring Losses" By George Anders, Wall Street Journal, June 17, 1997, p. B4."

268 "Physicians Buying Back Their Practices from PPMs, Hospitals" By Julie A. Jacob, American Medical Association, August 1, 2000, http://www.ama-assn.org/amednews/2000/08/21/bil20821.htm (Accessed 5/4/2012); "Disintegration: How Employed Doctors are Landing on Their Feet" By Martha C. Collins, Family Practice Management, Vol. 6, No. 10, November-December, 1999, p. 38; "Regrouping After Disintegration" By Rod Aymond and Theodore Hariton, Family Practice Management, Vol. 7, No. 3, March 2000, http://www.aafp.org/fpm/2000/0300/p37.html?printable=fpm (Accessed 8/27/2012).

269 "Medicare Program; Final Waivers in Connection With the Shared Savings Program; Continuation of Effectiveness and Extension of Timeline for Publication of Final Rule" Federal Register, Vol. 79, No. 201, (October 17, 2014) p. 62357; "ACOs: Fraud & Abuse Waivers and Analysis" By Robert G. Homchick and Sarah Fellows, Davis Wright Tremaine, LLP, https://www.healthlawyers.org/Events/Programs/Materials/Documents/HCT13/h_homchick.pdf (Accessed 3/27/15) p. 1.

270 "Co-management emerges as alternative to joint ventures, employment by hospitals" By Melanie Evans, Modern Physician, May 10, 2010, http://www.modernphysician.com/apps/pbcs.dll/article?AID=/20100510/MODERNPHYSI# (Accessed 0718/2012).

specialty service line.[271] A *co-management arrangement* incentivizes physicians to develop, manage, and improve quality and efficiency, as well as makes the service line more competitive in the target market.[272]

Accountable Care Organizations (ACOs)

ACOs are the latest iteration in an evolving dialogue as to how to manage rising healthcare costs in a manner that addresses both *cost* and *quality*. The concept of *accountable care* has existed in the American healthcare industry for decades, long before the emergence of ACOs. Most notably, the 1990s managed care boom promised some of the same fundamental objectives of *accountable care*, i.e., lower costs and higher quality outcomes for patients. Managed care took off in response to the emergence of HMOs, pre-paid health plan models that utilized provider networks with a system of *primary care gatekeepers* and capitated payments to providers, which incentivized decreases in utilization and increases in the efficiency of care for HMO members.

ACOs hold the promise of being more successful than their managed care predecessors. Current trends in hospital-physician alignment have led to physician consolidation and have made incentives for physician compensation more agreeable to realignment with healthcare reform goals and reimbursement models. Integrated health systems, particularly those with an internal payor, have already recognized physician employment as beneficial to their quality and cost efficiencies. The clinical and management collaborations between healthcare providers within ACOs will likely result in the desired synchronization of patient care and reduction in the duplication of patient care, both of which are necessary to lower healthcare costs for both providers and payors.

Ultimately, the success or failure of ACOs will be in their ability to achieve the required cost reductions and quality metrics. The success of ACOs may not be contingent on addressing other healthcare reform issues, such as the referral of patients by primary care physicians to specialists, healthcare access, and the increasing health disparities across socioeconomic classes. Their potential success, continued evolution, and positive public perception within the healthcare industry may be the definitive distinction between the ACOs to today and the managed care of the 1990s and is likely to be the primary measure of their value.[273]

CONCLUSION

The healthcare professional practice, while still a business, has been buffered from the full onslaught of commercialism, including the ever-present attraction of competition. Whether to control quality or cost, outside forces have regulated competitive forces within the healthcare industry. Supported by the provider shortage and increased population demands (i.e., the *baby boomer* generation), regulations regarding the scope of midlevel providers have been lessening and physicians have begun expanding the services they offer. This is creating an overlap of

271 "Clinical Co-Management: Hospitals and Oncologists Working Together" By Paul F. Danello, Journal of Oncology Practice, Vol. 2 No. 1, 2006.

272 "Clinical Co-Management: Hospitals and Oncologists Working Together" By Paul F. Danello, Journal of Oncology Practice, Vol. 2 No. 1, 2006.

273 For a more complete discussion of ACOs, see Volume 2, Chapter 6 Emerging Models of this Guide.

services, which will likely continue to fuel the emergence of new competitors in the healthcare market. Additionally, the rise in CDHC will continue to change the way in which the healthcare professional practice, as a business, is run, further removing the buffer between healthcare and pure commercialism. As the impact of competitive forces grows in response to a changing system, government regulations will also need to adapt to the new healthcare environment.

Key Sources

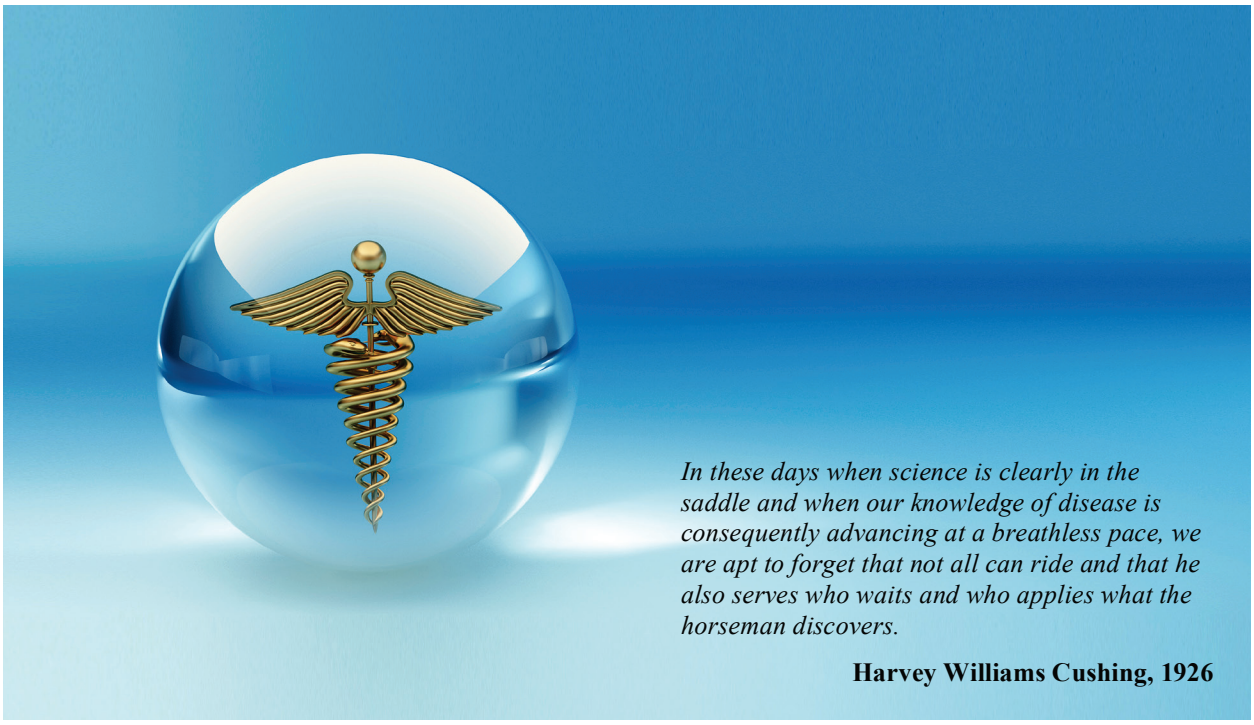
Key Source	Description	Citation	Website
Medicare Physician Fee Schedule (PFS)	The Medicare PFS is how reimbursement is determined for physicians and nonphysicians by CMS for their services.	"Physician Fee Schedule" Centers for Medicare & Medicaid Services, https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/PhysicianFeeSched/index.html?redirect=/PhysicianFeeSched/ (Accessed 4/1/15).	https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/PhysicianFeeSched/index.html?redirect=/PhysicianFeeSched/
Physician Hospitals of America (PHA)	"Offers support, advocacy and educational services to the physician owned hospital industry, reflecting at all times the best interests of the patients, physicians, and other providers who play an inextricable and essential role in the provision of healthcare services."	"About PHA" Physician Hospitals of America, http://www.physicianhospitals.org/?page=About (Accessed 4/1/15).	http://www.physicianhospitals.org/
Government Accountability Office (GAO)	Referred to as the congressional watchdog, the GAO is an "independent, nonpartisan agency that works for Congress" to "investigate how the federal government spends taxpayer dollars."	"About GAO" U.S. Government Accountability Office, http://www.gao.gov/about/ (Accessed 4/1/15).	www.gao.gov
American Academy of Family Physicians (AAFP)	The AAFP attempts to "influence and shape health care policy through interactions with government, the public, business, and the health care industry."	"Vision and Strategic Plan" American Academy of Family Physicians, 2015, http://www.aafp.org/about/the-aafp/vision.html (Accessed 4/1/15).	www.aafp.org
Centers for Medicare and Medicaid Services (CMS)	CMS, a portion of the U.S. Department of Health and Human Services, controls "Medicare health plans, Medicare financial management, Medicare fee for service operations, Medicaid and children's health, survey & certification and quality improvement."	"CMS Consortia" Centers for Medicare & Medicaid Services, http://www.cms.gov/About-CMS/Agency-Information/Consortia/index.html (Accessed 4/1/15).	www.cms.gov
Medicare Payment Advisory Commission (MedPAC)	"An independent Congressional agency established by the Balanced Budget Act of 1997 (P.L. 105-33) to advise the U.S. Congress on issues affecting the Medicare program."	"About MedPAC" Medicare Payment Advisory Commission, http://www.medpac.gov/-about-medpac- (Accessed 4/1/15).	www.medpac.gov
Federal Trade Commission (FTC)	The FTS, "is the only federal agency with both consumer protection and competition jurisdiction in broad sectors of the economy."	"About the FTC" Federal Trade Commission, https://www.ftc.gov/about-ftc (Accessed 4/1/15).	www.ftc.gov

Associations

Type of Association	Professional Association	Description	Citation	Contact Information
National	American Hospital Association	"The national organization that represents and serves all types of hospitals, health care networks, and their patients and communities."	"About the AHA" American Hospital Association, 2015, http://www.aha.org/about/index.shtml (Accessed 4/1/15).	American Hospital Association 155 N. Wacker Dr. Chicago, IL 60606 Phone: 312-422-3000 www.aha.org
National	American Medical Association	An association that "is dedicated to ensuring sustainable physiican practicse that result in better health outcomes for patients."	"Strategic Focus" American Medical Association, 2015, http://www.ama-assn.org/ama/pub/about-ama/strategic-focus.page? (Accessed 4/1/15).	American Medical Association AMA Plaza 330 North Wabash Ave., Suite 39300 Chicago, IL 60611-5885 Phone: 800-262-3211 www.ama-assn.org/
National	Ambulatory Surgery Center Association	"The national membership association that represents ambulatory surgery centers and providers advocacy and resources to assist ASCs in delivering high quality, cost-effective ambulatory surgery to all the patients they serve."	"Mission" Ambulatory Surgery Center Association, 2015, http://www.ascassociation.org/Mission (Accessed 4/1/15).	Ambulatory Surgery Center Association 1012 Cameron St Alexandria, VA 22314 Phone: 703-836-8808 Fax: 703-549-0976 E-mail: ASC@ascassociation.org http://ascassociation.org
National	America's Health Insurance Plans	"The national association representing the health insurance industry."	"About Us" America's Health Insurance Plans, 2015, https://www.ahip.org/about/ (Accessed 4/1/15).	American Health Insurance Plans 601 Pennsylvania Avenue, NW South Building Suite 500 Washington, DC 20004 Phone: 202-778-3200 E-mail: ahip@ahip.org www.ahip.org
National	Radiological Society of North America (RSNA)	"The RSNA is an international society of radiologists, medical physicists, and other medical professionals with more than 54,000 members from 136 countries across the globe…"	"Purpose and Vision" Radiological Society of North America, 2015, http://www.rsna.org/About RSNA.aspx (Accessed 4/1/15).	Radiological Society of North America, Inc. 820 Jorie Blvd. Oak Brook, IL 60523 Phone: 630-571-2670 or 800-381-6660 www.rsna.org
National	American College of Radiology (ACR)	"The American College of Radiology, founded in 1924, is a professional medical society dedicated to serving patients and society by empowering radiology professionals to advance the practice, science, and professions of radiological care."	"About Us" American College of Radiology, http://www.acr.org/About-Us (Accessed 4/1/15).	American College of Radiology 1891 Preston White Dr Reston, VA 20191 Phone: 703-648-8900 E-mail: info@acr.org www.acr.org

Chapter 5

Technology Development



In these days when science is clearly in the saddle and when our knowledge of disease is consequently advancing at a breathless pace, we are apt to forget that not all can ride and that he also serves who waits and who applies what the horseman discovers.

Harvey Williams Cushing, 1926

KEY TERMS

Adverse Drug Effect (ADE)
Alert Fatigue
Biologics
Biopharmaceuticals
Biosimilar Production
Brachytherapy
Clinical Decision Support (CDS)
Computerized Physician Order Entry (CPOE)
Degrees of Freedom
Electronic Health Record (EHR)
Enteral
Epidural
External Beam Radiation Therapy (EBT)
Follow-on biologics
Gamma Knife
Gene Therapy
Genomics
Intensity Modulated Radiation Therapy (IMRT)
Intravenous
Laparoscopy
Linear Accelerator (LINAC)
Medical Imaging
NightHawk Radiology Services
Nonparenteral Drug Delivery
Nurse Licensure Compact
Personalized Medicine
Picture Archives and Communications Systems (PACS)
Point-of-Care Technology
Radiation Therapies
Reciprocal (Limited) Licensure
Reparative Medicine
Stem Cells
Stereotactic Radiosurgery
Store and Forward
Subcutaneous
Telehealth
Telemedicine
Teleradiology
The National Center for Human Genome Research Institute (NCHGRI)
Two-Way Interactive Television

Key Concept	Definition	Citation	Concept Mentioned on Page #
Rural Health Care Pilot Program	Created by the Federal Communications Commission to increase patient access to telemedicine and support the transfer of EMRs. Sixty-seven nationwide projects in forty-two states and 6,000 health facilities are eligible for the $417 million in grants under the program.	"Wireline Competition Bureau Evaluation of Rural Health Care Pilot Program Staff Report" By Federal Communications Commission, August 13, 2012, https://apps.fcc.gov/edocs_public/attachmatch/DA-12-1332A1.pdf (Accessed 3/18/15).	359
The Medicare Telehealth Enhancement Act (HR 2068)	Provided $30 million in grants to health facilities to pay for telehealth equipment and expand telehealth support services. Was introduced to Congress on April 23, 2009, referred to the House Ways and Means committee (without further advancement) and addressed The Joint Commission and CMS credentialing issues.	"Medicare Telehealth Enhancement Act of 2009" 111th Congress, Bill H.R. 2068, introduced April 23, 2009; "Waters: Telemedicine Boosts Access to Needed Care" By Robert J. Waters, Roll Call, June 8, 2009, http://www.rollcall.com/features/Mission-Ahead_Health-Care/ma_healthcare/-35540-1.html (Accessed 4/1/15).	362
Licensed Independent Practitioners (LIPs)	The Joint Commission (TJC) accreditation, according to TJC standards, suffices to license practitioners who diagnose or treat patients by way of telemedicine link. CMS, however, requires LIPs to be credentialed at their originating site.	"Existing Requirements for Telemedicine Practitioners Explained" The Joint Commission, Joint Commission Perspectives, Feb. 2003.	362
The Joint Commission Revised Standards (section MS.13.01.01)	The revised standards released in November 2008 compromise the difference between JCAHO and CMS standards, but the commission reverted back to their original opinion in March of 2009.	"The Joint Commission and Telemedicine: The Final Word?" Accreditation Monthly, May 13, 2009.	362
GRNOPC1	Geron Corporation's investigational new drug that became the first human embryonic stem cell-based therapy approved for clinical trial. It is used in patients with acute spinal cord injury.	"Geron Receives FDA Clearance to Begin World's First Human Clinical Trial of Embryonic Stem Cell-Based Therapy" Geron, Press Release, January 23, 2009, http://ir.geron.com/phoenix.zhtml?c=67323&p=irol-newsArticle&ID=1636192 (Accessed 4/1/15).	368
Molecular Diagnostics	A more accurate and effective diagnosis than traditional methods. The capabilities of molecular diagnostics have since evolved to include genetic disorder screening, pre-implantation screening, and cancer screening procedures.	"Proteomics—Technologies, Markets, and Companies," by LeadDiscovery, http://www.researchandmarkets.com/reports/39072/proteomics_technologies_markets_and_companies (Accessed 4/1/15).	369
CMD Technology	Allows practitioners to diagnose cancer, choose and develop personalized treatment plans, and identify predispositions twice as quickly as other assays and for only a fraction of the drug development costs.	"Cancer Molecular Diagnostics Take the Stage: CMDS Are at the Forefront of Evolving Healthcare Practices" By Sudeep Basu, Genetic Engineering and Biotechnology News, Vol. 29, No. 7 (April 1, 2009).	370
Advanced Imaging Modalities	Magnetic resonance imaging, computerized tomography (CT), and nuclear medicine; these modalities are also expensive services, accounting for 54 percent of total imaging expenditures.	"Medicare Part B Imaging Services: Rapid Spending Growth and Shift to Physician Offices Indicate Need for CMS to Consider Additional Management Practices," Government Accountability Office, June 2008, GAO-08-452.	371

Key Concept	Definition	Citation	Concept Mentioned on Page #
Multidetector Row CT (MDCT)	MDCT has raised the standard for image quality and accuracy in identifying differences in patients. In addition to greater acuity, MDCT (namely 64-slice technology) also operates at an increased speed compared to previously existing CT technology.	"CT Flexes Muscle in Coronary Disease Detection" By James Brice, Rheumatology Network, November 29, 2005, http://www.rheumatology network.com/ct/ct-flexes-muscle-coronary-disease-detection (Accessed 4/1/15).	373
"Fusion" Imaging	A hybrid technology that combines nuclear medicine cameras with CT detection methods.	"Nuclear Medicine Usage, Grows, Led By PET" IMV Medical Information Inc. Newsline, Vol. 47, No. 10 (2006), p. 13N.	375
Positron emission tomography-CT (PET-CT) and single, photon emission computed tomography-CT (SPECT-CT) systems	PET technology allows for substantially higher sensitivity than single-photon imaging technologies, such as SPECT. However, due to the longer half-life of single-photon emitters, SPECT tracers last six hours; PET tracers have only a 75 second half-life. A longer half-life enables the use of a wider observational time window. SPECT is much more available, widely used, and more affordable than PET-CT technology. However, SPECT is subject to longer scan times and can produce low-resolution images that are prone to artifacts and attenuation (especially in larger patients).	"PET Versus SPECT: Strengths, Limitations, and Challenges" By Arman Rahmim and Habib Zaidi, Nuclear Medicine Communications, Vol. 29 (2008).	375
Image Guided Radiotherapy (IGRT)	Technology implemented by one-third of all radiation oncology sites at the time of publication and implements ultrasound, x-ray, and CT most frequently.	"IMV Reports Increased Use of Image-Guided Radiotherapy in Radiation Oncology" By Gale Group, BusinessWire, April 9, 2007, http://www.businesswire.com/news/home/20070409005049/en/IMV-Reports-Increased-Image-Guided-Radiotherapy-Radiation-Oncology (Accessed 4/1/15).	384
Stereotactic Radiosurgery	A nonsurgical innovation that serves as an increasingly preferred alternative to invasive surgery for soft tissue tumors.	"DOTmed Industry Sector Report: Linear Accelerators and Simulators," by Barbara Kram, DOTmed News, November 19, 2008, www.dotmed.com/news/story/7013/ (Accessed 4/1/15).	384
Minimally Invasive Procedures	Procedures that avoid many of the risks traditionally associated with surgical procedures through use of several small incisions to guide fiber-optic cameras to areas that necessitate treatment.	Minimally Invasive Surgery," Mayo Clinic, 2009, www.mayoclinic.org/minimally-invasive-surgery/ (accessed April 6, 2009).	385
Cell Culture Market	Influential in the manufacture of biopharmaceuticals, most specifically vaccines, monoclonal antibodies, recombinant proteins, and stem cells.	"Biopharmaceutical benchmarks 2006: The rate of biopharmaceutical approvals has leveled off, but some milestones bode well for the future," by Gary Walsh, Nature Biotechnology, Vol. 24, No. 7, July 2006, p. 769–76.	377

(continued)

Key Concept	Definition	Citation	Concept Mentioned on Page #
Molecular Engineering	Molecular revision has defined development and advancement in biopharmaceuticals.	"Biopharmaceutical benchmarks 2006: The rate of biopharmaceutical approvals has leveled off, but some milestones bode well for the future," by Gary Walsh, Nature Biotechnology, Vol. 24, No. 7, July 2006, p. 769–76.	378
Gendicine	The first gene therapy commercially approved (2004) for treatment of head and neck squamous cell carcinomas.	"Biopharmaceutical Benchmarks 2006: The Rate of Biopharmaceutical Approvals has Leveled Off, but some Milestones Bode Well for the Future" By Gary Walsh, Nature Biotechnology, Vol. 24, No. 7 (July 2006), p. 773.	379
Public Health Service Act	Legislation that has kept generic biopharmaceuticals from being marketed.	"Rx Watchdog Report, Trends in Manufacturer Prices of Specialty Prescription Drugs Used By Medicare Beneficiaries, 2004-2007" By Stephen W. Schlondelmeyer, Leigh Purvis, and David J. Gross, American Association of Retired Persons, September 2008, http://assets.aarp.org/rgcenter/health/2008_15_specialty_q407.pdf (Accessed 4/1/15)	380
Da Vinci System	A robotic system that was introduced in 1996 that revolutionized minimally invasive surgery by overcoming the limitations of both traditional surgical procedures and conventionally implemented noninvasive technology.	"Minimally Invasive and Robotic Surgery" By Michael J. Mack, MD, Journal of the American Medical Association, Vol. 285 No. 5 (2001), p. 568; "Robot-Assisted Surgery" Mayo Clinic, 2009, http://www.mayoclinic.org/robotic-surgery/ (Accessed 4/1/15).	386
Automated Endoscopic System for Optimal Positioning (AESOP)	The first laparoscopic camera holder.	"Robotic Assisted Laparoscopic Radical Prostatectomy: A Review of the Current State of Affairs" By V.R. Patel, M. F. Chammas Jr., and S. Shah, International Journal of Clinical Practice, Vol. 61, No. 2 (February 2007).	385
EndoWrist Technology	Allows the surgeon to fully rotate his or her hand, therefore giving the surgeon the capacity to reach around, beyond or behind The EndoWrist technology provides the surgeon with seven degrees of freedom.	"Robotic Technology in Surgery: Past, Present, and Future" By David B. Camarillo, Thomas M. Krummel, and J. Kenneth Salisbury, The American Journal of Surgery, Vol. 188, No. 4A (Supplement to October 2004), p. 11S.	386

OVERVIEW

The term *technology* has a broad meaning in the healthcare industry. It can range from the tangible tools, pharmaceuticals, and software that healthcare providers utilize when providing care and managing patient records to the procedures that standardize the course of care. The word *technology* stems from the Greek word *tekhnologia*, meaning systematic treatment.[1] While the scope of technology has changed dramatically since the 17th century, the concept of technology still resembles its origins.

Improvements in diagnostic and therapeutic medicine, paired with the efficient use of available resources in both management and clinical arenas, have the capacity to improve quality of care while minimizing the number of medical errors. Through the effective use of electronic health records and prescription management systems providers are able to save money for themselves as well as for their patients.[2] Also, progressive and dynamic research findings in molecular and imaging technology continue to affect the diagnostic industry's influence as a driver of the therapeutic market.[3]

MANAGEMENT TECHNOLOGY

The patient demand for healthcare services is increasing at a rapid rate due to: (1) improved access to care; (2) the growth of the general population;[4] (3) the increase in the number of individuals over the age of 65;[5] and (4) the worsening of the physician manpower shortage.[6] Particularly due to the influx of previously uninsured individuals (an estimated 9.5 million adults gained insurance by the end of the *Patient Protection and Affordable Care Act's* (ACA's) first open enrollment period),[7] providers will have to implement methods of managing added patient throughput. This growth in demand for healthcare services is a significant driver of more sophisticated patient management technologies as well as the infrastructure for gathering and interpreting quality and outcomes data to support evidence-based performance metrics as the foundation for value-based reimbursement. The demand for management technology *vis à vis* the current U.S. healthcare delivery system was characterized in the *2012 Futurescan Report*, to wit:

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1 "Merriam-Webster's Collegiate Dictionary" Tenth Edition, Springfield, MA: Merriam-Webster, Inc., 1999, p. 1210.

2 "Studies Show Electronic Medical Records Make Financial Sense" By Stacy Lawrence, CIO Insight, September 14, 2005, http://www.cioinsight.com/c/a/Health-Care/Studies-Show-Electronic-Medical-Records-Make-Financial-Sense/ (Accessed 8/12/08), http://www.genengnews.com/articles/chitem_print.aspx?aid=2852&chid=0 (Accessed 07/06/09).

3 "Studies Show Electronic Medical Records Make Financial Sense" By Stacy Lawrence, CIO Insight, September 14, 2005, http://www.cioinsight.com/c/a/Health-Care/Studies-Show-Electronic-Medical-Records-Make-Financial-Sense/ (Accessed 8/12/08); "Cancer Molecular Diagnostics Take the Stage: CMDS Are at the Forefront of Evolving Healthcare Practices" By Sudeep Basu, Genetic Engineering and Biotechnology News, Vol. 29, No. 7 (April 1, 2009), http://www.genengnews.com/articles/chitem_print.aspx?aid=2852&chid=0 (Accessed 07/06/09).

4 "Population" in "Statistical Abstract of the United States: 2015" U.S. Census Bureau, Washington, DC, 2014, p. 9.

5 "Why Population Aging Matters: A Global Perspective" National Institute on Aging, National Institute of Health, the United States Department of Health and Human Services, http://www.nia.nih.gov/sites/default/files/WPAM.pdf (Accessed 05/14/12).

6 "Physician Shortages to Worsen Without Increases in Residency Training" Association of American Medical College, 2010, https://www.aamc.org/download/286592/data/physicianshortage.pdf (Accessed 8/2/12).

7 "New Survey: After First ACA Enrollment Period, Uninsured Rate Dropped from 20 Percent to 15 Percent; Largest Declines Among Young Adults, Latinos, and Low-Income People" The Commonwealth Fund, July 10, 2014, http://www.commonwealthfund.org/publications/press-releases/2014/jul/after-first-aca-enrollment-period (Accessed 3/5/15).

> "The healthcare industry cannot bend the cost and quality curve without relentless technology-enhanced innovation—a constant stream of new ideas, new methods, and new ways of providing and payment for care. Such innovations will be most effective if it comes from healthcare executives and clinicians 'in the trenches' who are no longer willing to do things in ways that clearly have been shown not to work."[8]

Management technologies include: (1) the *processes* and *procedures* through which providers organize patient encounters, charge entry, and the billing process and (2) the *software* and *devices* that support these activities. While there are myriad methods through which a healthcare enterprise may choose to approach *management*, the most publicized involve the interoperable exchange and consolidation of patient data and treatment standards. Most of the current *management systems* are implemented as a single package and many contain: (1) *electronic health records* (EHRs); (2) *computerized physician order entry* (CPOE); and (3) *billing* components.

TECHNOLOGY AS *PROCESS*

Typically, the term *medical technology* conjures images of large, industrial machines or complex computer programs used to organize and track patient data. While this chapter focuses on *management* and *clinical technologies*, the term *healthcare technology* goes beyond the hardware and software utilized by providers to include intangible concepts such as *healthcare processes*.

Process technologies can affect the manner and structure by which healthcare is *delivered* and *measured* on both a *clinical* and *management* level, including *treatment protocols*, *care mapping*, and *case management*. For example, a three-year study of a pediatric intensive care unit found that more rigorous hand hygiene, oral care, and central-line catheter care protocols reduced *hospital-acquired infections* (HAIs) and associated healthcare costs, as patients spent, on average, 2.3 fewer days in the hospital.[9]

Management protocols, on the other hand, aim to reduce the cost of healthcare without lowering the level of quality care delivered by establishing protocols that allow providers to appropriately identify those procedures in which the expected treatment benefits to the patient are outweighed by the costs of delivering such care,[10] including early prostate cancer detection testing, routine EKGs, or annual Pap smears.[11] In addition to the utilization of such *management technologies* by providers, payors may also influence providers in this regard. For example, in 2008 Medicare

8 "Chapter 1: Healthcare Reform: The Transformation of America's Hospitals: Economics Drives a New Business Model" in "Futurescan 2012: Healthcare Trends and Implications 2012-2017" By Kenneth Kaufman and Mark E. Grubs, Irving, TX: VHA Inc. (2012), p. 8-9.

9 "Strict Hand Hygiene and Other Practices Shortened Stats and Cut Costs and Mortality in a Pediatric Intensive Care Unit" By Bradford D. Harris, et al., Health Affairs, Vol. 30, No. 9 (September 2011), p. 1751.

10 "Is Health Spending Excessive? If So, What Can We Do About It?" By Henry J. Aaron and Paul B. Ginsberg, Health Affairs, Vol. 28, No. 5 (September/October 2009), p. 1273.

11 "Let's (Not) Get Physicals" By Elisabeth Rosenthal, The New York Times, June 2, 2012.

began withholding payments for the treatment of conditions arising from 28 "*never events,*" [12] defined by the *National Quality Forum* (NQF) as: (1) *serious medical errors*, such as performing the wrong surgical procedure; (2) *product or device events*, such as contaminated drugs or devices; and (3) *criminal events*, such as abduction of a patient.[13]

Although the 2012 Institute of Medicine Report (IOM) entitled, "Best Care at Lower Cost: The Path to Continuously Learning Health Care in America," did not specifically define the concept of technology as process, it nevertheless recommended several steps to facilitate the development of relationships between technology and providers if the U.S. healthcare delivery system is to learn from its past errors, asserting that:

"…[t]o help achieve a learning healthcare system, digital technology developers need to play the following roles:

- Ensure that electronic health record systems and other digital technologies capture and deliver the core data elements needed to support knowledge generation.
- Partner with patients, the delivery system, insurers, researchers, innovators, regulators, and other stakeholders.
- Collaborate in the development of core data sets for different diseases and conditions to support clinical care, improvement, and research.
- Develop tools that assist individuals in managing their health and health care and that provide opportunities for building communities to support patient efforts.
- Consider interoperability and integration in clinical workflows in designing digital health systems."[14]

Further, the *2012 IOM Report* emphasized the importance of maintaining a *digital infrastructure* as the backbone for U.S. healthcare delivery, and recommended that the U.S. healthcare system:

> "Improve the capacity to capture clinical, care delivery process and financial data for better care, system improvement, and the generation of new knowledge. Data generated in the course of care delivery should be digitally collected, compiled and protected as a reliable and accessible resource for care management, *process improvement*, public health, and the generation of new knowledge."[15] [Emphasis added].

The development of *minimally invasive technology*, *pharmaceutical advances*, *increased demand for services*, and *higher costs* associated with inpatient care has fueled a growth in outpatient care, whereby outpatient visits to community hospitals nearly doubled from over 366 million in 1993 to nearly 678 million in 2013.[16] Simultaneously, the technology utilized in the delivery of healthcare has augmented the quality and efficiency of care for inpatient beneficiaries

12 "Strict Hand Hygiene and Other Practices Shortened Stats and Cut Costs and Mortality in a Pediatric Intensive Care Unit" By Bradford D. Harris, et al., Health Affairs, Vol. 30, No. 9 (September 2011), p. 1751; "State Medical Director Letter" By Herb B. Kuhn, Centers for Medicare & Medicaid Services, To State Medical Director, July 31, 2008, http://downloads.cms.gov/cmsgov/archived-downloads/SMDL/downloads/SMD073108.pdf (Accessed 10/07/12).

13 "Never Event Fact Sheet" By The Leapfrog Group, March 2008, http://www.leapfroggroup.org/media/file/Leapfrog-Never_Events_Fact_Sheet.pdf (Accessed 2/8/11).

14 "Best Care at Lower Cost: The Path to Continuously Learning Health Care in America" By Mark Smith et al., Institute of Medicine, Washington, DC: The National Academics Press, 2012, p. 10-21 (pre-publication copy-uncorrected page proofs).

15 Ibid.

16 "Table 3.4: Outpatient Utilization in Community Hospitals, 1993-2013" in "Trendwatch Chartbook 2015" American Hospital Association, February 19, 2015, http://www.aha.org/research/reports/tw/chartbook/ch3.shtml (Accessed 3/5/15).

over the age of 65, the population of which is projected to surpass 71 million by 2029.[17] This demographic shift indicates that efforts to maximize technological implementation in the delivery of home care and patient compliance monitoring systems should be employed to increase both access to and quality of care.

> Outpatient visits to community hospitals nearly doubled from 366 million, in 1993, to nearly 678 million in 2013.
>
> ***American Hospital Association, February 19, 2015.***

ELECTRONIC HEALTH RECORDS (EHR)

Electronic health records (EHR) work through a system of longitudinal data collection and maintenance to "automate and streamline the clinician's workflow."[18] As noted by the Healthcare Information and Management Systems Society (HIMSS), "EHR has the ability to generate a complete record of a clinical patient encounter—as well as supporting other care-related activities directly or indirectly via interface –including evidence-based decision support, quality management, and outcomes reporting."[19] Facilities that use EHR systems increase the ease with which practitioners can file, manage, organize, and find their patients' demographic data, progress notes, problems, medications, vital signs, past medical histories, immunizations, laboratory data, and radiology reports.[20]

Healthcare providers are responsible for the *collection*, *maintenance*, and *analysis* of patient data during the course of each *patient encounter*.[21] Electronic patient records may avoid some of the pitfalls of *paper records*, such as: (1) *wasted resources*; (2) *storage concerns*; (3) *misplacement*; and (4) *retrieval issues*. Further, *paper records* do not allow for the efficient search for the requisite data extraction and analysis of voluminous *patient clinical*, *demographic*, and *financial information*.[22] In contrast to *paper records*, most EHR systems can be instantly *searched*, *categorized*, and *analyzed* electronically, thereby improving providers' ability to provide more *informed treatment plans* to their patients.[23] Although EHR systems have been in the market for well over a decade, the *prevalence* of these systems had been relatively low until various *health reform efforts* and *legislations* promoted the utilization of EHR systems. EHR systems come in a variety of forms with small, but important, differences.

Of note, there is a distinction between an *electronic medical record* (EMR) and an EHR, although the two terms are often incorrectly used synonymously. Although both terms refer to

17 "The Boomer Challenge" By Paul Barr, Hospitals & Health Networks, January 14, 2014, http://www.hhnmag.com/display/HHN-news-article.dhtml?dcrPath=/templatedata/HF_Common/NewsArticle/data/HHN/Magazine/2014/Jan/cover-story-baby-boomers (Accessed 3/5/15).

18 "Adaptive Health Management Information Systems: Concepts, Cases, and Practical Applications" By Joseph Tan and Fay Cobb Payton, Sudbury, MA: Jones and Bartlett Publishers, 2010, p. 121.

19 "Electronic Health Record" Healthcare Information and Management Systems Society, http://www.himss.org/ASP/topics_ehr.asp (Accessed 6/22/09).

20 Ibid.

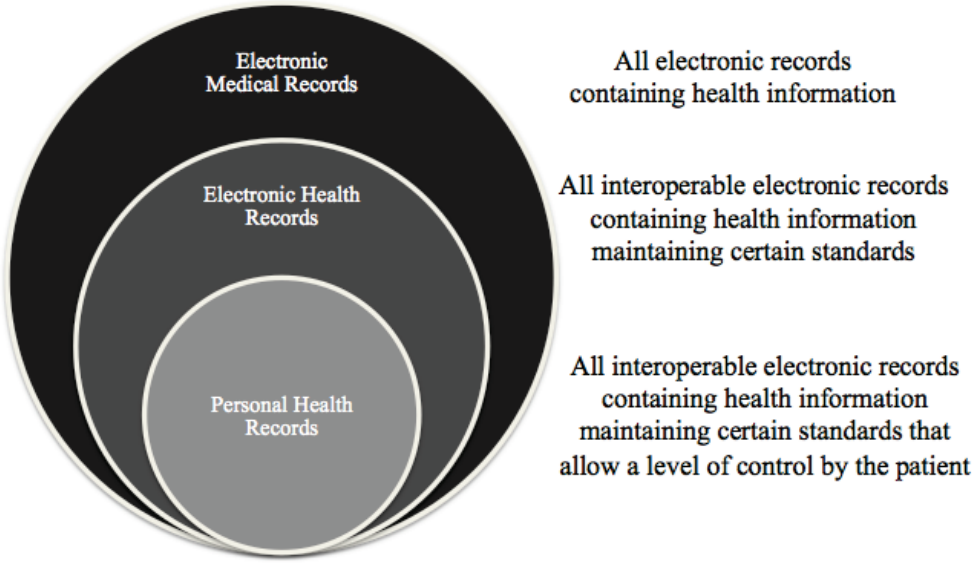
21 "Defining Key Health Information Technology Terms" National Alliance for Health Information Technology, To The National Coordinator for Health Information Technology, Department of Health & Human Services, April 28, 2008, p. 16.

22 "Benefits of EMR" Medical Systems Development Corporation, 2003, http://msdc.com/EMR_Benefits.htm (Accessed 8/13/09).

23 "Defining Key Health Information Technology Terms" By The National Alliance for Health Information Technology, To The National Coordinator for Health Information Technology—Department of Health & Human Services, April 28, 2008, p. 16.

the *electronic collection* and *management* of *health related information*, EHRs are subject to additional *regulatory scrutiny* and *interoperability standards*, i.e., *meaningful use* (discussed below). Both terms can be juxtaposed with *personal health records* (PHRs), another related but distinct term that describes an *electronic record system* that is controlled by the *patient*, in contrast to the *provider*.[24] To note the importance of *interoperability* in regards to *regulation funding*, and *emerging healthcare initiatives*, discussion in this chapter will be focused on EHRs and PHRs. The varying scopes of these terms are illustrated below in Figure 5-1: *Scope of Electronic Record Systems*.

Figure 5-1: Scope of Electronic Record Systems[25]



Through the use of EHRs, healthcare providers are able develop and maintain a complete record of a clinical patient encounter, as well as supporting other care-related activities, such as "*evidence-based decision support, quality management, and outcomes reporting*."[26] Enabled by advances in computers and electronic communication, EHRs collect observations, test results, and narratives by multiple providers in one location,[27] which allows for the communication among different providers in the treatment of a patient. If presented in a simple, user-friendly interface, EHRs have the potential to improve the ability of healthcare providers to make diagnosis, treatment, and health management decisions.[28]

24 "Defining Key Health Information Technology Terms" By TheNational Alliance for Health Information Technology, To The National Coordinator for Health Information Technology, Department of Health & Human Services, April 28, 2008, p. 15.
25 Ibid.
26 "Electronic Health Record" Healthcare Information and Management Systems Society, http://www.himss.org/ASP/topics_ehr.asp (Accessed 6/22/09).
27 "Defining Key Health Information Technology Terms" By The National Alliance for Health Information Technology, To The National Coordinator for Health Information Technology—Department of Health & Human Services, April 28, 2008, p. 17.
28 "Defining Key Health Information Technology Terms" National Alliance for Health Information Technology, To The National Coordinator for Health Information Technology, Department of Health & Human Services, April 28, 2008, p. 17.

Trends in EHR Utilization

The first EHRs were adopted in the 1960s, but many healthcare providers at the time did not consider updates to their *anachronistic* medical record systems to be a priority.[29] Modern EHR systems are based on the research and pilot testing conducted in academic medical centers developed for use by governmental clinical care organizations. Some noteworthy attempts in EHR development are set forth below, in Table 5-1: *Notable Precursors of EHR Technology*.

Table 5-1: Notable Precursors of EHR Technology[30]

Year	Program	Developer	Impact
1960s-1970s	Technicon Data System (TDS)	Lockheed and El Camino Hospital	Processing speed and flexibility let multiple users into the system at one time
1960s	Health Evaluation through Logical Processing (HELP)	University of Utah and Latter-Day Saints Hospital (brought to market by the 3M Corporation)	One of the first clinical decision support programs
1968-1975	Computer Stored Ambulatory Record (COSTAR)	Harvard University and Massachusetts General Hospital	Compartmentalized design increased efficiency; flexible vocabulary accounted for terminology variations; first to be made available in public domain
1970s	Decentralized Hospital Computer Program (DHCP)	U.S. Department of Veterans' Affairs	First time the federal government began using EHR
1983	THERESA	Emory University and Grady Memorial Hospital	First system to encourage direct physician data entry
1986	The Medical Record (TMR)	Duke University Medical Center	Made data easy to manipulate and sort for ease of reference, giving way to Duke's Health Information System
1988	Composite Health Care System (CHCS)	U.S. Departments of Defense	Renowned for lowering medical errors integrating various health record components

Early attempts to design and implement EHR technology encountered several difficulties and, although many improvements have been made, certain lingering problems with current EHR systems may explain why EHRs were not widely implemented on an expedited basis (See Table 5-2, below, as well as the Barriers to Implementation section).

29 "Electronic Health Records Overview" MITRE Center for Enterprise Modernization, To National Institutes of Health, National Center for Research Resources, McLean, VA: MITRE, April 2006, p. 2.

30 "Electronic Health Records Overview" MITRE Center for Enterprise Modernization, To National Institutes of Health, National Center for Research Resources, McLean, VA: MITRE, April 2006, p. 2; "History of Medicine: Development of the Electronic Health Record" By Jim Atherton, American Medical Association Journal of Ethics, Vol. 13, No. 3 (March 2011), p. 187; "Computer-Based Patient Record Technologies" National Research Council, The Computer-Based Patient Record: An Essential Technology for Health Care, Revised Edition, Washington, DC, The National Academies Press, 1997, p. 114-115, 117-118; "History of Health Informatics at Duke" Duke Center for Health Informatics, Durham, N.C.: 2010, http://www.google.com/url?sa=t&rct=j&q=%22the%20medical%20record%22%20duke&source=web&cd=2&ved=0CFEQFjAB&url=https%3A%2F%2Fwww.dchi.duke.edu%2Fabout-us%2Fdchi-book%2FThe%2520evolution%2520of%2520Duke%2520systems.pdf&ei=5DT7T8akDYHs8wS0i4zXBg&usg=AFQjCNFpqc5cfDVHWXsDMsvNtN3i-tTGgA (Accessed 7/9/12), p. 2.

Table 5-2: Status of Electronic Health Record Implementation (2011)[31]

Stage of Implementation	Percentage
Not Yet Begun	2%
Developed a Plan	7%
Signed a Contract	2%
Begun to Install in One Facility	34%
Fully Operational in One Facility	26%
Fully Operational Across Whole Organization	27%
Unknown	1%

Though paper health records have been used effectively by providers in the past, practices that continue to utilize non-electronic documentation of patient information are experiencing significant drawbacks.[32] In addition to hindering the delivery of quality medical care, studies have indicated that paper records are costly, cumbersome, easily misplaced, and difficult to use for meaningful decision analysis.[33] Furthermore, paper records cannot be effectively searched or used to track, analyze, or chart voluminous clinical medical information and they cannot be easily copied or saved off-site.[34]

Although EHR implementation has progressed at a relatively slow rate, it has continued to increase steadily since 2003. Notably, the share of office based physicians that utilize any EHR system has increased from 18% in 2001 to 78% in 2013, while the percentage of office based physicians that utilize a "basic" EHR system has increased from 11% in 2001 to 48% in 2013.[35] The states with the greatest percentage of office-based physicians using basic EHR systems include: (1) North Dakota, 82.9%; (2) Minnesota, 75.5%; (3) Massachusetts, 70.6%; (4) Wisconsin, 67.9%; (5) Iowa, 65.5%; and (6) Utah, 65.5%.[36] States with the lowest percentage of office-based physicians using basic EHR systems include: (1) New Jersey, 21.2%; (2) Connecticut, 30.1%; (3) Washington, DC, 31.0%; (4) Nevada, 33.0%; (5) West Virginia, 36.9%; and (6) Oklahoma, 36.9%.[37]

EHR system adoption also seems to be creating a widening divide between specialists (47%) and primary care providers (78%) who have implemented EHR systems that meet *meaningful use* criteria.[38] Other divergences in EHR adoption include: (1) *age*, i.e., in 2012, office-based physicians under the age of 45 were approximately 15% more likely to use an EHR system than office-based physicians age 55 and older; (2) *practice size*, i.e., in 2012, practices with eleven or more physicians were approximately 19% more likely to use EHR systems than practices with only one or two physicians; and (3) *ownership*, i.e., in 2012, practices owned by a community health center were more likely to adopt an EHR system than those owned by a physician or

31 "2011 HIMSS Leadership Survey: Senior IT Executive Results" Health Information and Management Systems Society, 2011, p. 27.
32 "Electronic Health Records" Healthcare Information and Management Systems Society, http://www.himss.org/ASP/topics_ehr.asp (Accessed 6/22/09).
33 "Benefits and Drawbacks of Electronic Health Record Systems" By Nir Menachemi & Taleah H. Collum, Risk Management and Healthcare Policy, Vol. 4, No. 1 (2011), p. 50-51.
34 "Electronic Health Record" Healthcare Information and Management Systems Society, http://www.himss.org/ASP/topics_ehr.asp (Accessed 6/22/09).
35 "Use and Characteristics of Electronic Health Record Systems Among Office-based Physician Practices: United States, 2001-2013" By Chun-Ju Hsiao, PhD and Esther Hing, MPH, NCHS Data Brief No. 143, Centers for Disease Control and Prevention, January 2014, http://www.cdc.gov/nchs/data/databriefs/db143.pdf (Accessed 3/5/15), p. 1.
36 Ibid, p. 2.
37 Ibid, p. 2.
38 "Regional Extension Centers (REC) Enrolled Physicians Adoption of Electronic Health Records" Office of the National Coordinator for Health Information Technology, February 2015, http://dashboard.healthit.gov/quickstats/pages/FIG-REC-Physicians-Live-MU-Speciality.php (Accessed 3/11/15).

physician groups.[39]Additionally, EHR adoption seems to be further along outside of physician practices with 97% of physicians in *health maintenance organizations* (HMOs) utilizing EHRs in 2012 and 80% of physicians in *community health centers* utilizing EHRs in 2012.[40]

Cost-Benefit Analysis

Using computer-based programs to track patients' medical records, approve physician orders, and prescribe medication can drastically improve patient outcomes and reduce costs. According to the *American Medical Association* (AMA), practices that implement EHR technology will benefit from a system of documenting patient vitals and test results, better supporting documentation in medical malpractice claims, improved reporting regarding patient practices, and improved communication between physicians.[41] Furthermore, research suggests that implementation of EHRs has a positive impact on physician productivity and may generate savings by slowing the growth of healthcare costs.[42]

Additionally, EHR system implementation allows for the utilization of a *computerized physician order entry* (CPOE), which may aid in reducing adverse drug events in inpatient and ambulatory settings.[43] These *point-of-care technology* systems make patient clinical data readily available, and they provide physicians with access to scientific information essential to patient care and decision-making.[44]

Practices that utilize EHR technology reduce their costs associated with utilizing and maintaining traditional paper medical records.[45] In addition to superior physician accessibility, EHRs allow physicians to enter key findings and progress notes at the point of care, minimizing duplicate documentation.[46] Additionally, problems with legibility are eliminated, reducing potential interpretation errors and saving time.[47]

Barriers to Implementation

Obstacles such as cost and physician resistance to change have delayed the widespread adoption of EHRs.[48] In 2014, 19% of senior healthcare executives noted that the most significant barrier to

39 "Trends in Electronic Health Record System Use Among Office-Based Physicians: United States, 2007-2012" By Chun-Ju Hsiao, PhD, MHS, et al., National Center for Health Statistics, U.S. Centers for Disease Control and Prevention, May 20, 2014, http://www.cdc.gov/nchs/data/nhsr/nhsr075.pdf (Accessed 3/11/15), p. 11.

40 Ibid.

41 "Benefits" By American Medical Association, 2008, http://www.ama-assn.org/ama/pub/category/16756.html. (Accessed 8/13/2008).

42 "The Impact of Electronic Health Record Use on Physician Productivity" By Julia Adler-Milstein, PhD and Robert S. Huckman, PhD, American Journal of Managed Care, Vol. 19, No. 10, November 25, 2013, http://www.ajmc.com/publications/issue/2013/2013-11-vol19-SP/The-Impact-of-Electronic-Health-Record-Use-on-Physician-Productivity (Accessed 3/5/15); "Effect of Electronic Health Records on Health Care Costs: Longitudinal Comparative Evidence From Community Practices" By Julia Adler-Milstein et al., Annals of Internal Medicine, Vol. 159, No. 2, July 16, 2013, http://annals.org/article.aspx?articleid=1709804 (Accessed 3/5/15).

43 "Can Electronic Medical Record Systems Transform Health Care? Potential Health Benefits, Savings, and Costs" Health Affairs, Vol. 24 No. 5 (2005), p. 1103-1117; see below in the Electronic Prescribing: Computerized Physician Order Entry section.

44 "Working Group 6: The Role of Technology to Enhance Clinical and Educational Efficiency" By Steven E. Nissen, MD, et al., Journal of American College of Cardiology, Vol. 44, No. 2 (2004), p. 258.

45 "Better Technology...Better Patient Care Since 1994" ChartLogic Products, 2008, http://www.chartlogic.com/products.php.

46 "Better Technology...Better Patient Care Since 1994" ChartLogic Products, 2008, http://www.chartlogic.com/products.php; "Working Group 6: The Role of Technology to Enhance Clinical and Educational Efficiency" By Steven E. Nissen, MD, et al., Journal of American College of Cardiology, Vol. 44, No. 2 (2004), p. 258.

47 "Working Group 6: The Role of Technology to Enhance Clinical and Educational Efficiency" By Steven E. Nissen, MD, et al., Journal of American College of Cardiology, Vol. 44, No. 2 (2004), p. 258.

48 "Working Group 6: The Role of Technology to Enhance Clinical and Educational Efficiency" By Steven E. Nissen, MD, et al., Journal of American College of Cardiology, Vol. 44, No. 2 (2004), p. 258.

implementing health information technologies such as EHRs involved a "lack of financial resources," serving as the most widely cited obstacle in the survey.[49] The cost associated with utilizing EHR technology can vary based on facility size, patient volume, and type of software, which extends beyond the software license. Often, the cost of the software is only 50% of the cost for a new system.[50] For example, the cost of implementing an EHR system that is small in scope (for a small physician group practice) has been estimated at approximately $46,00 in the first year when including both financial costs (i.e. depreciable capital expenses, e.g. the cost of hardware) and nonfinancial costs (e.g. the time expended by physicians and other staff).[51] Accounting for the potential loss of productivity associated with the initial implementation may further increase the cost of transitioning to an EHR system.[52]

However, research suggests that providers who increase their utilization of EHRs could have a 5% increase in physician productivity, while providers who increase their delegation of EHR tasks could have an 11% increase in physician productivity.[53] Some cardiology practices have already reported substantial EHR benefits, including: (1) improvements in lowering Medicare rejection rates; (2) improvements in their days in accounts receivable; (3) ability to increase patient volume without increasing staff; (4) increased revenue; and (5) reduction in transcription and postage costs.[54] EHR benefits may also extend to hospitals, with an article in *Healthcare Financial Management* estimating potential benefits over a 5-year period of over $37 million.[55]

In addition to governmental incentives and requirements (discussed further below in this section), EHRs are imperative for current emerging value-based purchasing and evidence-based trends, e.g., *accountable care organizations* (ACOs) and the *hospital value-based purchasing program*. Variations on, or extensions of, EHR systems facilitate the growth and success of such programs in addition to furthering consumer driven healthcare and accountability and access to care.

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49 "25th Annual HIMSS Leadership Survey" Healthcare Information and Management Systems Society, February 24, 2014, http://himss.files.cms-plus.com/FileDownloads/2014-HIMSS-Leadership-Survey.pdf (Accessed 3/13/15), p. 2, 10.

50 "A Cost Benefit Analysis of Electronic Medical Records in Primary Care" By S. J. Wang, et al. American Journal of Medicine, Vol. 114 No. 5 (April 2003), p. 398; "Electronic Medical Record Systems: Know the Total Cost of Ownership" By D. J. Cavolo, Nursing Homes, July 2007.

51 "The Financial and Nonfinancial Costs of Implementing Electronic Health Records in Primary Care Practices" By Neil S. Fleming, et al., Health Affairs, Vol. 30, No. 3 (2011), p. 484-487.

52 "Productivity and Cost Implications of Implementing Electronic Medical Records Into an Ambulatory Surgical Subspecialty Clinical" By Mukul Patil, Lalit Puril, and Chris M. Gonzalez, Urology, Vol. 71, No. 2 (2008), p. 177.

53 "The Impact of Electronic Health Record Use on Physician Productivity" By Julia Adler-Milstein, PhD and Robert S. Huckman, PhD, American Journal of Managed Care, Vol. 19, No. 10 (November 25, 2013), http://www.ajmc.com/publications/issue/2013/2013-11-vol19-SP/The-Impact-of-Electronic-Health-Record-Use-on-Physician-Productivity (Accessed 3/5/15).

54 "GEMMS Mid-Carolina Cardiology: Q3 2006" Future Healthcare, 2006, http://www.futurehealthcareus.com/?mc=gemms-mid-carolina&page=card-viewarticle (Accessed 9/22/09) (Cardiology practice, MMC, stated that since the implementation of an EMR system, their rejection rate for Medicare claims has been reduced to 0.05 percent and their days in accounts receivable has dropped from 110 days to 34 days); "How One Practice Made EMR Improve Workflow, Patient Care, & Revenue" By Cardiology Practice Advisor, Advisor Publications, May 2001, http://www.medinformatix.com/pdf/pr_Case_Studies_cardiology_Practice_advisor.pdf (Accessed 8/13/09) (stating that EMR has facilitated 25 percent patient increase without increase in staff, 35 percent more revenue, substantially improved Medicare denial rate, reduction in transcription and postage costs, and improved accounts receivable); "Cardiology Practice Raises the Level of Patient Care: Electronic Medical Records Prove to Pay at a Higher Rate than Paper Claims" Clear Technologies, 2004, http://www.comparecrm.com/crm-vendors/c2crm/case-studies/csant.pdf (Accessed 8/13/09) (stating that a cardiology practice in Texas has seen substantial improvements in Medicare & Medicaid reimbursements since implementation of EMR).

55 "From Promise to Reality: Achieving the Value of an EHR" By Beverly Bell & Kelly Thornton, Healthcare Financial Management, Vol. 65, No. 2 (February 2011), p. 52.

> Providers who increase their utilization of EHRs could have a 5% increase in physician productivity, while providers who increase their delegation of EHR tasks could have an 11% increase in physician productivity.
>
> ***Julia Adler-Milstein, PhD and Robert S. Huckman, PhD, November 25, 2013.***

Regulatory and Reimbursement

Regulatory

As with all medical records, EHRs must align with current *Health Insurance Portability and Accountability Act* (HIPAA) regulations.[56] Due to the ease of transferability and accessibility, practitioners and healthcare facilities that use EHR technology must be abundantly cautious about compliance.

In 2007, the *Federal Trade Commission* (FTC) issued a set of regulations known as the *Red Flags Rules*, which required that certain entities develop and enforce written identity theft prevention and detection programs by August 1, 2009.[57] These programs are targeted at all transferable personal files, including EHRs.[58]

On February 17, 2009, President Barack Obama signed into law the *American Recovery and Reinvestment Act of 2009* (ARRA), which allotted $19.2 billion to ensure that every patient has a complete, interoperable EHR by 2014.[59] The ARRA established both the *Health Information Technology for Economic and Clinical Health (HITECH) Act*[60] and an *Office of National Coordinator for Health Information Technology (ONC)* within the *Department of Health and Human Services* (HHS).[61] Under HITECH and subsequent regulations, Medicare hospitals must achieve "*meaningful use*" of EHR by October 2014 to avoid reimbursement penalties, while Medicare-eligible professionals must achieve "*meaningful use*" by January 2015 to avoid penalties.[62] HITECH also provides both programmatic support and financial incentives to overcome barriers that have previously dissuaded providers from adopting some form of an electronic record system.[63]

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56 See the Health Insurance Portability and Accountability Act of 1996 (HIPAA) section in Chapter 3: Regulatory Environment.

57 "FTC Will Grant Three-Month Delay of Enforcement of Red Flags Rule Requiring Creditors and Financial Institutions to Adopt Identity Theft Prevention Programs" Federal Trade Commission, Press Release, April 30, 2009, https://www.ftc.gov/news-events/press-releases/2009/04/ftc-will-grant-three-month-delay-enforcement-red-flags-rule (Accessed 4/1/15), p. 1.

58 See the Red Flags Rule section in Chapter 3: Regulatory Environment.

59 "American Reinvestment and Recovery Act" Pub. L. No. 111-5, § 13101, 123 Stat. 115, 404 (February 7, 2009); "Signed, sealed, delivered: ARRA" By Macon Phillips, The White House, February 17, 2009, http://www.whitehouse.gov/blog/09/02/17/signed-sealed-delivered-arra (Accessed 5/15/12).

60 Specific provisions of the ARRA, namely, Title IV of Division B and Title XIII of Division A, are collectively known as the Health Information Technology for Economic and Clinical Health Act (HITECH Act).

61 "Office of the National Coordinator for Health Information Technology" 42 U.S.C. § 300JJ-11 (July 9, 2010); "American Recovery and Reinvestment Act of 2009, Sec. 13101" Pub. L. No. 111-5, 123 Stat. 115, 226, 230-234 (February 17, 2009).

62 "American Reinvestment and Recovery Act" Pub. L. No. 111-5, § 13101, 123 Stat. 115, 231 (February 7, 2009); "Payment Adjustments & Hardship Exceptions" Centers for Medicare & Medicaid Services, March 5, 2015, http://www.cms.gov/Regulations-and-Guidance/Legislation/EHRIncentivePrograms/paymentadj_hardship.html (Accessed 3/13/15).

63 "Meaningful Use of Health Information Technology: From Public Policy to Changing Care" By Paul Tang, Futurescan 2011: Healthcare Trends and Implications 2011-2016, 2011, p. 33.

Under the HITECH Act, the *HIT Policy Committee* was established to develop a framework to be used by CMS to decide whether a provider has met the *meaningful use* requirements.[64] The framework established by the *HIT Policy Committee* consists of five categories (four clinical and one foundational), including:

(1) "*Improve quality, safety, and efficiency of healthcare to reduce healthcare disparities.*
(2) *Engage patients and families.*
(3) *Improve care coordination.*
(4) *Improve population and public health.*
(5) *Ensure privacy and security of health information.*"[65]

For both Medicare and Medicaid healthcare providers to qualify for HITECH incentives, they must fulfill the three *meaningful use* requirements of EHRs:

"*(1) Use of certified EHR technology in a meaningful manner (for example, electronic prescribing);*
(2) The certified EHR technology is connected in a manner that provides for the electronic exchange of health information to improve the quality of care; and
(3) In using certified EHR technology, the provider submits…information on clinical quality measures and such other measures selected by the Secretary."[66]

Since the introduction of HITECH, CMS has rolled out the Medicare and Medicaid EHR Incentive Programs in stages. In March 2015, CMS issued its Stage 3 Meaningful Use Proposed Rule consisting of eight objectives to which all providers will be required to attest beginning in 2018. However, CMS proposed to incorporate flexibility within some of the objectives by allowing providers to choose measures for meeting those requirements that are "most relevant to their unique practice setting," meaning that while providers must report on all required reportable measures, they need only meet thresholds for a certain percentage of them and can choose on which measures to do so.[67] CMS intends for Stage 3 to be the final stage of meaningful use, but has not foreclosed the possibility of future rule makings addressing EHR technology.[68] It should be noted however, that this proposed rule could change following the public comment period and should be monitored accordingly by healthcare professionals working closely with EHRs.

Medicaid also requires that healthcare providers receiving incentives under the HITECH Act must indicate their efforts to "adopt, implement, or upgrade certified EHR technology" wherever possible.[69] States may implement additional requirements for *meaningful use* beyond the minimum standard upheld by Medicare, but such requirements must relate to four public health objectives:

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64 Ibid.
65 Ibid.
66 "Medicare and Medicaid Programs; Electronic Health Record Incentive Program; Final Rule", Federal Register Vol. 75, No. 144 (July 28, 2010), p. 44326-44327.
67 "Medicare and Medicaid Programs; Electronic Health Record Incentive Program—Stage 3" Federal Register Vol. 80, No. 60 (March 30, 2015), p. 16743.
68 "Stage 3—The Final Frontier of Meaningful Use: CMS Issues Its Stage 3 Proposed Rule" By Kevin Alonso, AHLA Health Information and Technology Practice Group Email Alert, March 26, 2015.
69 "Medicare and Medicaid Programs; Electronic Health Record Incentive Program; Final Rule" Federal Register Vol. 75, No. 144 (July 28, 2010), p. 44503.

(1) Generation of "*lists of patients by specific conditions to use for quality improvement, reduction of disparities, research, or outreach*;"
(2) "*Capability to submit electronic data to immunization registries…*;"
(3) "*Capability to submit electronic data on reportable…lab results to public health agencies*;" and
(4) "*Capability to submit electronic syndromic surveillance data to public health agencies*."[70]

Reimbursement

As discussed above, in response to the slow transition to EHRs, the government has prioritized proactive legislation promoting universal access to electronic records, in part, by passing the ARRA and the HITECH Act. The net return of this investment was anticipated to include improved outcomes, long-term cost savings, and increased ease of communication between providers.[71] In an effort to incentivize the implementation of EHR use, beginning in 2011, reimbursement funding increased for Medicare and Medicaid providers (up to $65,000 per physician and $11 million per hospital) who use EHRs.[72] Conversely, physicians who were not using EHRs by January 2015 were penalized through reduced reimbursement.[73]

> The ARRA allotted $19.2 billion to ensure that each American has a complete, interoperable EHR by 2014.[74]

From May 2011 to January 2015, CMS provided more than $19.5 billion in Medicare EHR incentive payments to Medicare providers.[75] Although providers were first eligible to demonstrate Stage 2 *meaningful use* in 2014,[76] the HITECH Act Final Rule allowed any Medicare *eligible professional* (EP) or hospital that was able to demonstrate *meaningful use* in the two-year reporting period, prior to the 2015 payment adjustment year, to avoid the Medicare payment adjustments.[77] Providers that first demonstrated *meaningful use* in 2014 were able to avoid this penalty if they registered and attested to their achievement of *meaningful use* standards by July 1, 2014 for hospitals, or October 1, 2014 for EPs.[78] EPs who were eligible for either Medicare or Medicaid could also make *meaningful use* attestations to state Medicaid agencies in order to avoid the Medicare penalty.[79]

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70 Ibid, p. 44325.
71 "Improving Patient Care: Systematic Review: Impact of Health Information Technology on Quality, Efficiency, and Costs of Medical Care" By Basit Chaudhry, MD, Jerome Wang, MD, Shinyi Wu, PhD, Margaret Maglione, MPP, Walter Mojica, MD, Elizabeth Roth, MA, Sally C. Morton, PhD, and Paul G. Shekelle, MD, PhD, Annals of Internal Medicine, Vol. 144, No. 10 (May 16, 2006), p. 747-748.
72 "Health Care and the American Recovery and Reinvestment Act" By Robert Steinbrook, The New England Journal of Medicine, Vol. 360 No. 11 (March 12, 2009), p. 3.
73 "Payment Adjustments & Hardship Exceptions" Centers for Medicare & Medicaid Services, March 5, 2015, http://www.cms.gov/Regulations-and-Guidance/Legislation/EHRIncentivePrograms/paymentadj_hardship.html (Accessed 3/13/15).
74 "Healthcare and the American Recovery and Reinvestment Act," by Robert Steinbrook, MD, The New England Journal of Medicine, March12, 2009, http://content.nejm.org/cgi/content/full/NEJMp0900665 (accessed February 20, 2009).
75 "Data and Program Reports" Centers for Medicare & Medicaid Services, March 12, 2015, http://www.cms.gov/Regulations-and-Guidance/Legislation/EHRIncentivePrograms/DataAndReports.html (Accessed 3/13/15).
76 "Stage 2" Centers for Medicare & Medicaid Services, November 5, 2014, http://www.cms.gov/Regulations-and-Guidance/Legislation/EHRIncentivePrograms/Stage_2.html (Accessed 3/13/15).
77 "Medicare and Medicaid Programs; Electronic Health Record Incentive Program - Stage 2" Federal Register Vol. 77, No. 171 (September 4, 2012), p. 54157-54158; "At a Glance: Stage 2 Final Rule" Healthcare IT News Staff, Healthcare IT News, August 23, 2012, http://www.healthcareitnews.com/news/glance-stage-2-final-rule (Accessed 9/22/12).
78 "At a Glance: Stage 2 Final Rule" Healthcare IT News Staff, Healthcare IT News, August 23, 2012, http://www.healthcareitnews.com/news/glance-stage-2-final-rule (Accessed 9/22/12).
79 Ibid.

ELECTRONIC PRESCRIBING: COMPUTERIZED PHYSICIAN ORDER ENTRY (CPOE)

Computerized physician order entry (CPOE) allows physicians and other healthcare providers "to electronically order laboratory, pharmacy, and radiology services."[80] Entering orders electronically minimizes error by eliminating the hassle and ambiguity associated with handwritten orders.[81] CPOE is designed to "streamline medication ordering by standardizing the process, introducing controls, eliminating bad handwriting, making an order easily traceable to a provider; additionally, with decision support installed, CPOE can also help assure adherence to evidence-based guidelines."[82]

Approximately 7,000 patients die every year in U.S as the result of *medication errors*.[83] A 2012 Joint Commission study noted that, on average, *adverse drug events* (ADE) cost hospitals more than $3,000 per incident.[84] In the aggregate, *preventable medical errors* cost society, at a minimum, $73.5 billion in quality-adjusted life years.[85] An ADE is any injury caused by a medication error, often in the form of an allergic reaction or adverse physiological response to a certain combination of medications, i.e., (1) a *drug to drug* interaction or (2) a *drug to allergy* interaction, while *preventable ADEs* are injuries resulting from human error, such as prescribing or administering the wrong dose of a drug.[86]

Trends in CPOE

CPOE systems were first introduced in the late 1960s, but CPOE use was fairly sporadic until a 1999 study by the IOM entitled, "To Err Is Human," found that 44,000 deaths were attributable to *medical errors* annually.[87] The study touted CPOE adoption as the solution to this newly recognized national crisis.[88]

A 2008 Leapfrog Group study further touted the benefits of CPOE systems for hospitals, finding that *fully implemented* CPOE systems could potentially reduce the frequency of ADEs by as much at 88%.[89] To qualify as having a *fully implemented* CPOE system, hospitals had to achieve certain requirements, including: (1) 75% of all orders had to go through its CPOE system; (2) the system had to alert physicians of possible errors; and (3) the system had to require a physician

80 "Electronic Health Records Overview" National Institutes of Health: National Center for Research Resources, April 2006, p. 7.
81 "Welcome to CPOE.org" Oregon Health and Science University, http://www.ohsu.edu/academic/dmice/research/cpoe/index.php (Accessed 6/22/09).
82 "Full Implementation of Computerized Physician Order Entry and Medication-Related Quality Outcomes: A Study of 3364 Hospitals" By Feliciano B. Yu et al., American Journal of Medical Quality, American College of Medical Quality (June 5, 2009), p. 6.
83 "To Err is Human: Building a Safer Health System" The Institute of Medicine, Washington, DC: National Academy Press, 2000, p. 1.
84 "The Cost of Adverse Drug Events in Community Hospitals" By Balthasar L. Hug, MD, MBA, MPH et al., The Joint Commission Journal on Quality and Patient Safety, Vol. 38, No. 3 (March 2012), p. 125.
85 "The Economics of Health Care Quality and Medical Errors" By Charles Andel et al., Journal of Health Care Finance, Vol. 39, No. 1 (Fall 2012), p. 49.
86 "Saving Lives, Saving Money: The Imperative for Computerized Physician Order Entry In Massachusetts Hospitals" Massachusetts Technology Collaborative, New England Healthcare Institute, February 2008, p.14.
87 "Impact of a Computerized Physician Order-Entry System" By William M. Stone et al., Journal of the American College of Surgeons, Vol. 208, Issue 5 (May 2009), p. 7; "To Err is Human: Building a Safer Health System" Institute of Medicine, November 1999, p. 1.
88 "To Err is Human: Building a Safer Health System" The Institute of Medicine, November 1999, p. 1.
89 "Leapfrog Hospital Survey Results" The Leapfrog Group, 2008, p. 3.

response if an alert was overridden.[90] Based on the Leapfrog Group's findings, HHS, specifically the *Agency for Healthcare Research & Quality* (AHRQ), encouraged (through federal funding) CPOE adoption by hospitals as a way to improve care and reduce costs.[91]

As of 2013, 616 U.S. hospitals had *some form of CPOE* system in place.[92] The ARRA and its incentive program have significantly increased the number of providers implementing CPOE systems with the incidence of *fully implemented CPOE* increasing from 87 hospitals annually pre-ARRA, to 233 in 2010 and 616 in 2013.[93] This increased adoption rate may be driven in part by the *Stage I meaningful use* requirements, applicable to all healthcare providers, which mandates that 30% of patients have a least one medication ordered through a CPOE system.[94] The status of CPOE implementation by hospitals is illustrated below, in Table 5-3: *Increased Rate of CPOE Implementation, 2009 to 2013*.

Table 5-3: Increased Rate of CPOE Implementation, 2009 to 2013[95]

Year	Percent Implementation	Growth in Implementation
2009	10%	N/A
2010	14%	40%
2011	18%	29%
2012	31%	72%
2013	43%	39%

> Only 8% of hospitals have fully implemented CPOE systems. In addition, CPOE hospitals tend to be larger, nonprofit, and teaching hospitals.
>
> ***Feliciano B. Yu et. al, June 5, 2009.***

CPOEs received much public attention following both the IOM's call for the use of electronic prescribing systems in all healthcare organizations by 2010 and the decision by the Leapfrog Group to encourage CPOE adoption by hospitals as a means to improve care and reduce costs.[96] Despite these initiatives, a 2009 study published in the *American Journal of Medical Quality*

90 "CPOE Adoption Slowly Gaining Ground: Survey" By Joseph Conn, Modern Healthcare, March 19, 2007, http://www.modernhealthcare.com/article/20070319/FREE/70319001 (Accessed 6/22/09).

91 "Inpatient Computerized Provider Order Entry (CPOE): Findings from the AHRQ Health IT Portfolio" By Brian E. Dixon and Atif Zafar, U.S. Department of Health & Human Services, Agency for Healthcare Research and Quality, January 2009, http://healthit.ahrq.gov/images/jan09cpoerport/cpoe_issue_paper.htm (Accessed 6/22/09); "Full Implementation of Computerized Physician Order Entry and Medication-Related Quality Outcomes: A Study of 3364 Hospitals" By Feliciano B. Yu et al., American Journal of Medical Quality, American College of Medical Quality, June 5, 2009, p. 1.

92 "Results of the 2013 Leapfrog Hospital Survey" The Leapfrog Group" July 2014, http://www.leapfroggroup.org/media/file/2013LeapfrogHospitalSurveyResults_Final071714.pdf (Accessed 3/13/15), p. 9..

93 "CPOE Rates Ratchet up with Passage of ARRA-HITECH" By Jennifer Prestigiacomo, Healthcare Informatics, August 16, 2011 (citing "CPOE 2011: The ARRA Effect" By Jason Hess, KLAS, July 2011; "Results of the 2013 Leapfrog Hospital Survey" The Leapfrog Group" July 2014, http://www.leapfroggroup.org/media/file/2013LeapfrogHospitalSurveyResults_Final071714.pdf (Accessed 3/13/15)).

94 "CPOE Rates Ratchet up with Passage of ARRA-HITECH" By Jennifer Prestigiacomo, Healthcare Informatics, August 16, 2011.

95 "Results of the 2013 Leapfrog Hospital Survey" The Leapfrog Group, July 2014, http://www.leapfroggroup.org/media/file/2013LeapfrogHospitalSurveyResults_Final071714.pdf (Accessed 3/13/15).

96 "Inpatient Computerized Provider Order Entry (CPOE): Findings from the AHRQ Health IT Portfolio" By Brian E. Dixon and Atif Zafar, U.S. Department of Health and Human Services, Agency for Healthcare Research and Quality, January 2009, http://healthit.ahrq.gov/images/jan09cpoerport/cpoe_issue_paper.htm (Accessed 6/22/09); "Full Implementation of Computerized Physician Order Entry and Medication-Related Quality Outcomes: A Study of 3364 Hospitals" By Feliciano B. Yu et al., American Journal of Medical Quality, American College of Medical Quality, June 5, 2009, p. 1.

found that only 8.0% of hospitals had a *fully implemented* CPOE system, much of which were larger, nonprofit teaching hospitals.[97]

Studies indicate that institutions that adopt CPOE systems are primarily focused on the safe and proper delivery of clinical services.[98] Political interests in clinical safety are more prevalent in governmental facilities than in for-profit hospitals. Physicians are also the stakeholders most opposed to the adoption of CPOE systems, due to a "perceived negative impact on physicians' workflow,"[99] and, accordingly, "[i]t may be that physicians are sufficiently powerful to prevent (CPOE) adoption at private hospitals but not sufficiently powerful to delay (CPOE) adoption at public institutions."[100] Additionally, the large percentage of teaching hospitals implementing CPOE systems could be explained as a correlation between education and a heightened commitment to innovation, as "results suggest that information about CPOE's benefits has not spread widely enough among key physicians or hospital decisionmakers [sic] outside of teaching institutions."[101]

Cost-Benefit Analysis

Prudent prescription and medication use has a substantial impact on the total cost of healthcare.[102] Overall, the financial impact of reported CPOE use has had a positive effect on the net operating income of an institution.[103] A 2014 study published in *Perspectives in Health Information Management* noted that "cost savings due to avoided ADEs rang[ed] from $7 to $16 million," with further annual savings of $92,000 due to reductions in tests performed by hospital physicians.[104] Further, a 2013 study published in the *Journal of the American Medical Informatics Association* noted that CPOE systems reduced medication errors by 12.5%.[105]

Although some studies have shown that implementation of CPOE systems has resulted in considerable gains in ordering process efficiency, other potential benefits of CPOE systems appear to have been disproved.[106] For example, although CPOEs are touted for their potential to promote effective leadership and other quality performance indicators, studies have so far shown that hospitals with complete CPOE systems do not systematically outperform, with regard to these factors, as compared to those without.[107] In addition, studies of CPOE systems are

97 "Full Implementation of Computerized Physician Order Entry and Medication-Related Quality Outcomes: A Study of 3364 Hospitals" By Feliciano B. Yu et al., American Journal of Medical Quality, American College of Medical Quality, June 5, 2009, p. 1.
98 "U.S. Adoption of Computerized Physician Order Entry Systems" By David M. Cutler, Naomi E. Feldman and Jill R. Horitz, Health Affairs, Vol. 24, No. 6 (November/December 2005), p. 1660.
99 "Overcoming Barriers To Adopting And Implementing Computerized Physician Order Entry Systems In U.S. Hospitals"
100 "U.S. Adoption of Computerized Physician Order Entry Systems" By David M. Cutler, Naomi E. Feldman and Jill R. Horitz, Health Affairs, Vol. 24, No. 6 (November/December 2005), p. 201, 1661.
101 Ibid, p. 1662.
102 "Saving Lives, Saving Money: The Imperative for Computerized Physician Order Entry In Massachusetts Hospitals" By Mitchell Adams et al., Massachusetts Technology Collaborative, New England Healthcare Institute, February 2008, p. 15.
103 "Impact of a Computerized Physician Order-Entry System" By William M. Stone et al., Journal of the American College of Surgeons, Vol. 208, Issue 5 (May 2009), p. 9.
104 "Can Utilizing a Computerized Provider Order Entry (CPOE) System Prevent Hospital Medical Errors and Adverse Drug Events?" By Krista Charles, MS, et al., Perspectives in Health Information Management, Fall 2014, p. 4.
105 "Reduction in Medication Errors in Hospitals due to Adoption of Computerized Provider Order Entry Systems" By David C. Radley et al., Journal of the American Medical Informatics Association, Vol. 20, No. 3 (March 2013), p. 473.
106 "Impact of a Computerized Physician Order-Entry System" By William M. Stone et al., Journal of the American College of Surgeons, Vol. 208, Issue 5 (May 2009), p. 7.
107 "Full Implementation of Computerized Physician Order Entry and Medication-Related Quality Outcomes: A Study of 3364 Hospitals" By Feliciano B. Yu et al., American Journal of Medical Quality, American College of Medical Quality, June 5, 2009, p. 7.

constrained by the technology's comparative youth, continued evolution, emphasis on evaluation of potential rather than actual errors, and limited dissemination.[108]

Despite these cost concerns, research has indicated that many hospitals respond proactively to financial incentives, especially for-profit hospitals, which have been shown to make calculated decisions based on profitability.[109] According to The Joint Commission, "investments in patient safety—although a moral obligation—usually provide financial benefits to payors and purchasers rather than to the organization, a point not lost on stressed organization leaders."[110] Additionally, changing the reimbursement structure to favor adoption of CPOE systems could offer a short-term solution to increasing investment in these systems.[111]

From 2004 to 2008, the AHRQ awarded more than $260 million in funding for *health information technology* (HIT), much of which focused on implementation and evaluation of CPOE.[112] This amount only covered part of the capital needed to secure and implement a CPOE system. Providers were required to utilize alternate funding sources, including payors, state-based loan programs, and organizational IT budgets. However, with the significant capital outlays required as well as resistance from physicians, the task of funding CPOE implementation can be daunting for hospital administrators.[113] To demonstrate, the 2014 *Perspectives in Health Information Management* study noted that only 30% of small hospitals had adopted CPOE, significantly lower than the 56% adoption rate by large hospitals.[114]

> *"*Since 2004, AHRQ has invested over $260 in contracts and grants to over 150 communities, hospitals, providers, and health care systems in 48 states to promote access to and encourage adoption of health IT.*"*
>
> ***Agency for Healthcare Research and Quality, August 2008,.***

Clinical Decision Support (CDS)

Clinical decision support (CDS) is a technology that provides clinicians with real-time feedback for a wide range of diagnostic- and treatment-related decisions as they are entering electronic patient records.[115] CPOE systems with CDS can minimize the incidence of medical errors by informing practitioners of potential drug interactions; patient allergies to prescribed medication(s); medication contraindications; and renal- and weight-based dosing by providing pop-up warnings when a complication exists with an order. However, *alert fatigue,* an

108 "Role of Computerized Physician Order Entry Systems in Facilitating Medication Errors" By Ross Koppel et al, Journal of the American Medical Association, Vol. 293, No. 10 (March 9, 2005), p. 1198.
109 "Making Profits and Providing Care: Comparing Non-profit, For-profit, and Governmental Hospitals" By Jill R. Horwitz, Health Affairs, Vol.24, No.3, (May/June 2005), p. 796.
110 "Patient Safety: Instilling Hospitals with a Culture of Continuous Improvement" Testimony of Dennis O'Leary, The Joint Commission, Testimony Before the Senate Committee on Governmental Affairs, (June 11, 2003), p. 4.
111 "Information Technology for Healthcare Quality Act" S.1223, Introduced (June 9, 2005); "The Future of Healthcare—Granting Access to Innovation in America Act" H.R.3607, Introduced (July 28, 2005).
112 "Decisionmaker Brief: Computerized Provider Order Entry" Agency for Healthcare Research and Quality, August 2008, http://healthit.ahrq.gov/sites/default/files/docs/page/08-0093_cpoe.pdf (Accessed 3/13/15).
113 "Lessons Learned from Implementation of Computerized Provider Order Entry in 5 Community Hospitals: A Qualitative Study" By Steven R. Simon et al., BMC Medical Informatics and Decision Making, Vol. 13, No. 67, June 24, 2013, p. 2.
114 "Can Utilizing a Computerized Provider Order Entry (CPOE) System Prevent Hospital Medical Errors and Adverse Drug Events?" By Krista Charles, MS, et al., Perspectives in Health Information Management, Fall 2014, p. 5.
115 "Inpatient Computerized Provider Order Entry (CPOE): Findings from the AHRQ Health IT Portfolio" By Brian E. Dixon and Atif Zafar, U.S. Department of Health and Human Services, Agency for Healthcare Research and Quality, January 2009, http://healthit.ahrq.gov/images/jan09cpoerport/cpoe_issue_paper.htm (Accessed 6/22/09).

overabundance of warnings that can occur when there is a combination of critical medical alerts and a high volume of marginally medically consequential alerts,[116] may desensitize and annoy practitioners, causing them to ignore vital alerts and potentially harm their patients.[117]

Quality of Care Improvements

A 2009 study in the *American Journal of Medical Quality* found significant positive associations between specific objective quality indicators and CPOE implementation.[118] Hospitals with CPOE systems noted that errors related to the legibility of paper orders were eliminated and alerts for potential allergies, drug interactions, and dosing standards improved patient safety. Further, the ability of a pharmacy to receive orders instantaneously resulted in "*stat*"[119] orders being filled faster.[120] In addition to preventing ADEs, CPOE systems also alert providers to available generic options for any prescription drug; notify clinicians of redundant orders or laboratory test entries; and list the drug delivery methods suitable for any prescribed drug to prevent delivery errors (e.g., intravenous administration of orally administered drugs). [121] CPOE systems could be even more beneficial to long-term care facility residents who, on average, have over six concurrent drug therapies, which, exacerbated by problems associated with advanced age, can increase the risk of an ADE.[122]

Barriers to Implementation

In addition to the costs associated with implementing a CPOE system, several other challenges should be considered, including: (1) technical issues; (2) unintended errors; and (3) physician reluctance.[123]

Technical Issues

It should be noted that there is no "one size fits all" CPOE system; therefore, many hospitals may need to customize their systems, including the integration of current systems.[124] This process necessitates thorough project planning and execution, which may hinder production and cause unforeseen delays.

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116 Ibid.
117 "CPOE: It Don't Come Easy" By Howard J. Anderson, Health Data Management, Vol. 17, No. 1 (January 2009), p. 19.
118 "Full Implementation of Computerized Physician Order Entry and Medication-Related Quality Outcomes: A Study of 3364 Hospitals" By Feliciano B. Yu et al., American Journal of Medical Quality, June 5, 2009, p. 1.
119 The term "stat" is short for the Latin word "statim," for immediately.
120 "CPOE: It Don't Come Easy" By Howard J. Anderson, Health Data Management, Vol. 17, No. 1 (January 2009), p. 20.
121 "Can Utilizing a Computerized Provider Order Entry (CPOE) System Prevent Hospital Medical Errors and Adverse Drug Events?" By Krista Charles, MS, et al., Perspectives in Health Information Management, Fall 2014, p. 2; "The Value of Computerized Provider Order Entry in Ambulatory Settings" Center for Information Technology Leadership, Partners HealthCare, http://www.partners.org/cird/pdfs/CITL_ACPOE_Full.pdf (Accessed 3/13/15), p. 4, 12, 54.
122 "Clinical Application of a Computerized System for Physician Order Entry With Clinical Decision Support to Prevent Adverse Drug Events in Long-Term Care" By Paula A. Rochon et al., Canadian Medical Association Journal, Vol. 174, No.1 (January 3, 2006), p. 52..
123 "Principles for a Successful Computerized Physician Order Entry Implementation" By Joan S. Ash, et al., American Medical Informatics Symposium Proceedings, 2003, p. 23; see Cost-Benefit Analysis, above.
124 "Inpatient Computerized Provider Order Entry (CPOE): Findings from the AHRQ Health IT Portfolio" By Brian E. Dixon and Atif Zafar, U.S. Department of Health and Human Services, Agency for Healthcare Research and Quality, January 2009, http://healthit.ahrq.gov/images/jan09cpoerport/cpoe_issue_paper.htm (Accessed 6/22/09).

Given the customization needed to integrate a CPOE system into any facility's infrastructure, a fair amount of training is required to ensure that clinicians, technicians, and practitioners will maintain and use the system consistently and correctly.[125]

Unintended Errors

CPOE system technology introduces other potential unintended errors, which include delivery of orders on incorrect patients, errors of clinician omission, lack of communication among clinical staff regarding the status of an order, loss of information during care transitions, and overlapping medication orders.[126] A 2005 study in the *Journal of the American Medical Association* found that one CPOE system facilitated 22 types of medication error risks generated by: (1) data fragmentation; (2) failure to integrate various computer and information systems; and (3) human-machine interface flaws.[127] However, as CPOE systems become more advanced, some of these unforeseen problems have decreased in frequency. For example, the average number of electronic patient entries in 2003 being re-entered was 48%, which percentage dropped to 21% by 2008.[128]

Physician Reluctance

Another potential barrier to use of CPOE is related to utilization by providers, i.e., (1) resistance to workflow changes (63%) and (2) too many clicks to place an order (32%).[129] User satisfaction has been identified as an important predictor of the success of CPOE adoption and compliance.[130] Typically, younger interns and residents are more willing to use CPOE, while older, more experienced physicians tend to be less satisfied with CPOE.[131]

One of the primary complaints from physicians is that it takes longer to enter an order electronically. Physicians also have reported a loss of professional autonomy because CPOE systems can prevent them from ordering the type of test(s) or medication(s) they prefer, force them to comply with clinical guidelines they do not embrace, and limit their flexibility through structured, rather than free-text clinical, documentation.[132]

125 Ibid.
126 "Impact of a Computerized Physician Order-Entry System" By William M. Stone, et al., Journal of the American College of Surgeons, Vol. 208, Issue 5 (May 2009), p. 7.
127 "Role of Computerized Physician Order Entry Systems in Facilitating Medication Errors" By Ross Koppel et al, Journal of the American Medical Association, Vol. 293, No. 10 (March 9, 2005), p. 1201.
128 "Computerized Physician Order Entry Usage in North America: The Doctor is In" By Stacilee Oakes Whiting and Adam Gale, HIT Report from KLAS, Healthcare Quarterly, Vol. 11, No. 3 (2008), p. 95.
129 "2012 CPOE and Meaningful Use Research Brief" Imprivata, p. 5.
130 "Does User Satisfaction Relate to Adoption Behavior?: An Exploratory Analysis using CPRS Implementation" By Charlene R. Weir et al, American Medical Informatics Association Symposium, 2000, p. 916.
131 "User Satisfaction with Computerized Order Entry System and its Effect on Workplace Level of Stress" By Nasrollah Ghahramani et al, Journal of Medical Systems, Vol. 33, No. 3 (July 2, 2008), p. 199.
132 "Types of Unintended Consequences Related to Computerized Provider Order Entry" By Emily M. Campbell, et al., Journal of the American Medical Informatics Association, Vol. 13, No. 5 (September/October 2006), p. 552.

Regulatory and Reimbursement

Regulatory

Individual states have enacted laws to reduce medical errors. The California Health and Safety Code Section 1339.63 states: "As a condition of licensure under this division, every general acute care hospital…special hospital…and surgical clinic…shall adopt a formal plan to eliminate or substantially reduce medication-related errors….This plan shall include technology implementation, such as, but not limited to, computerized physician order entry."[133] This law required all plans to be submitted by 2002, with the licensure changes taking effect on January 1, 2005.[134] A similar law in Massachusetts requires statewide implementation of CPOE systems by 2012.[135]

On a federal level, there have been several bills proposed in both the U.S. Senate and the U.S. House of Representatives regarding implementation of CPOE systems.[136] Although none of the bills specifically requiring CPOE implementation has been passed, the *Patient Safety and Quality Improvement Act of 2005* called for a report including suggestions on the reduction of medical errors to be submitted to the IOM.[137] In addition, the CMS 2004 Final Rule entitled, *Medicare and Medicaid Programs; Hospital Conditions of Participation: Quality Assessment and Performance Improvement*, created a quality assessment and performance improvement program to reduce medical errors, including medication errors.[138]

Reimbursement

In the past, financial incentives to support investments in CPOE technology were lacking, in part because public payors paid the same reimbursement for *unsafe care* as they did for *safe care*.[139] To combat this, some private insurers are leading the charge to incentivize hospitals to incorporate CPOE.[140]

The *Medicare Improvements for Patients and Providers Act of 2008* (MIPPA) created an incentive program for professionals to start e-prescribing. Section 132 of MIPPA established incentives for years 2009 through 2013, in which Medicare professionals who are successful e-prescribers received payments of 2.0 percent for 2009 and 2010, 1.0 percent for 2011 and 2012, and 0.5 percent for 2013.[141] The goal of these incentives was to allow the *Government*

133 "Minimization of Medication-Related Errors" Health and Safety Code Section 1339.63, California Code, September 2000.
134 Ibid.
135 "An Act to Promote Cost Containment, Transparency and Efficiency in the Delivery of Quality Health Care" The Commonwealth of Massachusetts, Senate, No. 2863, July 31, 2008.
136 "The Future of Healthcare—Granting Access to Innovation in America Act" House of Representatives Bill, H.R. 3607, July 28, 2005; "Information Technology for Health Care Quality Act" Senate Bill 1223, June 9, 2005; "A Bill to Provide for the Use of Improved Health Information Technology with Respect to Certain Safety Net Health Care Providers" United States Senate, S.890, April 23, 2009.
137 "Patient Safety and Quality Improvement Act of 2005" Pub. L. No. 109-41,119 Stat. 424, 430-431 (July 29, 2005).
138 "Medicare and Medicaid Programs; Hospital Conditions of Participation: Quality Assessment and Performance Improvement" Centers for Medicare & Medicaid Services, Department of Health & Human Services, Federal Register Vol. 68, No. 16 (January 24, 2003), p. 3435.
139 "Patient Safety: Instilling Hospitals with a Culture of Continuous Improvement" Testimony of Dennis O'Leary, The Joint Commission, Testimony Before the Senate Committee on Governmental Affairs (June 11, 2003), p. 2.
140 "Massachusetts Hospitals Should Adopt CPOE Systems, Group Says" iHealth Beat, February 15, 2008, http://www.ihealthbeat.org/Articles/2008/2/15/Massachusetts-Hospitals-Should-Adopt-CPOE-Systems-Groups-Say.aspx (Accessed 6/26/09).
141 "Medicare Improvements for Patients and Providers Act of 2008" H.R. Bill 6331 (January 3, 2008), p. 34-38.

Accountability Office (GAO) to submit a report on the implementation of the incentives for electronic prescribing to Congress by September 1, 2012.[142]

OUTSOURCING BILLING SERVICES

With physician professional practices under economic pressure to cut costs and adhere to heightened regulations regarding security and compliance, a greater number of practices use *outsourcing* as a "tool for survival and growth."[143]

Outsourcing in healthcare has yielded higher efficiency levels and more cost-effective outcomes and has also provided increased physician and patient satisfaction.[144] Many health practices are utilizing foreign companies for medical billing in response to those companies' guarantees of dramatic savings compared to their American counterparts.[145]

Despite the financial benefits of outsourcing billing, it also raises issues of compliance with HIPAA. A 2005 study showed that although many outsourcing service providers have implemented HIPAA requirements, others have chosen not to comply, citing "no public relations or brand problems anticipated with noncompliance" and "no anticipated legal consequences for non-compliance."[146] With lawmakers increasing penalties for noncompliance with privacy laws,[147] it is likely that outsourcing services providers will begin to increase their compliance efforts. The HITECH Act, enacted as part of ARRA,[148] delineates a tiered system for determining the appropriate penalties for HIPAA privacy violations.[149] HITECH Act provisions significantly increased the penalties for violations of HIPAA, allowing for penalties up to $1.5 million.[150]

TELEMEDICINE AND TELEHEALTH

Telemedicine is the transfer of electronic medical data (high resolution images, sounds, live video, and patient records) from one location to another in order to enhance the quality and efficiency of patient comfort and care. This technology utilizes a variety of telecommunication technologies, including, but not limited to, ordinary phone lines, integrated services digital network, fractional to full T-1 lines, ATMs, the Internet, and satellites.[151] *Telehealth* is closely

142 "CRS Report for Congress: P.L. 110-275: Medicare Improvement for Patients and Providers Act of 2008" By Hinda Chaikind et al., July 23, 2008, p. 11-12.
143 "Outsourcing of Healthcare Services: Issues & a Framework for Success" By Ram Misra, et al., Journal of Information Technology and Applications, Vol. 1, No. 2 (September 2006), p. 79-88.
144 Ibid.
145 "Offshore Outsourcing: Current and Future Effects on American IT Industry" By Laura L. Pfannenstein and Ray J. Tsai, Information Systems Management Journal (Fall 2004), p. 79.
146 "Outsourcing of Healthcare Services: Issues & a Framework for Success" By Ram Misra, et al., Journal of Information Technology and Applications, Vol. 1, No. 2 (September 2006), p. 79.
147 "Summary of the HIPAA Privacy Rule: Enforcement and Penalties for Noncompliance" U.S. Department of Health and Human Services, http://www.hhs.gov/ocr/privacy/hipaa/understanding/summary/index.html (Accessed 3/16/15).
148 "HHS Strengthens HIPAA Enforcement" News Release, U.S. Department of Health and Human Services, October 30, 2009, http://www.hhs.gov/news/press/2009pres/10/20091030a.html (Accessed 11/20/09).
149 "HIPAA and the HITECH Act: Know the Level of Penalties" HIPAA Weekly Advisor, Mar. 16, 2009, http://www.hcpro.com/print/HIM-229707-866/HIPAA-and-the-HITECH-Act-Know-the-level-of-penalties.html (Accessed 11/20/09).
150 "HHS Strengthens HIPAA Enforcement" News Release, U.S. Department of Health and Human Services, October 30, 2009, http://www.hhs.gov/news/press/2009pres/10/20091030a.html (Accessed 11/20/09).
151 "Telemedicine 101: A Brief History of Telemedicine" By Nancy Brown, Telemedicine Information Exchange, American Telemedicine Association, http://tie.telemed.org, May 30, 1995.

related to telemedicine and is used to describe remote healthcare, in a broader sense, that does not necessarily involve clinical services, although the two terms are often used interchangeably.[152]

According to former acting CMS Administrator Kerry Weems, utilizing communication equipment to link healthcare practitioners and patients in different locations "results in cost efficiency, reduced transportation expenses, improved patient access to specialists and mental health providers, improved quality of care, and better communication among providers."[153]

As of 2012, *telemedicine* services have been integrated into approximately 50 different medical subspecialties,[154] and approximately 200 telemedicine networks are established in the country, involving over 3000 medical and healthcare institutions.[155] Services offered through telemedicine include, but are not limited to:

(1) Specialized and primary care consultations; imaging services;
(2) Remote patient monitoring;
(3) Remote medical education and consumer information;
(4) *Networked programs* linking hospitals to rural clinics;
(5) *Point-to-point connection* using private networks between hospitals and ambulatory care sites;
(6) Primary or specialty care to the home connections;
(7) Home to monitoring centers; and
(8) Web-based e-health patient service sites.[156]

> Telemedicine services have been successfully integrated into approximately 50 different medical subspecialties.
>
> ***American Telemedicine Association, 2012)***

Trends in Telemedicine

The range of telemedicine technology is divided into two main application groups: (1) *Store and forward* is the transfer of digital images between locations, most commonly seen in teleradiology and telepathology (the use of pathology slides for diagnostic consultation)[157] and (2) *two-way interactive television* is used in telemedicine for face-to-face consultation. These real-time consultations often occur between patients or nurses in rural environments and practitioners.[158]

152 "Telemedicine Defined?" American Telemedicine Association, http:// www.@americantelemed.org/i4a/pagees/index.cfm?pageid=3333 (Accessed 6/30/09).
153 "Medicare's and Medicaid's New Reimbursement Policies for Telemedicine" By Alan Naditz, Telemedicine and eHealth, Vol. 14, No. 1 (January/February 2008), p. 21.
154 "Telemedicine Defined" American Telemedicine Association, http://www.americantelemed.org/i4a/pages/index.cfm?pageid=3333 (Accessed 07/16/12).
155 "About Telemedicine" American Telemedicine Association, 2012, http://www.americantelemed.org/i4a/pages/index.cfm?pageid3331 (Accessed 07/16/12); "What is Telemedicine" American Telemedicine Association, http://www.americantelemed.org/about-telemedicine/what-is-telemedicine#.VQcGgdJ4oqc (Accessed 3/16/15).
156 "Telemedicine Defined" American Telemedicine Association, http://www.americantelemed.org/i4a/pages/index.cfm?pageid=3333 (Accessed 7/16/12).
157 "Telemedicine 101: Telemedicine Coming of Age" By Nancy Brown, Telemedicine Information Exchange, American Telemedicine Association, http://tie.telemed.org, January 13, 2005.
158 Ibid.

One form of *store and forward* technology is related to the use of *patient monitoring*. Some of the situations most associated with telemedicine are those where patients' levels are monitored through a device that reports their health status to a remote provider through a satellite or cellular network. The top five conditions for *remote monitoring* are: (1) *diabetes*; (2) *prescription compliance*; (3) *active heart monitoring*; (4) *blood pressure*; and (5) *sleep apnea*.[159] Remote monitoring allows patients to receive more treatments in an outpatient setting and to be discharged more quickly because the patient can be observed outside of the hospital. As access to faster and higher bandwidth Internet and cellular providers improves, access to remote technologies similarly improves.[160]

One example of *remote monitoring* is the *Savacor Dynamic Rx* patient-operated handheld digital assistant, which is part of an integrated system that, using implantable heart monitoring devices, regularly monitors the patient for specific indicators (which are pre-programmed by the physician) specific to the individual patient. Those *indicators* then instruct the patient on how to adjust their medication, and they even provide instructions if the patient requires medical attention.[161] A potentially viable alternative to invasive techniques is *noninvasive physiologic monitoring*, such as wearable *body sensors* that *measure heart and respiratory rates, posture,* and *activity levels*. These vitals are then analyzed to identify potential diseases before the patient becomes symptomatic.[162]

Virtual clinics using telehealth technologies have been implemented nationwide and typically require patients to pay a flat fee to communicate with a physician using a webcam and an instant messaging program over the Internet for approximately ten minutes.[163] Telehealth clinics have been implemented on a broader scale throughout the country, with many states requiring coverage of the services. As of 2014, 46 states and the District of Columbia provide reimbursement through Medicaid, and 20 states and the District of Columbia require reimbursement through private insurance for telehealth services.[164] However, most states have restrictions on physician licensure that make interstate telemedicine difficult to implement.[165]

Hospitals, in efforts to reduce readmission rates, have begun utilizing telehealth technology. One such patient monitoring system, *VitalPoint Pro* by *CJPS Healthcare Supplies & Equipment, LLC*, emails or texts patient data to physicians for monitoring and also alerts clinicians when any of the 61 physiological indicators falls out of the preset parameters.[166] The capability to manage patients through *telemedicine* and the use of a *monitoring network* accessible through mobile devices has improved patient outcomes for conditions such as stroke by allowing providers to

159 "Top 5 Conditions for Telemedicine Treatment" By Steff Descgebes, Healthcare IT News, July 27, 2012, http://www.healthcareitnews.com/news/top-5-health-conditions-telemedicine-treatment (Accessed 9/26/12).
160 "Telecommuting" National Learning Consortium, October 21, 2011, p. 31.
161 "Heart Failure Devices: Raising Roadblocks To Readmission" By Mary Thompson, Medtech Insight, Vol. 14, No. 1 (January 2012), p. 7.
162 Ibid, p. 7-8.
163 "Visiting Your Doctor Online is a Virtual Reality" By Megan Johnson, U.S. News, http://health.usnews.com/health-news/family-health/articles/2009/10/27/visiting-your-doctor-online-is-a-virtual-reality (Accessed 3/16/15).
164 "50 State Telemedicine Gaps Analysis: Coverage & Reimbursement" By Latoya Thomas and Gary Capistrant, American Telemedicine Association, September 2014, http://www.americantelemed.org/docs/default-source/policy/50-state-telemedicine-gaps-analysis---coverage-and-reimbursement.pdf (Accessed 3/16/15), p. 2.
165 "50 State Telemedicine Gaps Analysis: Physician Practice Standards & Licensure" By Latoya Thomas and Gary Capistrant, American Telemedicine Association, September 2014, http://www.americantelemed.org/docs/default-source/policy/50-state-telemedicine-gaps-analysis--physician-practice-standards-licensure.pdf (Accessed 3/16/15), p. 2-3.
166 "CJPS Medical Systems VitalPoint® PRO User Manual" CJPS Medical Systems, 2011, p. v, 36-42.

view patient scans and send *emergency room* (ER) notifications to specialists immediately, facilitating more timely and accurate care decisions.[167]

Another example hospital utilization of telehealth technologies is *Mercy*, a multistate healthcare system in the Midwest, which announced the development of a $50 million, 120,000 square-foot virtual care center in 2015.[168] A 2015 projection estimated this center to manage more than three million telehealth visits between 2015 and 2020.[169] Currently, the system uses home monitoring for discharged patients with conditions such as heart failure and chronic obstructive pulmonary disease and is testing patients' follow-up coordination with their primary care physician through telehealth technology.[170] Mercy hopes to expand this innovation to hospitals without an intensivist or neurologist on staff in an effort to prevent readmissions and enable the treatment of potential *Intensive Care Unit* and stroke patients.[171]

The chief catalyst of *teleradiology* is the demand for *night coverage*, also known as *nighthawk coverage*, i.e., where physicians provide preliminary readings remotely when a patient need arises at a hospital operating with a limited staff during the night. Almost 50% of all radiology practices have supplemented their staff with external, remote providers,[172] and many teleradiology firms are competing to provide those services. As competition in this field has increased, pricing has become a significant market factor and, consequently, the *average price per procedur*e has begun to decline, which in turn has triggered aggressive *merger and acquisition* activities among *teleradiology firms*[173] that are now attempting to establish themselves as full-service professional radiology service providers.[174] The largest provider on the market according to FTEs and total studies done is currently *Virtual Radiologic (vRad)*,[175] which acquired its main competitor, *Nighthawk*, in September 2010.[176]

Advances in robotics now allow telehealth to have a tangible component. Mercy Folsom Hospital in California recently unveiled a robot diagnostic tool (costing approximately $500,000) that can be operated by a neurospecialist remotely to examine stroke victims.[177] Additionally,

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167 "Smartphone Teleradiology Application is Successfully Incorporated into a Telestroke Network Environment" By Bart M. Demaerschalk, et al., Stroke, Journal of the American Heart Association, Vol. 43, No. 11 (November 2012), p. 1-2.

168 "Transforming the Health of Our Communities" Mercy, 2015, http://www.mercy.net/about/transforming-the-health-of-our-communities (Accessed 3/26/15); "Telehealth Promises to Reshape Health Care" By Geri Aston, Hospitals & Health Networks: American Hospitals Association, March 10, 2015, http://www.hhnmag.com/display/HHN-news-article.dhtml?dcrPath=/templatedata/HF_Common/NewsArticle/data/HHN/Magazine/2015/Mar/cov-telehealth-patients-connect, (Accessed 3/26/15).

169 "Telehealth Promises to Reshape Health Care" By Geri Aston, Hospitals & Health Networks: American Hospitals Association, March 10, 2015, http://www.hhnmag.com/display/HHN-news-article.dhtml?dcrPath=/templatedata/HF_Common/NewsArticle/data/HHN/Magazine/2015/Mar/cov-telehealth-patients-connect, (Accessed 3/26/15).

170 Ibid.

171 Ibid.

172 "What Primary Considerations Govern Vendor Selection and Contract Administration in the Burgeoning Teleradiology Market" By Dara O'Brien, Imaging Economics, April 2012, http://www.imagingeconomics.com/issues/articles/2012-04_02.asp (Accessed 10/8/12).

173 "Teleradiology Firms Move in on PACS" By Nadim Daher, Diagnostic Imaging.com, http://www.diagnosticimaging.com/radblog/display/article/113619/1978195 (Accessed 10/8/12).

174 "Lines Blur Between Private and Corporate Radiology as Teleradiology Evolves" By Cheryl Proval, Radiology Business Journal, http://www.radiologybusiness.com/topics/care-delivery/lines-blur-between-private-and-corporate-radiology-teleradiology-evolves?nopaging=1 (Accessed 3/16/15).

175 "The 20 Largest Radiology-Services Companies: 2014" Radiology Business Journal, February 2014, https://s3.amazonaws.com/imagingbiz/img/top20.pdf (Accessed 3/16/15).

176 "Teleradiology Firms Move in on PACS" By Nadim Daher, Diagnostic Imaging.com, http://www.diagnosticimaging.com/radblog/display/article/113619/1978195 (Accessed 10/8/12).

177 "State Telehealth News" Telemedicine Information Exchange, April 30, 2009, http://tie.telemed.org/funding/news.asp (Accessed 7/1/09), p. 15.

Night Hospitalist Company, LLC (NHC) provides telephonic medical care from 7 PM to 7 AM for hospitals with ongoing staffing shortages. NHC employs both allopathic and osteopathic physicians who are licensed in multiple states to provide medical services from their homes for $500 per night.[178] NHC costs $60 per hour for services in hospitals with up to 50 beds, approximately half the cost of an in-house hospitalist.[179] Another pilot telehealth initiative, the RP-7 robot at Eagle Hospital in Atlanta, Georgia, is a mobile computer work station linked through a telehealth connection that is remotely controlled by a physician to traverse clinics, take histories, perform physicals, and admit patients remotely.[180] While the pilot program began with only ten hospitalists,[181] Eagle is continually seeking greater physician participation in the program.[182]

Digital telemedicine is allowing *x-rays* to be read overnight in India, psychotherapy to be conducted remotely, and mammograms to be screened automatically through digital scanning. As noted by PricewaterhouseCoopers, "[t]his explosion of technology applications holds not only the promise of more efficient and more effectively distributed care but also the potential for significant disruption for certain medical specialties."[183]

Cost-Benefit Analysis

A 2015 study performed by IHS Inc. at the request of the Association of American Medical Colleges (AAMC) predicted that, by 2025, there may be a shortage of up to 94,800 physicians (an estimated shortage of 12,500 to 31,100 primary care physicians and an estimated shortage of 28,200 to 63,700 non-primary care physicians[184]—including medical, surgical, and other specialists).[185] For hospitals that are experiencing physician shortages, telemedicine facilitates hospitalist recruitment, providing more attractive work hours for providers and allowing a single practitioner to provide services to multiple hospitals at one time. Additionally, telemedicine has improved access between hospitalists and specialists. Telemedicine also allows hospitals to expand their market service area by employing telemedicine technology at outlying medical clinics and offices.[186]

The VA is the largest provider of remote medical services, serving over 690,000 veterans in Fiscal Year 2014 alone.[187] Through telemedicine, by 2009 the VA had reduced the average

178 "Physician Partners" Night Hospitalist Company, http://www.nighthospitalist.com/physician-partners/ (Accessed 3/16/15).
179 "FAQ" Night Hospitalist Company, http://www.nighthospitalist.com/faq/ (Accessed 3/16/15).
180 "Night-Shift Solutions" By Lisa Ryan, The Hospitalist, April 2009, http://www.the-hospitalist.org/detains/article/183090/NightShift_Solutions.html (Accessed 6/20/09).
181 Ibid.
182 "Eagle Telemedicine FAQs" Eagle Hospital Physicians, http://www.eaglehospitalphysicians.com/pdf/TelemedicineFAQs.pdf (Accessed 3/16/15).
183 "What Works: Healing the Healthcare Staffing Shortage" PricewaterhouseCoopers' Health Research Institute, 2007, p. 27.
184 "The Complexities of Physician Supply and Demand: Projections from 2013 to 2025" IHS Inc. for Association of American Medical Colleges, March 2015, https://www.aamc.org/download/426242/data/ihsreportdownload.pdf (Accessed 3/16/15).
185 "Physician Supply and Demand Through 2025: Key Findings" Association of American Medical Colleges, https://www.aamc.org/download/426260/data/physiciansupplyanddemandthrough2025keyfindings.pdf (Accessed 3/16/15).
186 "Night-Shift Solutions" By Lisa Ryan, The Hospitalist, April 2009, http://www.the-hospitalist.org/detains/article/183090/NightShift_Solutions.html (Accessed 6/20/09).
187 "VA Telehealth Services Served Over 690,000 Veterans in Fiscal Year 2014" U.S. Department of Veterans Affairs, http://www.va.gov/opa/pressrel/pressrelease.cfm?id=2646 (Accessed 3/18/15).

length of stay at hospitals by 25%, and hospitalization by 19% for patients using home health services.[188]

> Through telemedicine, by 2009 the VA had reduced the average number of days hospitalized by 25% and reduced hospitalization by 19% for patients using home health.
>
> ***Government Health IT News, 2009.***

On May 5, 2011, CMS issued a *Final Rule* on telemedicine *credentialing* and *privileging*, which may aid in facilitating the implementation of *innovative medicine* at non-urban hospitals. This *Rule* allows *privileges* and *credentialing reciprocity* between an institution where a physician seeks to provide *telemedicine services* to Medicare and Medicaid patients and the hospital where a physician is *already privileged*.[189] Several professional associations have expressed approval of the new regulations. *The Joint Commission*, which controls much of telemedicine accreditation and has intimately involved with CMS policy surrounding this topic, touted the *Final Rule* as a positive step for improving access to care for patients in rural areas.[190] Additionally, the *American Hospital Association* (AHA) commended the *Final Rule's* flexibility and the inclusion of non-hospital entities, such as radiology groups and independent physicians, within the scope of the law.[191]

Despite this *Final Rule*, regulatory hurdles still remain. Physicians still face restrictions by state licensure laws in areas that do not extend *reciprocity* to physicians seeking to provide *telemedicine services* to hospitals in another state. Although every state, the District of Columbia, Puerto Rico, and Guam have some form of legislation addressing licensure for *telemedicine services*, these laws vary widely in flexibility and the scope of services covered, with many only permitting *consultations*.[192] Additionally, the degree of regulatory variations becomes even more fragmented in some states, with different laws for *allopathic physicians* (MD) and for *osteopathic physicians* (DO).[193]

Many healthcare practitioners have obtained federal funds for investments in telemedicine technology through grants, contracts, and direct services. The ARRA set aside $2.5 billion to be put into affiliated grants and loans for telemedicine. The act also called for complete adoption of EHRs by 2014, without which the implementation of telemedicine may have been hindered.[194] Additionally, the *Federal Communications Commission* created the *Rural Health Care Pilot Program* to increase patient access to telemedicine and support the transfer of EHRs. Sixty-nine nationwide projects across 38 states and the territories of Guam, American Samoa, and the

188 "VA Study Finds Home Telehealth Reduces Amount and Duration of Hospitalizations" Government Health IT News, Feb 26, 2009 http://telemed.org/homehealth/news.asp#item1744 (Accessed 9/24/09).
189 "Medicare and Medicaid Programs: Changes Affecting Hospital and Critical Access Hospital Conditions of Participation: Telemedicine Credentialing and Privileging" Federal Register Vol. 76, No. 87 (May 5, 2011), p. 25550.
190 "The Joint Commission Applauds CMS' Revised Telemedicine Requirements" By Elizabeth E. Zhani, The Joint Commission, News Details, May 6, 2011, http://www.jointcommission.org/the_joint_commission_applauds_cms_revised_telemedicine_requirements/ (Accessed 5/19/11).
191 "CMS Issues Final Rule on Telemedicine Credentialing Privileging" American Hospital Association, AHA News Now, May 2, 2011, http://www.ahanews.com/ahanews_app/jsp/display.jsp?dcrpath=AHANEWS/AHANewsNowArticle/data/ann_050211_telemedicine&domain=AHANEWS (Accessed 5/19/11).
192 "Telemedicine Overview: Board-by-Board Approach" Federation of State Medical Boards, August 2012.
193 Ibid.
194 "The American Recovery and Reinvestment Act of 2009: Summary of Key Health Information Technology Provisions" Healthcare Information and Management Systems Society, February 18, 2009.

Northern Mariana Islands were granted one-time funding (combined total of $418 million) to cover up to 85% of the cost of the construction of broadband networks to support participating healthcare providers in rural and urban areas.[195]

Barriers to Implementation

The two main barriers to telemedicine implementation are: (1) reimbursement obstacles from Medicare and certain private health insurers and (2) medical licensing. Depending on the licensing practices of the state, practitioners who utilize interstate telemedicine may have to be licensed in each of the states in which they treat patients, which can be time-consuming and expensive.[196]

Some physicians refrain from using telemedicine systems due to liability issues and skepticism regarding the competency of the technology. Generally, patients expect physicians at their bedside, not a video or voice transmitted through the Internet or satellite. Without traditional bedside care, there may be an increased likelihood of being sued if a problem occurs.[197] As with any form of technology, startup and training costs are associated with telemedicine. These vary depending on the technology being implemented and have the potential to hinder implementation for some providers, including some of the rural geographic locations most in need.[198]

Regulatory and Reimbursement

Regulatory

State

Physicians practicing medicine in any state must be approved by the licensure board of that particular state. In 2014, the American Telemedicine Association (ATA) released a comprehensive report addressing state telemedicine gaps in physician practice standards and licensure.[199] The report investigated the licensure and out-of-state practice laws of all 50 states and assigned a report card grade to each state ranging from A to F depending on how restrictive or friendly each state's laws were toward telemedicine.[200] Not a single state received an "A" grade, with the report finding that every state has some type of policy that makes practicing medicine across state lines difficult.[201] According to the report, five states (Massachusetts, Michigan, North Dakota, Pennsylvania, and South Dakota) received "F" grades and have fully restrictive licensure laws regarding interstate telemedicine,[202] which generally require a

195 "Wireline Competition Bureau Evaluation of Rural Health Care Pilot Program Staff Report" By Federal Communications Commission, August 13, 2012, https://apps.fcc.gov/edocs_public/attachmatch/DA-12-1332A1.pdf (Accessed 3/18/15), p. 2.
196 "Interstate Licensure of Telemedicine Practitioners" By Glenn W. Wachter, Telemedicine Information Exchange, March 10, 2000, updated by TIE on November 15, 2006.
197 "Night-Shift Solutions" By Lisa Ryan, The Hospitalist, April 2009, http://www.the-hospitalist.org/detains/article/183090/NightShift_Solutions.html (Accessed 6/20/09).
198 "Wireline Competition Bureau Evaluation of Rural Health Care Pilot Program Staff Report" By Federal Communications Commission, August 13, 2012, https://apps.fcc.gov/edocs_public/attachmatch/DA-12-1332A1.pdf (Accessed 3/18/15), p. 2-4.
199 "State Telemedicine Gap Analysis: Physician Practice Standards & Licensure" American Telemedicine Association, September 2014, http://www.americantelemed.org/docs/default-source/policy/50-state-telemedicine-gaps-analysis--physician-practice-standards-licensure.pdf?sfvrsn=12 (Accessed 3/18/15).
200 Ibid, p. 1-3.
201 Ibid, p. 9.
202 Ibid, p. 9.

practitioner to be fully licensed in *each* state in which he or she provides medical care to deliver telemedicine care across state lines.[203] However, other states with restrictive laws typically have several exceptions that allow telemedicine to be practiced interstate without a license from both states if:

(1) Interstate telemedicine is infrequent;
(2) A contractual relationship with compensation is not formed;
(3) Consultations are between two providers only (i.e., there is no patient involvement);
(4) Telemedicine is used for educational purposes;
(5) Telemedicine is used in a medical emergency or natural disaster;
(6) The referring practitioner retains primary medical control; or
(7) Telemedicine is used in service of the U.S. military.[204]

Reciprocal, or *limited licensure*, provides an interstate license for use with telemedicine for which practitioners can apply through a simple application process with reduced licensing fees. Reciprocal licenses work through a mutual exchange of privileges and permit one state to recognize the license of another jurisdiction, subjecting the practitioner to the rules of the jurisdiction in which the practitioner resides.[205] This license is solely for the practice of *telemedicine* and may not be used by practitioners to provide *bedside care* in another state. The 2014 ATA report found that D.C., Maryland, New York, and Virginia allowed reciprocal licenses for bordering states and found that Alabama, Louisiana, Minnesota, Montana, Nevada, New Mexico, Ohio, Oregon, Tennessee, and Texas extended reciprocal licenses to out of state physicians.[206] See table 5-4, below, for a summary of ATA's state telemedicine licensing grades.

Table 5-4: Summary of ATA State Ratings for Licensure and Out-of-State Practice, 2014[207]

Grade Received	"A"	"B"	"C"	"D"	"F"
Number of States	0	13 + DC	32	0	5

In contrast to physician reciprocal licenses, an interstate license for nurses, first created in 2000, has been widely accepted by the *National Council of State Boards of Nursing*. A nurse residing in a state that participates in the *Nurse Licensure Compact* may hold a license in his or her "home state" and practice either *physically* or *remotely* in another state, while being subject to the practice laws and regulations of both states.[208]

203 "Telemedicine Licensure Report" Center for Telemedicine Law, Office for the Advancement of Telehealth, June, 2003; "Updated numbers from "Interstate Licensure of Telemedicine Practitioners" By Glenn W. Wachter, Telemedicine Information Exchange, March 10, 2000, undated By TIE on November 15, 2006, http://tie.telemed.org/articles/article.asp?path=article&article=interstateLicensure_gw_tie0 (Accessed 7/1/09).

204 Ibid.

205 "Telemedicine Licensure Report" Center for Telemedicine Law, Office for the Advancement of Telehealth, June, 2003; "Interstate Licensure of Telemedicine Practitioners" By Glenn W. Wachter, Telemedicine Information Exchange, March 10, 2000, undated By TIE on November 15, 2006, http://tie.telemed.org/articles/article.asp?path=article&article=interstateLicensure_gw_tie0 (Accessed 7/1/09).

206 "State Telemedicine Gap Analysis: Physician Practice Standards & Licensure" American Telemedicine Association, September 2014, http://www.americantelemed.org/docs/default-source/policy/50-state-telemedicine-gaps-analysis--physician-practice-standards-licensure.pdf?sfvrsn=12 (Accessed 3/18/15).

207 "State Telemedicine Gap Analysis: Physician Practice Standards & Licensure" American Telemedicine Association, September 2014, http://www.americantelemed.org/docs/default-source/policy/50-state-telemedicine-gaps-analysis--physician-practice-standards-licensure.pdf?sfvrsn=12 (Accessed 3/18/15).

208 "Nurse Licensure Compact" Nurse Licensure Compact Administration, National Council of State Boards of Nursing, https://www.ncsbn.org/nlc.htm (Accessed 7/2/09).

Telehealth and telemedicine are also subject to The Joint Commission standards.[209]

Federal

Similar to any electronic transfer of patient medical information, telemedicine practitioners must comply with HIPAA regulations. Telehealth and telemedicine are also subject to *The Joint Commission* standards.[210] Current *Joint Commission* standards focus on services provided by *licensed independent practitioners* (LIPs) who diagnose or treat patients by way of a telemedicine link.[211] Under the current standards, most recently revised in 2012, a hospital may rely on the site of the LIP providing the service (referred to as the *distant site*) for credentialing as long as that site is accredited by the *Joint Commission*.[212] Otherwise, the LIP must be credentialed at the site where the patient is located (the *originating site*).[213] Additionally, the originating site must make certain that all distant-site credentialing and privileging processes cooperate with the Medicare Conditions of Participation at a minimum.[214]

The same *Joint Commission* standards also apply to practitioners who provide *interpretive services* (e.g., teleradiology and telepathology) and those who provide *consultations*, only "for the sole purpose of offering an expert opinion and/or advising the treating practitioner but not directing the patient's care."[215] These services are usually contracted out for and must therefore also meet the contracted service standard (i.e., LD.3.50).[216] In contrast, CMS requires LIPs to be credentialed at the *originating site*. In November 2008, the Joint Commission revised its standards to reflect this discrepancy, but reverted back to its original opinion in March 2009.[217] *The Medicare Telehealth Enhancement Act of 2009* (HR 2068), introduced to Congress on April 23, 2009, was referred to the House Ways and Means committee (without further advancement) and addressed *The Joint Commission* and CMS credentialing issues.[218]

209 "Hospital-wide PACS Need Tighter Data Security" Diagnostic Imaging PACS Supplement, Feb. 2000, www.dimag.com/db_area/archives/2000/0002pnews.3-7.html (accessed March 31, 2000).

210 "JCAHO Published New Hospital Credentialing Standards for Telemedicine" Mondaq Business Briefing, November 5 2003, http://www.thefreelibrary.com/_/print/PrintArticle.aspx?id=109771648 (Accessed 7/1/09); "Final HIPAA Privacy Rules" By the Health Resources and Services Administration, February 2001, http://www.hrsa.gov/telehealth/pubs/hippa.htm (Accessed 11/19/09).

211 "Existing Requirements for Telemedicine Practitioners Explained" Joint Commission Perspectives, February 2003, p. 4.

212 "Final Revisions to Telemedicine Standards" The Joint Commission, Joint Commission Perspectives, January 2012, http://www.jointcommission.org/assets/1/6/Revisions_telemedicine_standards.pdf (Accessed 3/18/15).

213 "The Joint Commission and Telemedicine: The Final Word?" Accreditation Monthly, May 13, 2009 http://www.accreditationcenter.com/The-Joint-Commission-and-Telemedicine-The-Final-Word.html (Accessed 7/1/09); "Existing Requirements for Telemedicine Practitioners Explained" Joint Commission Perspectives, February 2003; "JCAHO Published New Hospital Credentialing Standards for Telemedicine" Mondaq Business Briefing, November 5 2003, http://www.thefreelibrary.com/_/print/PrintArticle.aspx?id=109771648 (Accessed 7/1/09).

214 "Final Revisions to Telemedicine Standards" The Joint Commission, Joint Commission Perspectives, January 2012, http://www.jointcommission.org/assets/1/6/Revisions_telemedicine_standards.pdf (Accessed 3/18/15).

215 "Existing Requirements for Telemedicine Practitioners Explained" Joint Commission Perspectives, February 2003.

216 "JCAHO Published New Hospital Credentialing Standards for Telemedicine" Mondaq Business Briefing, November 5, 2003, http://www.thefreelibrary.com/_/print/PrintArticle.aspx?id=109771648 (Accessed 7/1/09).

217 "The Joint Commission and Telemedicine: The Final Word? Accreditation Monthly, May 13, 2009, http://www.accreditationcenter.com/The-Joint-Commission-and-Telemedicine-The-Final-Word.html (Accessed 7/1/09).

218 "Medicare Telehealth Enhancement Act of 2009" 111th Congress, Bill H.R. 2068, introduced April 23, 2009; "Waters: Telemedicine Boosts Access to Needed Care" By Robert J. Waters, Roll Call, June 8, 2009, http://www.rollcall.com/features/Mission-Ahead_Health-Care/ma_healthcare/-35540-1.html (Accessed 4/1/15).

Reimbursement

State

As of March 2015, approximately 22 states have laws requiring private insurers to reimburse for telehealth-related services at the same rate as in-person services (known as *parity laws*), while in states without such laws, it is at the discretion of the insurer whether or not to reimburse providers for telehealth services.[219] To track the reimbursement of healthcare services, some states utilize code modifiers in addition to their CPT codes to indicate that the service provided was through a telemedicine format. For example, Ohio uses their modifier to indicate that telemedicine was the originating service for the delivery of evaluation and management care or for psychiatric services.[220]

A 2007 survey study regarding private payer reimbursement for telemedicine, which updated a 2003 survey performed by ATA, found that 58% of telemedicine programs that offered billable services received private payer reimbursement, an increase of 5 from 2003.[221] As of February 2015, 46 states and the District of Columbia had one or more policies in place to provide at least some reimbursement through Medicaid, with only Massachusetts, New Hampshire, and Rhode Island not reimbursing for telehealth services.[222] Iowa does not have any formal codified policy but recently posted a letter on their website indicating that their Medicaid program will pay for covered services if they are rendered via telemedicine if the standard medical community would support rendering these services through telemedicine.[223]

Federal

The *Balanced Budget Act of 1997* limited the scope of Medicare telehealth coverage to consultation services only.[224] Section 223 of the Medicare, Medicaid and State Children's Health Insurance Program (SCHIP) *Benefits Improvement and Protection Act of 2000* (BIPA), however, revised Medicare reimbursement to cover telehealth serviced on or after October 1, 2001 to include consultations, office visits, individual psychotherapy, and pharmacologic management.[225] Services were only covered for cases with interactive audio and video telecommunication systems when the patient was present and participating in the telemedicine visit. Eligible

219 "State Telemedicine Gaps Analysis: Coverage & Reimbursement" American Telemedicine Association, September 2014, http://www.americantelemed.org/docs/default-source/policy/50-state-telemedicine-gaps-analysis---coverage-and-reimbursement.pdf (Accessed 3/18/15); "NY Governor Signs Telemedicine Law While Other States Make Progress with New Proposals" American Telemedicine Association, January 7, 2015, http://www.americantelemed.org/news-landing/2015/01/07/ny-governor-signs-telemedicine-law-while-other-states-make-progress-with-new-proposals#.VQnurU05Cig (Accessed 3/18/15).

220 "Medicaid Coverage of Telemedicine and Related Services" Ohio Department of Medicaid, Medicaid Handbook Transmittal Letter No. 3334-15-01, January 2, 2015, http://emanuals.odjfs.state.oh.us/emanuals/DataImages.srv/emanuals/pdf/pdf_books/GeneralInformationForMedicaidProviders.pdf (Accessed 3/26/15), p. 8.

221 "Private Payer Reimbursement for Telemedicine Services in the United States" By Pamela Whitten and Lorraine Buis, Telemedicine and e-Health, Vol. 13, No. 1 (2007), p. 15.

222 "State Telehealth Laws and Medicaid Program Policies" Center for Connected Health Policy, February 2015, http://cchpca.org/sites/default/files/resources/State%20Laws%20and%20Reimbursement%20Policies%20Report%20Feb%20%202015.pdf (Accessed 3/26/15), p. 5.

223 "State Telehealth Laws and Medicaid Program Policies" Center for Connected Health Policy, February 2015, http://cchpca.org/sites/default/files/resources/State%20Laws%20and%20Reimbursement%20Policies%20Report%20Feb%20%202015.pdf (Accessed 3/26/15), p. 5.

224 "The Balanced Budget Act of 1997" Pub. L. No. 105-33, § 4206, 111 Stat. 251, 377-378 (August 5, 1997).

225 "Medicare, Medicaid, SCHIP Balanced Budget Improvement and Protection Act of 2000" Pub. L. No. 106-554, §223, 114 Stat. 2763A-463, 2763A-487 - 2763A-490.

geographic areas included rural health areas with practitioner shortages and counties not classified as part of an established *metropolitan statistical area*.[226]

Additionally, section 149 of MIPPA amended BIPA to reimburse services provided on or after January 1, 2009 for telehealth services performed in the office of a physician or practitioner, hospital, *critical access hospital* (CAH), rural health clinic, federally qualified health center, hospital-based or CAH-based renal dialysis facility, skilled nursing facility, or community medical center.[227] In addition, the act requires both the distant practitioner and patient to be present at the telehealth "visit" and interact in real-time communication.[228]

Currently, Medicare only provides reimbursement for services to patients who receive care from facilities in rural *Health Professional Shortage Areas*, and only from those specific facilities that are listed in the law, e.g., skilled nursing facilities, physician offices, or hospitals.[229] Additionally, Medicare only reimburses for a small set of services (e.g., office visits, pharmacological management, individual and group diabetes self-management training services, and consultations) that are provided through a real-time video-and-voice telecommunication system.[230] These services amount to roughly 75 service codes out of 10,000.[231] In January 2015, the U.S. House of Representatives Committee on Energy and Commerce released a draft bill that would modernize Medicare's approach to telehealth reimbursement.[232] However, this draft has been heavily criticized by healthcare associations, such as the *American Hospital Association*, for not taking a more global approach to permitting the use of telehealth services.[233]

CLINICAL TECHNOLOGY

In addition to the *development* and *utilization* of *healthcare management information technology*, there have also been advances in the development of *clinical technology*, which have led to numerous treatment discoveries and innovations. *Clinical technology* encompasses any *method* or *device* used in *patient treatment procedures*, e.g., (1) *pharmaceuticals*; (2) *surgical devices*; and (3) *minimally invasive techniques*. Notably, in an *effective* and *efficiently* operated healthcare enterprise, *management* and *clinical technologies* complement each other and may, in many cases, *overlap*[234].

One significant effect of *clinical technology* advancements is the transition to more procedures being offered in outpatient settings. Specifically, advancements have resulted in: (1) less *invasive procedures*; (2) shorter *recovery times*; and (3) lower probability of *complications*, all of which

226 "Medicare Claims: Adding Certain Entities as Originative Sites for Payment of Telehealth Services—Section 149 on the Medicare Improvements for Patients and Providers Act of 2008 (MIPPA)" Centers for Medicare & Medicaid Services, Pub 100-04, November 14, 2008.
227 "Medicare Improvements for Patients and Providers Act of 2008" Pub. L. No. 110-275, §149, 122 Stat. 2494, 2549 (July 15, 2008).
228 "Medicare Claims: Adding Certain Entities as Originative Sites for Payment of Telehealth Services—Section 149 on the Medicare Improvements for Patients and Providers Act of 2008" Centers for Medicare & Medicaid Services, Pub 100-04, November 14, 2008.
229 "Re: Telehealth Discussion Draft" American Hospital Association, Letter to Chairman Upton, January 26, 2015, p. 1-2.
230 Ibid.
231 Ibid.
232 "[Discussion Draft]: Sec. ___. Advancing Telehealth Opportunities in Medicare" House Committee on Energy and Commerce, January 9, 2015.
233 "Re: Telehealth Discussion Draft" American Hospital Association, Letter to Chairman Upton, January 26, 2015, p. 3-4.
234 Discussed above in the Technology section as "Process".

have allowed for procedures that have traditionally been performed in an *inpatient setting* to be offered on an *outpatient basis*. Outpatient procedures comprised approximately 64% of U.S. surgeries in 2010, with that figure increasing slightly through 2013.[235] The increased costs associated with inpatient care, as well as the overall increase in healthcare demand, have contributed to increased outpatient service utilization from 366 million visits in 1993 to over 677 million in 2013,[236] a growth pattern that will likely continue in response to persistent *cost containment pressures*,[237] and the advancements in technology that have facilitated the shift from *inpatient* to *outpatient*.

As technology has advanced, so too has the way patient care is viewed, leading to technological developments related not only to the *treatment setting* (e.g., movement from *inpatient* to *outpatient*), but also the manner by which diseases are understood and treatments are managed by providers. Recent developments regarding *genetics*, *gene therapy*, and *personalized medicine* have largely been made possible by the science of *genomics*.

THE GATEWAY: GENETICS, GENOMICS, AND GENOME TECHNOLOGY

The term *personalized medicine* has been used in several venues, such as *customized pharmaceuticals* and *customized diagnoses*. The landmark discoveries accompanying the advent of genome sequencing was the first step toward much of the technological advancement that served as the basis for a new genre of pharmaceutical and therapeutic medicine. In 2003, the *Human Genome Project* at the *National Institutes of Health* completed the initial mapping of the human genome, a milestone that fueled interest in the field of *genomics*.[238] The technological advancements that followed served as the foundation for a new genre of pharmaceutical and therapeutic medicine. Biotechnology and biopharmaceuticals are influential drivers in today's market, accounting for the highest valued mergers and acquisitions in 2015.[239]

Genomics is the evaluation of the hereditary information provided by an organism's DNA and the application of research findings to the fields of genetic engineering and enhancement, cloning, stem cell research, and eugenics.[240] *The National Center for Human Genome Research Institute* (NCHGRI) is comprised of more than 50 researchers who are dedicated to specific facets of genetic and genomic research and contribute accordingly to one of seven branches of the NCHGRI: (1) Cancer Genetics; (2) Genetic Disease Research; (3) Genetics and Molecular Biology; (4) Genome Technology; (5) Inherited Disease Research; (6) Medical Genetics; and

235 "Chart 3.11: Percentage Share of Inpatient vs. Outpatient Surgeries, 1993—2013, in "Trendwatch Chartbook 2015: Trends Affecting Hospitals and Health Systems" American Hospital Association and Avalere, 2015, retrieved from http://www.aha.org/research/reports/tw/chartbook/ch3.shtml (Accessed 3/26/15).

236 "Table 3.4: Outpatient Utilization in Community Hospitals, 1993-2013" in "Trendwatch Chartbook 2015: Trends Affecting Hospitals and Health Systems" American Hospital Association and Avalere, 2015, retrieved from http://www.aha.org/research/reports/tw/chartbook/ch3.shtml (Accessed 3/26/15), p. A-29.

237 "Payments to Hospitals for Inpatient Hospital Services" 42 U.S.C. § 1395(ww)(b)(2) (2010).

238 "Human Genome Project: Fact Sheet" By National Institutes of Health, October 2010, http://report.nih.gov/NIHfactsheets/Pdfs/HumanGenomeProject(NHGRI).pdf (Accessed 3/19/15), p. 1.

239 "US M&A News and Trends" BY FACTSET, Flashwire US Monthly, February 2015, https://www.factset.com/mergerstat_em/monthly/US_Flashwire_Monthly.pdf (Accessed 3/18/15), p. 3.

240 "Talking Glossary of Genetic Terms: Genomics" By National Human Genome Research Institute, http://www.genome.gov/Glossary/index.cfm?id=532 (Accessed 3/19/15); "Biomedical Research Issues in Genetics" By the National Human Genome Research Institute, January 6, 2009, http://www.genome.gov/10001740 (Accessed 6/29/09).

(7) Social and Behavioral Research.[241] Several areas of *genomics, cell-based therapies*, and *molecular targeting therapies* also seem to hold promise for future advancements in the treatment of cardiac disease.[242] For example, *pharmacogenomics* applies the "genetic variability in patients' responsiveness to a drug in order to inform clinical decisions about dosing and selection."[243] A "broader vision for personalized medicine extends beyond the development of individual treatment [plans] to individualized [disease] prevention [and early intervention] strategies, e.g., Type 2 diabetes."[244]

One means of achieving this "*vision*" of *personalized medicine* may be through the use of mobile medical applications (*"m-health apps"*), which may be downloaded on smartphones and computer tablets. It is expected that these *"m-health apps",* which have expanded rapidly in the marketplace, will allow healthcare providers to efficiently develop and distribute *"best-practice"* standards and treatment protocols to providers.[245] Additionally, *"m-health apps*" are beginning to be utilized by patients to monitor chronic conditions by reporting such information as blood pressure levels or sugar levels to their physicians.[246]

Genomic understanding has given pharmaceutical companies new therapeutic targets as well as the ability to improve existing drugs.[247] It is possible that genetic composition may be at least partly responsible for some adverse drug reactions, and understanding that composition may allow pharmaceutical companies to design more compatible drugs or to identify those patients who should not be given particular therapies.[248] In recent years, certain genes have been associated with an increased risk of developing particular diseases or conditions, and the identification of such genes may allow individuals to take preventative measures against such conditions, particularly various forms of cancer. However, other findings indicate that such unsubstantiated information may present more harm than good,[249] e.g.: (1) stress on the individual being diagnosed or (2) unnecessary medical procedures, such as premature mastectomies.

As the market for personalized medicine expands and additional research related to genetic diagnoses saturates consumer driven healthcare channels, several companies offering personalized genetic mapping, known as *genotyping*, have appeared (e.g., 23andme.com). These direct-to-consumer genetic testing companies sell genetic kits that take a small sample of cells,

241 "Overview of the Division of Intramural Research" By National Human Genome Research Institute, August 27, 2009, http://www.genome.gov/10001634 (Accessed 11/25/09).

242 "A Tale of Coronary Artery Disease and Myocardial Infarction" By Elizabeth G. Nabel and Eugene Braunwald, The New England Journal of Medicine, Vol. 366, No. 1 (January 5, 2012), p. 61.

243 Ibid.

244 "Personalized Medicine To Identify Genetic Risks for Type 2 Diabetes and Focus" By Allen M. Spiegel, and Meredith Hawkins, Health Affairs, Vol. 31, No. 1 (January 2012), p. 44; "Improving Health by Taking It Personally" By Ralph Snyderman, and Michaela A. Dinan, Journal of the American Medical Association, Vol. 303, No. 4 (January 27, 2010), p. 363.

245 "Chapter 1: Healthcare Reform: The Transformation of America's Hospitals: Economics Drives a New Business Model" in "Futurescan 2012: Healthcare Trends and Implications 2012-2017" By Kenneth Kaufman and Mark E. Grubs, VHA Inc., Irving, Texas (2012), p. 8; "Beyond UX: Best Practices for Medical App Development" By Mithun Sridharan, Innovation Insights, August 4, 2014, http://insights.wired.com/profiles/blogs/beyond-ux-best-practices-for-medical-app-development#axzz3UleZE3Fn (Accessed 3/18/15).

246 "5 Critical Technologies Health Systems Should Require" By Michelle McNickle, Healthcare IT News, July 30, 2012, http://www.healthcareitnews.com/news/5-critical-technologies-health-systems-should-require (Accessed 9/21/12).

247 "Technology and the Boundaries of the Hospital: Three Emerging Technologies" By Jeff Goldsmith, Health Affairs, Vol. 23, No. 6 (2004), p. 150.

248 "Technology and the Boundaries of the Hospital: Three Emerging Technologies" By Jeff Goldsmith, Health Affairs, Vol. 23, No. 6 (2004), p. 150.

249 "Letting the Genome Out of the Bottle: Will We Get Our Wish?" By David J. Hunter, et al., New England Journal of Medicine, Vol. 358, No. 2 (January 10, 2008), p. 106-107.

typically via a cheek swab, and generate a genetic profile for the customer, which may indicate any diseases to which the individual may be prone.[250] The FTC and CDC have warned that some of these at-home genetic testing kits lack scientific validity and caution against reviewing test results without a doctor's counsel.[251] Some states, such as California and New York, have intervened in the distribution of an individual's genetic profile and potential future diseases without physician direction and have sent cease and desist letters to several companies.[252] Additionally, four states, i.e.: (1) California; (2) Nevada; (3) Nebraska; and (4) Pennsylvania have passed legislation prohibiting misleading advertisements for genetic tests.[253]

The realities of *personalized medicine* produce a multitude of regulatory and reimbursement issues. Although HIPAA was designed to protect individual health information, the advancement of genetic testing has surpassed the regulatory standards as set forth under HIPAA. Subsequent legislation has attempted to protect an individual's genetic information while allowing for the furtherance of personalized medicine.[254] Similar to HIPAA, the *Genetic Information Nondiscrimination Act of 2008* (GINA), enacted on May 21, 2008, was promulgated to protect against the *misuse* of their *personal health information*.[255] GINA prohibits the use of genetic information for *discriminatory* purposes by *employers* and *health insurance companies* and amends both the *Employee Retirement Income Security Act* and the *Internal Revenue Code*.[256]

STEM CELL RESEARCH

Within any living organism, each cell is specialized to a specific biological system. *Stem cells* are "unspecialized cells capable of renewing themselves through cell division, sometimes after long periods of inactivity," and capable of adapting their function to accommodate a certain type of tissue or organ under the proper conditions.[257] The unique regenerative capacity of stem cells has the potential to change the way health problems, e.g., diabetes and heart disease, are treated. As such, efforts to advance *reparative medicine* (therapies that heal the body's natural tissue) by developing efficacious cell therapies are at the forefront of medical research.[258] In June 2011, the first completely synthetic human organ (a trachea) was successfully grown from human stem cells and transplanted.[259] However, *synthetic organs* only function at a fraction of their *natural*

250 "How does 23andMe genotype my DNA?" 23andme Customer Care, https://customercare.23andme.com/entries/21263328 (Accessed 9/26/12).
251 "Direct-to-Consumer Genetic Tests" Federal Trade Commission: Consumer Information, January 2014, http://www.consumer.ftc.gov/articles/0166-direct-consumer-genetic-tests (Accessed 3/18/15).
252 "Federal and State Responses to Dangers of At-Home Genetic Testing" By Sara Hoverter and Danielle Perlman from Georgetown School of Law, Memorandum to Steve Sakamoto-Wengel, Maryland Office of the Attorney General Paul Ballard, Maryland Office of the Attorney General, February 4, 2011.
253 "Federal and State Responses to Dangers of At-Home Genetic Testing" By Sara Hoverter and Danielle Perlman from Georgetown School of Law, Memorandum to Steve Sakamoto-Wengel, Maryland Office of the Attorney General Paul Ballard, Maryland Office of the Attorney General, February 4, 2011; West's Annotated California Business & Professional Code § 17508(a); Nevada Revised Statutes Annotated § 598.0925(1)(a); Nebraska Revised Statute § 87-302(a)(14); 18 Pennsylvania C.S.A. § 4107 (a)(10).
254 "Personalized Medicine-Part 2: Ethical, Legal, and Regulatory Issues" By F. Randy Vogenberg, et al., Journal of Pharmacy and Therapeutics, Vol. 35, No. 11 (November 2010), p. 629. See the Privacy Laws section in Chapter 3: Regulatory Environment for a further discussion of HIPAA and protected health information
255 "Genetic Information Nondiscrimination Act" Pub. L. No. 110-233, 112 Stat. 881 (May 21, 2008).
256 Ibid.
257 "Stem Cell Information: Stem Cell Basics" By the National Institutes of Health, U.S. Department of Health & Human Services, April 28, 2009, http://stemcells.nih.gov/staticresources/info/basics/SCprimer2009.pdf (Accessed 3/19/15), p. 1-2.
258 Ibid, p. 2.
259 "World's First Synthetic Organ Transplant" Discovery News, July 8, 2011, http://news.discovery.com/human/first-artificial-organ-transplant-110708.html (Accessed 3/19/15).

counterparts, e.g., a *synthetic lung* grown from stem cells functioned at approximately five percent of the effective rate of a *natural lung when tested in rats at Yale University*.[260]

On January 23, 2009, the first *human embryonic stem cell* (hESC)-based therapy was approved for clinical trial when *Geron Corporation* announced the clearance of their *Investigational New Drug* (IND) application for the clinical trial of *GRNOPC1*, which manipulates the growth-stimulating properties of nerve cells to aid in rehabilitating acute spinal cord injuries.[261] Stem cell research is also being to: (1) investigate the causes of birth defects; (2) enhance drug development by providing molecular insight; and (3) expedite the drug approval process through the facilitation of preliminary drug testing.[262] Additionally, understanding the differences between embryonic and non-embryonic stem cell proliferation may be the key to understanding - and treating - cancer.[263] Recent trends and advances in stem cell technology have proved promising, with approximately 28 *adult stem cell* clinical studies completed, 20 actively underway, another 14 currently recruiting volunteers, and 5 approved for conducting a clinical study but not yet recruiting volunteers as of 2015.[264]

The completion of the draft human genome sequence in 2001 was followed by research inquiries targeting transcripts (transcriptomics); RNAi/miRNAs (interferomics and micro-RNomics); proteins (proteomics); interacting proteins (interactomics); DNA and chromatin modifications (epigenomics); and metabolites (metabolomics).[265] Developments in these areas contributed significantly to the molecular understanding of biology, pathology, and pharmacology; any advances in molecular research are dictated by progress in these genomic substrata.[266] Furthermore, molecular diagnostics represent the sector of the genomics market with the most promise.[267]

> On January 23, 2009, the first human embryonic stem cell (hESC)-based therapy was approved for clinical trial.
>
> ***Geron: Visionary Therapeutics, 2009.***

DIAGNOSTIC MEDICINE & TECHNOLOGY

Diagnostic medicine is utilized in both acute and chronic care for the purposes of prevention, screening, monitoring of health conditions, and disease detection and management. This staple of healthcare claims that, "a penny of prevention is worth a pound of cure . . . The pharmaceutical

260 "Scientist Are Solving Our Donor Crisis with Lab-Grown Organs" By Jennifer Welsh, Business Insider, August 28, 2012, http://www.businessinsider.com/lab-grown-organs-2012-8?op=1 (Accessed 3/19/15), p. 2.
261 "Geron Receives FDA Clearance to Begin World's First Human Clinical Trial of Embryonic Stem Cell-Based Therapy" Geron, Press Release, January 23, 2009, http://ir.geron.com/phoenix.zhtml?c=67323&p=irol-newsArticle&ID=1636192 (Accessed 4/1/15), p. 1.
262 "Stem Cell Basics" National Institutes of Health, U.S. Department of Health & Human Services, April 28, 2009, http://stemcells.nih.gov/staticresources/info/basics/SCprimer2009.pdf (Accessed 3/19/15), p. 2, 14.
263 Ibid, p. 14.
264 "List of Studies for Adult Stem Cell" National Institutes of Health, March 19, 2015, https://clinicaltrials.gov/ct2/results?term=%22Adult+stem+cell%22 (Accessed 3/19/15); Author looked up current status of clinical trials at the U.S. National Institutes of Health website, ClinicalTrial.gov, by searching "Adult Stem Cell".
265 "The Era of 'Omics Unlimited" By Raj P. Kandpal, Beatrice Saviola, and Jeffrey Felton, BioTechniques, Vol. 46, No. 5 (April 2009), p. 351.
266 Ibid, p. 352.
267 "Proteomics—Technologies, Markets, and Companies" By LeadDiscovery, 1999, https://www.leaddiscovery.co.uk/registration/ (Accessed 7/01/09).

industry has long been focused on treatment of disease but it will be far more cost-effective to prevent disease than cure it, and this will be a driver of innovation."[268] Recent diagnostic advances support an attitude of prevention that, though inherently accepted, has not been practiced sufficiently in healthcare to date.

In addition to *diagnostic medicine*, *diagnostic technology* is the backbone of much technological advancement, including, but not limited to: (1) *minimally invasive surgery*; (2) *preventative procedures*; (3) *telemedicine*; and (4) *therapeutics*. *Diagnostics* may also play an important role in the advancement of current *quality metrics reporting* and associated *value-based purchasing* initiatives. While these aforementioned characteristics provide *clinical benefits* to providers, patients, and payors, the *economic value metrics* of *diagnostic imaging* is unclear, as the technology is also associated with *patterns of overuse* and *increased healthcare costs*.[269] Diagnostics can be categorized in two distinct fields: (1) *molecular diagnostics* and (2) *imaging technology*.

Molecular Diagnostics

Molecular diagnostics were originally used to screen for infections (e.g., HIV, hepatitis, and tuberculosis) more accurately and effectively than traditional methods.[270] The capabilities of molecular diagnostics since have evolved to include genetic disorder screening, pre-implantation screening, and cancer screening procedures, thereby facilitating the transition toward preventative healthcare.[271] Similarly, advances in *genetic engineering* and *enhancement*, *pharmacogenetics*, and *pharmacogenomics* have led to a fusion of molecular diagnostics and therapeutic measures for specialized screening and treatment plans, which fusion is characteristic of *personalized medicine*. The capabilities afforded by molecular diagnostics have relied on developments in polymerase chain reaction (PCR)-based technology, electrochemical detection of DNA, biochip technology, nanotechnology, and proteomic technologies.[272] *Nanotechnology*, the *engineering* of *body systems* on a *molecular level*,[273] has been utilized in the study of: (1) *viruses*; (2) *biomarkers*; (3) *neural regeneration*; and (4) *drug delivery membranes*, among other fields.[274] The ability to influence healthcare delivery through "highly integrated, miniaturized, and smart micro-nano-bio-systems" is at the forefront of U.S. healthcare delivery, as it presents the capabilities to "enable the delivery of individualized health services with better access and outcomes at lower costs than previously deemed possible."[275] The developments that

268 "Biomarket Trends: Pharmaceutical Industry Undergoing Transformation, Companies Must Start Preparing Now for Changes to Come in 2020" By Steve Arlington and Anthony Farino, Genetic Engineering and Biotechnology News, Vol. 27, No. 15 (September 1, 2007), http://www.genengnews.com/articles/chitem.aspx?aid=2197 (Accessed 2/2/10).

269 "Expanding Use of Imaging Technology and the Challenge of Measuring Value" By Laurence C. Baker, et al., Health Affairs, Vol. 27, No. 6, November / December 2008, p. 1467-68, 1471-72.

270 "The Molecular Diagnostics Industry Today" By Harry Glorikan, Drug Discovery & Development, Vol. 9, No. 9 (September 1, 2006), p. 68.

271 "Proteomics—Technologies, Markets, and Companies" By LeadDiscovery, 1999, https://www.leaddiscovery.co.uk/registration/ (Accessed 7/1/09).

272 "Proteomics—Technologies, Markets, and Companies" By LeadDiscovery, 1999, https://www.leaddiscovery.co.uk/registration/ (Accessed 7/1/09).

273 "What is Nanotechnology" Center for Responsible Nanotechnology, http://www.crnano.org/whatis.htm (Accessed 10/25/12).

274 "NNI Accomplishments in Nanotechnology" National Nanotechnology Initiative, 2013, http://www.nano.gov/nanotechnology-initiatives/nano-achievements/results?keywords=health&category[0]=all&agencies[0]=all&submitted=1&op=Search%20Nano%20Achievements&form_build_id=form-af109379a72299af2604516ede8682ff&form_id=omni_achievements_filter_achievements_form (Accessed 10/15/12).

275 "R&D in Micro-Nano-Bio Systems and Contribution to pHealth" By Andreas Lymberis, Studies in Health Technology and Informatics, IOS Press, 2012, p. 26.

materialized as a result of these molecular capabilities continue to affect the molecular, nonmolecular, and in vitro diagnostic markets.[276]

The field of *cancer diagnostics*, utilizing molecular technologies, has been influential in the transition to personalized care. *Cancer molecular diagnostics* (CMD) most likely will not replace traditional pathological examinations, but rather serve to supplement and enhance these methods by employing them in conjunction with microarrays, reverse transcriptase polymerase chain reaction (RT-PCR), mass spectrometric proteomic analyses, and protein chips.[277] CMD technology will allow practitioners to diagnose cancer, choose and develop personalized treatment plans, and identify predispositions twice as quickly as other assays for only a fraction of the drug development costs.[278]

The identification of *medical predispositions* based on *genomic characteristics* is a relatively new market. In addition to the identification of *particular genes* that may be utilized to identify those individuals who may be predisposed to certain cancers or diseases, *molecular diagnostics* are able to identify over 1,900 *heritable disorders*.[279] Although clinical laboratories are seeking to obtain a broader base for more diagnostic tests, a lack of standards among laboratories has led to a high level of variability and, consequently, inconclusive results. Direct-to-consumer commercial "testing kits" have further diluted the standards for molecular diagnostics, raising concerns regarding the regulation of the field.[280]

Trends in Molecular Diagnostics

Although the field of *molecular diagnostics* has grown beyond its original scope, which focused on *screening for infectious disease*, this field is still the fastest growing segment of the *molecular diagnostics* market, making up 50% to 60% of the market's revenue.[281] As of 2012, the U.S. diagnostics market made up roughly 34% of the global market with an estimated value of $15.5 billion.[282] While the Asian Pacific markets have the highest growth region predicted, the U.S. diagnostics market has a forecasted five-year growth rate of 5.8%.[283] The potential *profitability* for *suppliers* in the *personalized medicine* market has led to increased transactional activity among *molecular diagnostic companies*, as large companies are diversifying to maximize their presence in market, by purchasing *specialized diagnostic entities* such as *in vitro diagnostic companies*.[284]

276 "The Molecular Diagnostics Industry Today" By Harry Glorikan, Drug Discovery & Development, Vol. 9, No. 9 (September 1, 2006), p. 68.
277 "Cancer Molecular Diagnostics Take the Stage: CMDS Are at the Forefront of Evolving Healthcare Practices" By Sudeep Basu, Genetic Engineering and Biotechnology News, Vol. 29, No. 7 (April 1, 2009), http://www.genengnews.com/articles/chitem_print.aspx?aid=2852&chid=0 (Accessed 7/6/09).
278 Ibid.
279 "Molecular Diagnostics: Harmonization Through Reference Materials, Documentary Standards and Proficiency Testing" By Marcia J. Holden et al., Expert Review of Molecular Diagnostics, Vol. 11, No. 7 (2011), p. 741.
280 Ibid, p. 741-742.
281 "Introduction to Molecular Diagnostics: The Essentials of Diagnostics Series" AdvaMedDx and DxInsights, 2013, http://advameddx.org/download/files/AdvaMedDx_DxInsights_FINAL(2).pdf (Accessed 3/20/15), p. 6.
282 Ibid.
283 Ibid.
284 "Integrated Diagnostics and Personalized Care: An Interview with GE Healthcare" By Anne Staylor and Mary Thompson, Windhover Information, an Elsevier Company, Medtech Insight, Vol. 13, No. 6 (June/July 2011), p. 16-17.

Regulatory and Reimbursement

Many *molecular diagnostic* technologies are not subject to the stringent compliance requirements set by the FDA for most *device technologies*. Rather, *the laboratory developed tests (LDT)* that encompass the many genetic diagnostic tests on the market are subject to FDA *discretional enforcement*, which is typically determined through the laboratory requirements prescribed in the *Clinical Laboratory Improvement Amendments (CLIA) of 1988*.[285]

As noted by The Lewin Group in its 2008 report on laboratory medicine, "[d]espite this scope of influence, spending on laboratory services accounts for only 2.3% of U.S. health care expenditures and 2% of Medicare expenditures."[286] However, with the shift from fee for service to paying for performance, it is evident that cost-related assessments that help improve the value per health expenditure are growing in popularity.[287] The result of this is that a growing number of stakeholders who seek evidence to support decisions are developing and utilizing laboratory tests.[288]

Despite this scope of influence, spending on laboratory services accounts for only 2.3% of U.S. health care expenditures and 2% of Medicare expenditures.[289]

Imaging Technology

Medical imaging is defined as a "non-invasive process used to obtain pictures of the internal anatomy or function of the anatomy using one of many different types of imaging equipment and media for creating the image."[290] Imaging is one the fastest growing categories of services covered under Medicare Part B across all modalities, namely computed tomography (CT), magnetic resonance imaging (MRI), nuclear medicine, ultrasound, x-ray, and other standard imaging techniques.[291] Under the 2005 Deficit Reduction Act, CMS moved to constrain spending on these services. The act stated that, with certain exceptions, physician payments under the CMS fee schedule must be capped at the levels established for independent diagnostic testing

285 "The Human Genome and Translational Research: How Much Evidence is Enough?" By Janet Woodcock, Health Affairs, Vol. 27, No. 6 (November/December 2008), p. 1617; "LDT Oversight Should be Strengthened: Frequently Asked Questions" College of American Pathologists, October 31, 2011, http://www.cap.org/apps/cap.portal?_nfpb=true&cntvwrPtlt_actionOverride=%2Fportlets%2FcontentViewer%2Fshow&_windowLabel=cntvwrPtlt&cntvwrPtlt{actionForm.contentReference}=advocacy%2Fldt%2Fldt_oversight_faq.html&_state=maximized&_pageLabel=cntvwr#regulated (Accessed 9/27/12). See the Other Federal Regulations section in Chapter 3: Regulatory Environment for a further discussion of FDA regulation regarding medical devices and the Clinical Laboratory Improvement Amendments of 1988.

286 "Laboratory Medicine: A National Status Report" By Julie Wolcott, Amanda Schwartz, and Clifford Goodman, To Division of Laboratory Systems National Center for Preparedness, Detection, and Control of Infectious Diseases, Center for Disease Control and Prevention, The Lewin Group, May 2008, p. 2.

287 "The Value of Laboratory Screening and Diagnostic Tests for Prevention and Health Care Improvement" By Julie Wolcott and Clifford Goodman, To American Clinical Laboratory Association and Advanced Medical Technology Association, The Lewin Group, September 2009, p. 7.

288 Ibid.

289 "A Policy Primer on Diagnostics" AdvaMedDx, June 2011, http://advameddx.org/download/files/sections/Policy/Innovation/AdvaMedDx-Policy-Primer-on-Diagnostics-June-2011.pdf (Accessed 3/20/15), p. 12-13; "Laboratory Medicine: A National Status Report" By Julie Wolcott, Amanda Schwartz, & Clifford Goodman, To Division of Laboratory Systems National Center for Preparedness, Detection, and Control of Infectious Diseases, Center for Disease Control and Prevention, The Lewin Group May 2008, p. 2

290 "Medicare Part B Imaging Services: Rapid Spending Growth and Shift to Physician Offices Indicate Need for CMS to Consider Additional Management Practices" Government Accountability Office, June 2008, GAO-08-452.

291 Ibid.

facilities under the Outpatient Prospective Payment System (OPPS).[292] The utilization of diagnostic imaging has grown at a much faster rate than other physician services, likely due to advances in technology allowing for more efficient, effective, and safe procedures. As indicated in the June 2012 MedPAC publication entitled, *A Data Book: Health Care Spending and the Medicare Program*, the number of CT and MRI scans per 1,000 Medicare B fee-for-service beneficiaries, grew significantly between 2000 and 2009, with a slight decrease from 2009 to 2010.[293] The number of CT scans performed on parts of the body other than the head more than doubled between 2000 and 2012, from 185 scans per 1,000 Medicare Part B beneficiaries in 2000 to 396 scans per 1,000 Medicare Part B beneficiaries in 2010.[294] Similarly, the number of MRI scans performed on parts of the body other than brain for Medicare Part B beneficiaries more than doubled between during the same time period.[295] Corresponding with the increased utilization of diagnostic imaging, Medicare spending for these services has also increased over time, though spending did actually decline from $10.6 billion in 2011 to $10 billion in 2012.[296] The allocation of Medicare spending for diagnostic imaging under the 2012 Physician Fee Schedule is set forth below, in Table 5-5: Medicare Spending on Diagnostic Imaging in 2010.

Table 5-5: Medicare Spending on Diagnostic Imaging in 2010[297]

Procedure	Percent of Total Medicare Spending
Standard Imaging	23%
CT	18%
MRI	15%
Echocardiography	10%
Other Echography (ultrasound)	17%
Nuclear Medicine	8%
Imaging Procedures	5%
PET	4%

Trends in Imaging Technology

Continuous development and improvement of existing technology has characterized much of imaging development. For example, ultrasound is undergoing extremely promising improvements, with greater speed and enhanced quality affording higher frequency, better resolution, and three-dimensional (3D) imaging. This increased strength will foster an array of possibilities, including added specificity of results, a reduction in the necessity of biopsies, and more standardized ultrasound use. One substantial drawback to ultrasound is its reliance on operator competence. Compounded by the healthcare manpower deficit, the shortage of professionals qualified to perform ultrasound procedures can be affected additionally by lagging reimbursement and liability concerns. Accordingly, professionals believe the repercussions of relying on operator capabilities will result in increased interest in technologies that promote ease-of-use.[298]

292 Ibid. See Chapter 2 for more detail regarding billing under OPPS
293 "A Data Book: Health Care Spending and the Medicare Program" Medicare Payment Advisory Commission, June 2012, p. 112.
294 Ibid, p. 106.
295 Ibid, p. 112.
296 Ibid, p. 106.
297 Ibid, p. 106.
298 "Trends in Radiology, Special Report: New Breast Ultrasound Techniques May Find More Cancers" By Kate Madden Lee, Siemens, March 1, 2007, www.usa.siemens.com (Accessed 6/29/09).

Advances in Magnetic Resonance Imaging (MRI)

Functional MRI (fMRI), a combined *positron emission tomography* (PET) and MRI system, enables physicians to observe brain function while patients perform physical and mental tasks.[299] FMRI is one of the most popular methods of brain imaging in today's market.[300] Open MRI systems, or short bore magnet systems, are another example of technological improvements to existing imaging technologies. These systems reduce claustrophobia for patients but generate images of comparable quality to those produced by traditional imaging technology.[301]

As a result of these technological advances, an estimated 34.9 million MRI procedures were performed in 2014, a significant growth from the 26.6 million procedures conducted in 2006.[302] Spending on MRI and CT services accounted for nearly one third of the approximate $10 billion expenditure on imaging services in 2012.[303]

Advances in Computed Tomography (CT)

CT has transformed both diagnostic and interventional medicine. The quality of CT images appears to surpass the anatomical detail of competing imaging technologies due to the cross-sectional scanning capabilities they afford.[304] CT produces *tomographic images* (slices) of a specific body part by using a computer to process numerous x-rays of the area to create a *cross-sectional image*, which is obtained by rotating the x-ray device around the patient's body in a process known as *CT scanning*.[305] The clearer images provided by CT are partly due to the elimination of image superimposition outside the area of interest and the high contrast resolution, which can differentiate between varying tissue densities. Additionally, CT appears to *expedite* and *improve* the initial triage of patients on an *outpatient basis*, as well as in the ER, allowing patients to either return home or be admitted to the hospital for further evaluation.[306] Since its inception in 1970, use of CT has grown rapidly;[307] as of 2011, approximately 85.3 million scans were performed in the U.S.[308]

Multidetector Row Computed Tomography (MDCT)

The advent of multidetector row (also known as multi-slice) CT (MDCT) technology has redefined imaging on the molecular and cellular levels[309] and thereby enhanced patient

299 "MRI Systems Market: Clinical Application Trends" Frost and Sullivan, October 10, 2007, http://www.frost.com/prod/servlet/market-insight-top.pag?docid=108958393 (Accessed 6/29/09).
300 Ibid.
301 "Magnetic Resonance Imaging: Market Trends" Darshana De-Frost and Sullivan Research Analyst, OBBeC Worldwide Biotech Exchange Network, March 4, 2008, http://www.obbec.com/analysis/1038-medical-imaging/1676-magnetic-resonance-imaging market-trends?showall=1 (Accessed 6/29/09).
302 "2014 MR Market Outlook Report" IMV, November 2014, http://www.imvinfo.com/index.aspx?sec=mri&sub=dis&itemid=200085 (Accessed 3/23/15); "Latest IMV Market Report Shows Continued Demand for High Field MRI Systems" IMV, January 16, 2007, http://www.imvinfo.com/user/documents/content_documents/nws_rad/MS_MRI_PressRelease.pdf (Accessed 6/29/09).
303 "A Data Book: Health Care Spending and the Medicare Program" Medicare Payment Advisory Commission, June 2014, p. 106.
304 "Computed Tomography—An Increasing Source of Radiation Exposure" By David J. Brenner, Eric J. Hall, and D.Phil, The New England Journal of Medicine, Vol. 357, No. 22 (November 29, 2007), p. 2277.
305 "Computed Tomography (CT): Questions and Answers" National Cancer Institute, September 8, 2003.
306 "CT Shines as Cardiac Triage Tool in the ER" By James Brice, Diagnosticimaging.com, November 2005, http://www.diagnostic imaging.com/showArticle.jhtml?articleID=174402997 (Accessed 7/14/06).
307 "CT Scanning: Patterns of Use and Dose" Fred A. Mettler, et al., Journal of Radiological Protection Vol. 20, No. 4 (2000), p. 353.
308 "Latest IMV CT Survey Shows Hospitals Seek to Improve Productivity to Manage Increased Outpatient and Emergency CT Procedure Volume" Press Release, PRWeb, June 5, 2012.
309 "Dynamic Volume: A Macroevolution?" By Jagat Narula, Radiology Today, Vol. 9, No. 23 (November 17, 2008), p. 10.

management and care. Through the evolution from the 4-slice CT scanner, the 16-slice CT scanner, and, finally, the 64-slice CT scanner, MDCT has raised the standard for image quality and accuracy allowing for the production of 3D images.[310]

64-Slice CT is the most popular CT technology in use, as it made cardiac and cerebral CT imaging possible.[311]

In addition to producing images with greater acuity, the 64-slice CT also operates at an increased speed compared to previously existing CT technology. The average scanning time for the 64-slice scanner was 313 seconds, which was 64 seconds faster than second generation 16-slice scanners.[312] A 64-slice CT scanner can complete a scan in as little as 8 to 12 seconds, compared to a traditional CT scanner's time of 20 to 30 seconds.[313]

With diagnostic imaging trends indicating that continued growth in the field is largely due to adult diagnosis and screening procedures by proxy of the available MDCT technology, the four areas of most interest at present are: (1) CT cardiac screening; (2) CT colonography; (3) CT lung screening; and (4) CT whole body screening.[314]

Dynamic Volume Computed Tomography

The latest in CT technologies, the 256- and 320- detector row systems, collectively are referred to as *dynamic volume CT*. Dynamic volume CT technology is capable of imaging an entire organ with isotropic resolution in one rotation and as a complete volume. The temporally uniform data are then reconstructed as a whole unit, thereby reducing the chance of artifacts and misregistrations in the image caused by creating a composite image.[315] In addition to being quicker and more accurate, dynamic volume CT exposes a patient to a significantly lower dose of radiation than both 64-slice imaging and invasive diagnostic technologies. Similarly, *dynamic volume CT scanning* is sensitive enough to allow physicians to detect subclinical problems, facilitating earlier diagnosis and treatment.[316]

310 "Computed Tomography in the 21st Century: Changing Practice for Medical Imaging and Radiation Therapy Professionals" By Sal Martino, Jerry Reid, and Teresa G. Odle, American Society of Radiologic Technologists, 2008, p. 2.

311 "Nuclear cardiology adopts hybrid and dynamic imaging" by David Berman, M.D., Diagnostic Imaging.com, October 2006, www.diagnosticimaging.com/display/article/113619/1193342 (Accessed 2/10/09).

312 "CT Flexes Muscle in Coronary Disease Detection" By James Brice, Rheumatology Network, November 29, 2005, http://www.rheumatologynetwork.com/ct/ct-flexes-muscle-coronary-disease-detection (Accessed 4/1/15).

313 "State-of-the-art Cardiac CT Prompts Better, Quicker, Diagnosis and Shorter Hospital Stays" Cardiovascular Business (March/April 2009) p. 22-2; "Cardiac CT for Calcium Scoring" By Radiological Society of North America, October 1, 2008, http://www.radiologyinfo.org/en/info.cfm?PG=ct_calscoring (Accessed 4/30/09).

314 "Cardiac CT: 64-Slice and Beyond" Clinical Advancements in Volumetric CT, Toshiba Medical Systems, February 2006; "Virtual Colonoscopy for Colorectal Cancer Screening: Current Status" By Jay P. Heiken, Christine M. Peterson, and Christine O. Menias, Cancer Imaging, Vol. 5 (2005), p. S133-S139; "Computed Tomography Screening and Lung Cancer Outcomes" By Peter B. Bach, James R. Jett, Ugo Pastorino, et al., Journal of the American Medical Association, Vol. 297, No. 9 (June 23, 2009), p. 953-961; "Cost-Effectiveness of Whole Body CT Screening" By Molly T. Beinfeld, Eve Wittenberg, G. Scott Gazelle, Radiology, Vol. 234, No. 2 (2005), p. 415-422.

315 "CT Beyond 64 Slices: 'Dynamic Volume CT' Promises to Streamline Workflow, Improve the Bottom Line" By Tony DeFrance, Cardiovascular Business, January/February 2009, p. 24.

316 "Dynamic Volume CT: A Macroevolution?" By Jagat Narula, Radiology Today, Vol. 9, No. 23 (November 17, 2008), p. 10.

"Fusion" Imaging—Nuclear Medicine and Combined Technologies

The adoption of CT in nuclear medicine has resulted in a hybrid technology known as "*fusion*" imaging that combines nuclear medicine cameras with CT detection methods.[317] *Positron emission tomography-CT* (PET-CT) as well as single, *photon emission computed tomography-CT* (SPECT-CT) systems have various qualities that may prove advantageous in addressing the problems posed by each independent system. By using a dual-system (SPECT-CT or PET-CT), patients can undergo both procedures at once, resulting in minimized error rates and better images.[318] According to *IMV Medical Information Inc*. (IMV), a leading market research firm, "PET-CT scanners have become the preferred technology for PET imaging, as the integration of functional PET images with anatomical visualization of CT has allowed more accurate and faster diagnosis."[319]

PET technology allows for substantially higher sensitivity than single-photon imaging technologies, such as SPECT.[320] However, due to the longer half-life of single-photon emitters, SPECT tracers last six hours; PET tracers have only a 75 second half-life. A longer half-life enables the use of a wider observational time window.[321] SPECT is much more available, widely used and more affordable than PET-CT technology (a SPECT camera costs between $400,000 and $600,000, and the PET-CT can cost $2 million).[322] Utilization trends are changing for SPECT and PET technologies. PET procedure volume increased by 11% from 2011-2012, while SPECT procedure volume remained flat from 2011-2012.[323] However, SPECT is subject to longer scan times and can produce low-resolution images that are prone to artifacts and attenuation (especially in larger patients).[324]

> Pr PET technology allows for substantially higher sensitivity than single-photon imaging technologies like the SPECT.[325]

IMV also reported increased use of SPECT-CT, capable of CT-based attenuation correction which, paired with CT calcium scanning, will significantly increase accuracy and interpreter confidence. Due to the insufficient sensitivity of current SPECT imaging technology, SPECT-CT may become the standard way in which SPECT studies are performed.[326]

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317 "Nuclear Medicine Usage, Grows, Led By PET" IMV Medical Information Inc. Newsline, Vol. 47, No. 10 (2006), p. 13N; "SPECT vs. PET, Which is Best?" By Dave Fornell, October 2008, http://www.dicardiology.net/node/28668 (Accessed 2/10/09).

318 "Nuclear cardiology adopts hybrid and dynamic imaging" By David Berman, Diagnostic Imaging.com, October 2006, http://www.diagnosticimaging.com/display/article/113619/1193342 (Accessed 2/10/09).

319 "Nuclear Medicine Usage, Grows, Led By PET" IMV Medical Information Inc. Newsline, Vol. 47, No. 10 (2006), p. 13N.

320 "PET Versus SPECT: Strengths, Limitations, and Challenges" By Arman Rahmim and Habib Zaidi, Nuclear Medicine Communications, Vol. 29 (2008), p. 193.

321 "PET Versus SPECT: Strengths, Limitations, and Challenges" By Arman Rahmim and Habib Zaidi, Nuclear Medicine Communications, Vol. 29 (2008), p. 193-207.

322 "Report: U.S. SPECT, PET Market Looks Promising in Coming Years" By Wayne Forrest, AuntMinner.com, July 30, 2013, http://www.auntminnie.com/index.aspx?sec=ser&sub=def&pag=dis&ItemID=104103 (Accessed 3/25/15).

323 "SPECT vs. PET, Which is Best?" By Dave Fornell. Diagnostic and Invasive Cardiology, October 2008, http://new.reillycomm.com/diagnostic/article_detail.php?id=672 (Accessed 02/10/09).

324 Ibid.

325 "PET versus SPECT: strengths, limitations, and challenges," by Arman Rahmim and Habib Zaidi, Nuclear Medicine Communications, Vol. 29, (2008) p. 193–207.

326 "Nuclear Cardiology Adopts Hybrid and Dynamic Imaging" By David Berman, Diagnostic Imaging.com, October 2006, http://www.diagnosticimaging.com/display/article/113619/1193342 (Accessed 2/10/09).

Despite these international trends, over 60% of all SPECT and PET purchases in the U.S. are still SPECT.[327] However, SPECT-CT trends are unlikely to mimic the dynamic increases in PET-CT use. Compounded by the current reimbursement environment, the main barrier to the SPECT-CT market is a shortage in technetium, the isotope most frequently needed for such nuclear procedures.[328] Additionally, the majority of SPECT procedures are performed in the field of cardiology,[329] where SPECT-CT is only beneficial if it can generate 64 or more slices. Often, the cost allocated to such technologies is beyond the budgeting capacity of many cardiology departments.[330] By contrast, PET-CT technology has been incorporated into many oncology practices, where budgets appropriately match the necessity of such technology.[331]

> PET-CT technology has been most incorporated in oncology practices, in instances when budgets appropriately match the need.
>
> ***Greg Freiherr, 2009.***

Telemedicine and Imaging: Picture Archives and Communications Systems (PACSs) and Other Advances in Teleradiology

Teleradiology is the electronic transfer and storage of electronic imaging data. It is the market's solution to ensure a greater number of radiologists in the marketplace (the number of radiology and diagnostic radiology physicians increased 8.2% from 2000 to 2010[332]) and to increase the number of images a radiologist must interpret.[333]

One of the fastest growing specialties in telemedicine is *teleradiology,* i.e., the *electronic transfer* and *storage* of *electronic imaging data*, which allows for an increased ability to read scans remotely, alleviating the off-hours burden that *night reads* pose to radiology groups.[334] Other advances in *teleradiology* technology have allowed for the connection of *digital x-rays* and other such *imaging modalities* to *Picture Archives and Communications Systems* (PACS), which has significantly improved the efficiency of imaging care by providing improved access to even higher quality images with reduced delays. Many of these systems result from infrastructures implemented in hospital radiology departments and have since expanded into a wider area of networks for *health systems*, *outpatient providers,* and *managed care organizations*.[335]

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327 "Report: U.S. SPECT, PET Market Looks Promising in Coming Years" By Wayne Forrest, AuntMinner.com, July 30, 2013, http://www.auntminnie.com/index.aspx?sec=ser&sub=def&pag=dis&ItemID=104103 (Accessed 3/25/15).

328 "Great Expectations and the Saga of SPECT-CT" By Greg Freiherr, Diagnostic Imaging, June 25, 2009, http://www.diagnostic imaging.com/display/article/113619/1425226?CID=rss (Accessed 6/29/09).

329 "PET versus SPECT: strengths, limitations, and challenges" By Arman Rahmim and HabibZaidi, Nuclear Medicine Communications, Vol. 29, No. 3 (2008), p. 193.

330 "Great Expectations and the Saga of SPECT-CT" By Greg Freiherr, Rheumatology Network, June 25, 2009, http://www.diagnostici maging.com/display/article/113619/1425226?CID=rss (Accessed 4/1/15).

331 Ibid.

332 "2012 Physician Specialty Data Book" Center for Workforce Studies, Association of American Medical Colleges, November 2012, https://www.aamc.org/download/313228/data/2012physicianspecialtydatabook.pdf (Accessed 3/25/15), p. 26.

333 Discussed above in the Trends in Telemedicine section.

334 "Teleradiology: New Players, High Stakes Create Capital Opportunity" By John C. Hayes, Diagnostic Imaging, November 1, 2006, http://www.diagnosticimaging.com/display/article/113619/1193477 (Accessed 6/29/09).

335 "DOTmed Industry Sector Report: PACS/RIS/HIS" By Barbara Kram, DOTmed Business News, March 2009, http://www.dotmed.com/news/story/8313/.

Companies providing day reads in subspecialty areas have begun to show market expansion.[336] Full-field digital mammography makes telemammography and computer-aided detection possible, increasing facility appeal without additional burden on staff. Furthermore, digital mammography has the potential to decrease patient anxiety because the technologist can stay in the exam room for the duration of the screening, and this technology has proven to be useful in imaging dense breast tissue, thereby improving quality of care.[337]

Regulatory and Reimbursement

With regard to PET technology, federal regulations were updated in 2009 to ensure compliance of drug production and manufacturing practices with federal regulations regarding safety and quality of radiologic tracers used in PET procedures.[338] These regulations required all PET production facilities to comply with the updated requirements, including updating standard operating procedure for manufacturing of all PET drugs and PET drug product and activities related to quality assurance; facilities; equipment; personnel; and production, process, and laboratory controls.[339]

THERAPEUTIC TECHNOLOGY

The range of use for *therapeutic technologies* has grown substantially over the last century, and innovation in the arena continues to lead to groundbreaking medical discoveries in the fields of *molecular pharmacology; radiation therapy*; *robotics* and *surgical technology*: *minimally invasive surgery*; *transplant technologies*; *home infusion therapy*; and *pain management*.

Molecular Pharmacology

Biopharmaceuticals are drugs and biologics that treat an organism through the genetic manipulation of foreign DNA. *Biologics* are therapeutic products that are developed using living sources, such as vaccines, blood and blood products, and allergenic extracts and tissues.[340] The manufacturing of biopharmaceuticals, most specifically vaccines, monoclonal antibodies, recombinant proteins, and stem cells relies heavily on the cell culture market.[341] In turn, the necessary in-depth knowledge of cell culture that fortifies molecular pharmacology was made possible with the advent of the genomic era.

The FDA has approved drugs and biologics in eight categories of biopharmaceuticals: (1) recombinant blood factors; (2) recombinant thrombolytics and anticoagulants; (3) recombinant hormones; (4) recombinant growth factors; (5) recombinant interferons and interleukins;

336 "Teleradiology: New Players, High Stakes Create Capital Opportunity" By John C. Hayes, DiagnosticImaging, November 1, 2006, http://www.diagnosticimaging.com/display/article/113619/1193477 (Accessed 6/26/09).
337 "Trends in Radiology, Special Report: Managing the Transition to Digital Mammography" By Kate Madden Lee, Siemens, March 1, 2007, http://www.auntminnie.com/index.aspx?sec=spt&sub=tir&pag=dis&itemID=74564, (Accessed 10/1/09).
338 "Current Good Manufacturing Practice for the Positron Emission Tomography Drugs" Federal Register Vol. 74, No. 236 (December 10, 2009), p. 65409.
339 "Current Good Manufacturing Practice for Positron Emission Tomography Drugs; Final Rule", Food and Drug Administration, U.S. Department of Health & Human Services, 21 CFR Part 212, Federal Register Vol. 74, No. 236 (December 10, 2009), p. 65409, 65432-65435.
340 "Biologics" Dictionary.com, Dictionary.com, 2009, http://dictionary.reference.com/browse/biologic (Accessed 10/1/09).
341 "Biopharmaceutical Benchmarks 2006: The Rate of Biopharmaceutical Approvals has Leveled Off, but some Milestones Bode Well for the Future" By Gary Walsh, Nature Biotechnology, Vol. 24, No. 7 (July 2006), p. 775.

(6) recombinant vaccines; (7) monoclonal antibody-based products; and (8) miscellaneous recombinant products.[342]

The NIH's Intramural Research Program (IRP) encourages "*bench-to-bedside*" translational research,[343] and includes programs such as: the Therapeutics for Rare and Neglected Diseases (TRND) Program under the National Center for Advancing Translational Sciences (NCATS); the Psychoactive Drug Screening Program under the National Institute of Mental Health (NIMH); and, the Laboratory of Molecular Pharmacology under the National Cancer Institute's (NCI) Center for Cancer Research (CCR).[344] The IRP has repositories for both natural and synthetic products and compounds and has access to the NCI-60, a databank of 60 cancer cell lines against which the NCI's Developmental Therapeutics Program screens hundreds of thousands of compounds.[345]

Trends in Molecular Pharmacology

Advances in Proteomics

Therapeutic protein technology has experienced developments of innumerable implications. *Insulin*, the first recombinant protein to be approved, remains the prototype for biopharmaceutical development, and it was one of the first biopharmaceuticals to undergo *molecular engineering*, a process that has since defined development and advancement in biopharmaceuticals.[346] Since the early 2000s, an increasing number of rapid-acting or time-releasing engineered analogs for insulin have been approved, including the most recent drug, Afrezza, an inhalable recombinant insulin that received FDA approval in June 2014.[347] With an increased incidence and prevalence rate of diabetes, it is probable that the demand and market for such products will continue to grow.[348]

Therapeutic proteomic technology has similarly seen developments *with innumerable implications* for correcting defective proteins or filling in a gap where a protein is absent.[349] Several *protein kinase inhibitors* are currently subjects of FDA clinical trials, and have boosted proteomic research in *phosphorylation-triggered signaling*, known as "*phosphoproteomics*."[350] Additionally, more accurate mass spectrometry techniques have allowed researchers to target cancer and tumor suppression proteins with more specificity.[351] Continued advances in this field are expected to support developments in *personalized medicine* technology, which are particularly emerging in the area of *oncology*, where specific therapies are being targeted to

342 Ibid, p. 769 (table 1).
343 "Molecular Pharmacology" Intramural Research Program, National Institutes of Health, http://irp.nih.gov/our-research/scientific-focus-areas/molecular-pharmacology (Accessed 9/28/12).
344 Ibid.
345 Ibid.
346 "Biopharmaceutical Benchmarks 2006: The Rate of Biopharmaceutical Approvals has Leveled Off, but some Milestones Bode Well for the Future" By Gary Walsh, Nature Biotechnology, Vol. 24, No. 7 (July 2006), p. 770.
347 "FDA Approves Afrezza to Treat Diabetes" Food and Drug Administration News Release, June 30, 2014, http://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm403122.htm (Accessed 3/19/15).
348 "Biopharmaceutical Benchmarks 2006: The Rate of Biopharmaceutical Approvals has Leveled Off, but some Milestones Bode Well for the Future" By Gary Walsh, Nature Biotechnology, Vol. 24, No. 7 (July 2006), p. 770.
349 "Current Topics: Proteomics" American Medical Association, 2012, http://www.ama-assn.org/ama/pub/physician-resources/medical-science/genetics-molecular-medicine/current-topics/proteomics.page# (Accessed 9/27/12).
350 "Proteomics Retrenches" By Peter Mitchell, Nature Biotechnology, Vol. 28, No. 7 (July 2010), p. 669-670.
351 Ibid, p. 670.

genetically derived tumor types. Consequently, many *pharmaceutical* and *diagnostic companies* are entering the *personalized medicine* market at an accelerating pace.[352]

Nucleic Acid-Based (RNAi) Therapeutics

Other advances in *therapeutic genome technology* include *nucleic acid-based technologies,* which have clinical applications involving both *deoxyribonucleic acid* (DNA) and *ribonucleic acid* (RNA). Advances in *DNA nanotechnology* have opened the door to specifically targeted drug delivery, while advances in *RNA technology* have moved toward therapeutic *interference* with the genome. *RNA interference* (RNAi) is a natural cellular process where specific genes (e.g., a cancer gene) can be *targeted* and *silenced* so that it cannot *reproduce* and become *symptomatic*. Since its initial discovery in 1998, *RNAi* has become increasingly prevalent in the biomedical industry.[353] Recent market reports predict RNAi therapeutics to generate sales of approximately $1.2 billion by 2020.[354] These biopharmaceuticals show tremendous promise in countless areas, the most notable of which are Hepatitis C and cancer treatment.[355] MicroRNAs are believed to regulate almost one-third of the entire genome, and they are anticipated to change therapeutic capabilities. "MicroRNAs developed as regulators over millions of years to regulate complex diseases… [They] may turn out to be enormously beneficial in terms of drug discovery."[356] Though this area of technology has developed at a relatively slow pace, with fifteen years of research and only two approved products, approval of the first commercial *gene therapy* (molecular means of cancer treatment), *Gendicine*, reset the tone for nucleic acid-based RNAi drug development.[357] Approval of *Gendicine* by the State Food and Drug Administration of China for treatment of head and neck squamous cell carcinoma will facilitate further developments in RNAi therapeutics and gene therapy.[358]

These *biopharmaceutical*s hold tremendous promise in countless areas, the most notable of which include *anti-viral, Hepatitis C,* and *cancer treatment*.[359] In general, the number of biopharmaceuticals that are available for commercial use is continually growing, with 22 new products approved by the FDA in 2014.[360] However, the rate of FDA approval slowed beginning in 2006, with the *approval* of *new biological entities* (NBEs), stated as a percentage of *all new approvals,* decreasing from 24% between 2003 and 2006, to 21% between 2006 and 2010.[361]

352 "Integrated Diagnostics and Personalized Care: An Interview with GE Healthcare" By Ann Staylor and Mary Thompson, Medtech Insight, June/July 2011, p. 16, 18.
353 "RNA Interference Fact Sheet" National Institute of General Medical Sciences, National Institutes of Health, January 30, 2012, http://www.nigms.nih.gov/News/Extras/RNAi/factsheet.htm (Accessed 9/24/12).
354 "Global RNA Based Therapeutics Market (Technology, Application, End Users and Geography)—Size, Share, Global Trends, Company Profiles, Demand, Insights, Analysis, Research, Report Opportunities, Segmentation and Forecast, 2013-2020: Report Overview" Allied Market Research, September 2014, http://www.alliedmarketresearch.com/RNA-based-therapeutics-market (Accessed 3/20/15).
355 "Improving Delivery of RNAi Drugs: Abundance of Vehicles are in Development to Help Translate the Technology into Therapeutics" By Nina Flanagan, Genetic Engineering and Biotechnology News, Vol. 29, No. 3 (February 1, 2009), http://www.genengnews.com/articles/chitem.aspx?aid=2758 (Accessed 6/26/09).
356 Ibid.
357 "Biopharmaceutical Benchmarks 2006: The Rate of Biopharmaceutical Approvals has Leveled Off, but some Milestones Bode Well for the Future" By Gary Walsh, Nature Biotechnology, Vol. 24, No. 7 (July 2006), p. 773.
358 Ibid.
359 "RNA Interference Fact Sheet" National Institute of General Medical Sciences, National Institutes of Health, January 30, 2012, http://www.nigms.nih.gov/News/Extras/RNAi/factsheet.htm (Accessed 9/24/12).
360 "Biopharmaceutical Products in the U.S. and European Markets: U.S. Approvals, 2002 - Present" Biotechnology Information Institute, 2012, http://www.biopharma.com/approvals.html (Accessed 3/20/15).
361 "Biopharmaceutical Benchmarks 2010" By Gary Walsh, Nature Biotechnology, Vol. 28, No. 9 (September 2010), p. 918.

More recently, however, the low FDA approval rate trend may be starting to reverse itself. A 2013 McKinsey study investigating 2012's ten-year high FDA pharmaceutical approval rate determined that an increase in the number of filings by biopharmaceutical companies and a quicker average review time helped drive a surge of greater approval, though the study was inconclusive as to whether the upward trend could continue.[362]

However, recent government initiatives could shed more light into the viability of the positive trend. In January 2015, President Obama announced a $215 million 2016 budget allotment to begin the Precision Medicine Initiative, which promised to "*accelerate biomedical discoveries* and provide clinicians with new tools, knowledge, and therapies to select which treatments will work best for which patients" [Emphasis added].[363] Participants in the initiative share their genomic information and biological specimens, which researchers will use to study how genomic variations and other health factors affect the development of disease.[364] Initial reaction to the initiative by groups such as the Pharmaceutical Research and Manufacturers of America (PhRMA) was positive and reinforced the strong commitment of the industry to the biopharmaceutical research sector.[365] Trends in biopharmaceutical approval will have to be tracked moving forward to determine the lasting effect of the initiative on the industry.

Regulatory and Reimbursement

As of 2014, 212 recombinant proteins, monoclonal antibodies, and nucleic acid-based drugs have been approved by the U.S. and Europe as treatments for cancer, diabetes, growth disturbance, hemophilia, and hepatitis.[366] In 2013, the market size for biopharmaceuticals was estimated to be roughly $140 billion, "a value which exceeds the reported gross domestic product (GDP) of three-quarters of the economies in the World Bank GDP ranking database."[367] Although biopharmaceuticals are nowhere near the peak of their development, they are already expensive, with some biologics costing up to $500,000 per year.[368] Furthermore, research by the *American Association of Retired Persons* (AARP) has indicated that prices of these biopharmaceuticals are rising at a rate greater than both inflation and the prices of other prescription drugs.[369]

The high-priced market for biopharmaceuticals is a result of a disparity in the approval processes of *biologic* and *nonbiologic* drugs. To date, the majority of biologics have been regulated by the *Public Health Service Act*, which prohibited generic biopharmaceuticals from being marketed.[370]

362 "What's Driving the Surge in New-drug Approvals?" By Phillip Ma et al., McKinsey & Company, November 2013, http://www.mckinsey.com/insights/public_sector/whats_driving_the_surge_in_new_drug_approvals (Accessed 3/20/15).
363 "Fact Sheet: President Obama's Precision Medicine Initiative" The White House, January 2015, https://www.whitehouse.gov/the-press-office/2015/01/30/fact-sheet-president-obama-s-precision-medicine-initiative (Accessed 3/20/15).
364 "Precision Medicine Initiative: What are the Longer-term Goals?" National Institutes of Health, February 2015, http://www.nih.gov/precisionmedicine/future.htm (Accessed 3/20/15).
365 "PhRMA Statement on Precision Medicine Initiative" Pharmaceutical Research and Manufacturers of America, January 21, 2015, http://www.phrma.org/media-releases/phrma-statement-on-precision-medicine-initiative (Accessed 3/20/15).
366 "Biopharmaceutical Benchmarks 2014" By Gary Walsh, Nature Biotechnology, Vol. 32, No. 10 (October 2014), p. 992.
367 Ibid, p. 994.
368 "Biopharmaceuticals: Entering a New World" Angle by NNE Pharmaplan, April 2012, p. 40.
369 "Rx Watchdog Report Trends in Manufacturer Prices of Specialty Prescription Drugs Used By Medicare Beneficiaries 2004-2007" By Stephen W. Schondelmeyer, Leigh Purvis, and David J. Gross, American Association of Retired Persons, September 2008, http://assets.aarp.org/rgcenter/health/2008_15_specialty_q407.pdf (Accessed 4/1/15).
370 "Rx Watchdog Report Trends in Manufacturer Prices of Specialty Prescription Drugs Used By Medicare Beneficiaries 2004 to 2007" By Stephen W. Schlondelmeyer, Leigh Purvis, and David J. Gross, American Association of Retired Persons, September 2008, http://assets.aarp.org/rgcenter/health/2008_15_specialty_q407.pdf (Accessed 4/1/15); "Biologics in Perspective: The Case For Generic Biologic Drugs" By Leigh Purvis, American Association of Retired Persons, May 2009, http://www.aarp.org/research/health/drugs/fs155_biologics.html (Accessed 7/06/09).

Biopharmaceutical companies require a substantially longer monopoly period to see a return on their investment, which can lead to higher prices charged for their products.[371]

A 2012 AARP Rx Price Watch Report suggested that the wholesale price of specialty drugs rose 8.9% during the course of 2009 while the average market price of those drugs rose 50.4% between December 2004 and December 2009.[372] In contrast, non-specialty branded drugs rose only 8.3%, and the price of generics fell 7.8%.[373] These inflated prices have not been received well by insurers, many of which have raised the percentage of medication costs that patients are expected to pay. Some insurers require that beneficiaries use cheaper alternatives before approving the use of an expensive biologic option.[374]

Legislation to accelerate the process of developing and approving *biosimilars* by way of an FDA process for biosimilar or *follow-on* generic drug approval could potentially save taxpayers, insurers, and patients billions of dollars.[375] The *Congressional Budget Office* (CBO) estimated in 2008 that such legislation could reduce total expenditures on biologics by roughly $25 billion over ten years from 2009 to 2018.[376] The Biologics Price Competition and Innovation Act of 2009 (adopted in Sections 7001-7003 of the Patient Protection and Affordable Care Act) which established an abbreviated pathway for biosimilars to navigate the FDA approval process, attempted to realize these goals.[377] However, recent evaluations of the process suggest that the prospects for significant cost savings are far more limited than the CBO originally estimated due to the high cost of bringing biosimilars to market, current regulatory hurdles, and competition from both new biologics in similar therapeutic classes and reference products.[378]

Radiation Therapy

Trends in Radiation Therapy

Much like imaging technology, *radiation therapies* have been developed, adapted, and improved since the discovery of the x-ray in 1895.[379] Radiation therapy uses high-energy light beams or charged particles to stunt the proliferation of cancer cells, which are very susceptible to damage

371 "Biologics in Perspective: The Case For Generic Biologic Drugs" By Leigh Purvis, American Association of Retired Persons, May 2009, http://www.aarp.org/research/health/drugs/fs155_biologics.html (Accessed 7/06/09).

372 "Rx Price Watch Report, Trends in Retail Prices of Specialty Prescription Drugs Widely Used by Medicare Beneficiaries 2005-2009" By Stephen W. Schondelmeyer and Leigh Purvis, American Association of Retired Persons, January 2012, http://www.aarp.org/content/dam/aarp/research/public_policy_institute/health/2011/rx-pricewatch-01-2012.pdf (Accessed 3/20/15), p. v, 1.

373 Ibid.

374 "Rx Watchdog Report, Trends in Manufacturer Prices of Specialty Prescription Drugs Used By Medicare Beneficiaries, 2004-2007" By Stephen W. Schlondelmeyer, Leigh Purvis, and David J. Gross, American Association of Retired Persons, September 2008, http://assets.aarp.org/rgcenter/health/2008_15_specialty_q407.pdf (Accessed 4/1/15), p. 1; "Priced Out Pain Relief: Insurers Balk At High Costs of Promising New Treatments" By Victoria Colliver, San Francisco Chronicle, May 8, 2007, http://www.sfgate.com/cgi-bin/article.cgi?f=/c/a/2007/05/08/BUGHAPMN021.DTL&type=printable (Accessed 7/06/09).

375 "Obama Backing Generic Biologics" By Lisa Wangsness and Todd Wallack, The Boston Globe, February 26, 2009, http://www.boston.com/business/healthcare/articles/2009/02/26/obama_backing_generic_biologics/ (Accessed 6/26/09); "Follow-on Biologics: The Right Model Means Differentiating from Traditional Drugs" By Zoe Lofgren, Michael Capuano, Mike Rogers, and Kevin McCarthy, the Congress of the United States, June 18, 2009, http://www.chi.org/uploadedFiles/Legislative_Action/Federal_Issues/FOBs percent20dear percent20colleague.pdf (Accessed 7/06/09).

376 "S. 1695 Biologics Price Competition and Innovation Act of 2007" Congressional Budget Office, June 2008, http://www.cbo.gov/sites/default/files/s1695.pdf (Accessed 3/20/15), p. 5.

377 "Patient Protection and Affordable Care Act" Pub. L. No. 111-148, §§ 7001-7003, 124 Stat. 119, 804-821 (2010).

378 "Regulatory and Cost Barriers are Likely to Limit Biosimilar Development and Expected Savings in the Near Future" By Henry G. Grabowski et al., Health Affairs, Vol. 33, No. 6 (2014), p. 1048.

379 "Introduction to Cancer Therapy (Radiation Oncology)" By Radiological Society of North America, RadiologyInfo, June 10, 2009, http://www.radiologyinfo.org/en/info.cfm?pg=intro_onco (Accessed 6/26/09).

from radiation due to rapid proliferation and an inability to regenerate.[380] However, radiation therapy also has the potential to damage healthy cells. Most side effects of radiation therapy are short term and are usually confined to the area being treated. Typically, treatments are administered on an outpatient basis over the course of multiple sessions.[381] Radiation may be administered alone or simultaneously with chemotherapy either prior to, or in the absence of, surgery. Approximately 60% of cancer patients are treated using radiation at some point during their disease.[382] The continuous development of increasingly sophisticated imaging technologies and procedures has resulted in earlier diagnoses and improved outcomes for patients through radiation therapies.[383]

Devices

Technology is the leading driver of radiation therapy's competitive market.[384] The development of linear accelerators and gamma knives has increased therapeutic capability, precision, and ease of use, all of which enhance the quality of care. These tools are utilized in the various modalities to deliver highly advanced therapy procedures, such as intensity-modulated radiation therapy and stereotactic radiosurgery. In addition to executing treatment plans developed based on imaging scans, image guided radiotherapy is implemented by one-third of all radiation oncology sites to date, with ultrasound, x-ray, and CT imaging technologies used most frequently.[385] As radiation therapy has become one of the dominant methods of cancer treatment, demand is likely to increase as the population ages.[386]

Linear Accelerators

The *linear accelerator (LINAC)* is the device most commonly used in external beam radiation therapy treatments for patients with cancer.[387] Linear accelerators deliver uniform doses of high-energy x-rays to the localized area of a patient's tumor. LINAC accelerates electrons to allow the electrons to collide with a heavy metal target, which scatters the high energy x-rays. Then, "[a] portion of these x-rays are collected and then shaped to form a beam that matches the patient's tumor."[388] The beam emanates from a gantry that rotates around the patient. During this process, the patient lies on a movable treatment couch.[389] Lasers are utilized to ensure that the patient is properly positioned to receive the treatment. Radiation can be delivered to the tumor from various angles by rotating the gantry and the treatment couch. By modifying LINAC systems to

380 "Radiotherapy Overview" International Radiosurgery Association, 2008, http://www.irsa.org/radiotherapy.html (Accessed 6/26/09).
381 Ibid.
382 "Introduction to Cancer Therapy (Radiation Oncology)" By Radiological Society of North America, RadiologyInfo, April 22, 2013, http://www.radiologyinfo.org/en/info.cfm?pg=intro_onco (Accessed 3/20/15).
383 "Radiotherapy Overview" International Radiosurgery Association, 2008, http://www.irsa.org/radiotherapy.html (Accessed 6/26/09).
384 "DOTmed Industry Sector Report: Linear Accelerators and Simulators" By Barbara Kram, DOTmed News, November 19, 2008, http://www.dotmed.com/news/story/7013/ (Accessed 6/29/09).
385 "IMV Reports Increased Use of Image-Guided Radiotherapy in Radiation Oncology" By Gale Group, BusinessWire, April 9, 2007, http://www.businesswire.com/news/home/20070409005049/en/IMV-Reports-Increased-Image-Guided-Radiotherapy-Radiation-Oncology (Accessed 4/1/15).
386 "DOTmed Industry Sector Report: Linear Accelerators and Simulators" By Barbara Kram, DOTmed News, November 19, 2008, http://www.dotmed.com/news/story/7013/ (Accessed 6/29/09).
387 Ibid. See Procedures section, below.
388 "Linear Accelerator" By Radiological Society of North America, RadiologyInfo, June 10, 2009, http://www.radiologyinfo.org/content/therapy/linear_accelerator.htm, (Accessed 6/29/09).
389 Ibid.

include multileaf collimators, they can be used in intensity modulated radiation therapy.[390] However, without the necessary modifications, LINAC systems are simply machines used for stereotactic radiosurgery.[391] A new linear accelerator can cost anywhere from $1.5 million to $3 million.[392]

Gamma Knives

Development of the *gamma knife* revolutionized stereotactic radiosurgery by employing computerized robotic technology to move patients at submillimeter increments during treatment. This maximizes the procedure's practical utility, allowing a physician to accurately target safe but high-dose radiation treatment.[393] Gamma knife treatments are administered in a single session and require CT or MRI communication with the gamma knife's computer planning system to identify targets and normal anatomical structures and calculate the gamma knife treatment parameters. The gamma knife can be used for treatment of a variety of health problems, namely malignant and benign brain tumors, blood vessel defects, and functional problems. Research is currently underway to implement gamma knife technology in epilepsy and Parkinson's disease treatments.[394]

Procedures

External beam radiation therapy (EBRT) involves the administration of high-energy x-ray beams to kill cancer cells and treat tumors.[395] Often, some x-ray, ultrasound, or CT imaging is used prior to the delivery to ensure that the path of the beam will align with the target area.[396] Proton therapy is administered in a similar manner, but instead of administering x-ray beams, beams of protons are used to irradiate a variety of tumors, skull base sarcomas, and eye melanomas.[397] Alternately, *brachytherapy*, a form of internal radiation therapy, is used to treat a smaller area in a shorter period of time at higher doses of radiation by placing radiopharmaceuticals directly inside or next to the tumor.[398] Brachytherapy can be temporary or permanent, with variable administration rates and doses. During permanent brachytherapy, also known as seed implantation, a radioactive seed is placed in or near the tumor where it gradually decreases in radioactivity over a predetermined period of time. After the seed is rendered inactive, it remains in the body with no lasting effect on the patient.[399]

390 "DOTmed Industry Sector Report: Linear Accelerators and Simulators" By Barbara Kram, DOTmed News, November 19, 2008, http://www.dotmed.com/news/story/7013/ (Accessed 6/26/09); "Linear Accelerator" By Radiological Society of North America, RadiologyInfo, June 10, 2009, http://www.radiologyinfo.org/content/therapy/linear_accelerator.htm, (Accessed 6/29/09).
391 "DOTmed Industry Sector Report: Linear Accelerators and Simulators" By Barbara Kram, DOTmed News, November 19, 2008, http://www.dotmed.com/news/story/7013/ (Accessed 6/29/09).
392 Ibid.
393 "Novalis TX (r), CyberKnife (r), TomoTherapy (r), Linac Radiosurgery and Radiation Therapy" By the International Radiosurgery Association, 2008, http://www.irsa.org/radiotherapy.html (Accessed 6/26/09).
394 "Gamma Knife Surgery" International RadioSurgery Association, irsa.org, June 10, 2009.
395 "External Beam Therapy (EBT)" By Radiological Society of North America, RadiologyInfo, June 10, 2009, http://www.radiology info.org/en/info.cfm?PG=ebt (Accessed 6/26/09).
396 Ibid.
397 "Proton Therapy" By Radiological Society of North America, RadiologyInfo, June 10, 2009, http://www.radiologyinfo.org/en/info.cfm?PG=protonthera (Accessed 6/26/09).
398 Ibid.
399 Ibid.

Intensity-Modulated Radiation Therapy (IMRT)

Intensity Modulated Radiation Therapy (IMRT) is an advanced form of radiation therapy using 3D imaging and treatment delivery. It differs from 3D conformal radiation therapy (3D CRT), which uses linear accelerators to administer varying intensities of radiation without IMRT capabilities.[400] Currently, CT scans are most commonly used for *IGRT,* such as *IMRT,* because the CT can provide timely volumetric data.[401] Despite reported safety concerns related to certain procedures, e.g., *nonmetastatic prostate cancer*, IMRT has been associated with *better patient outcomes* than other similar therapeutic radiation procedures. [402] IMRT treatments, custom-tailored using 3D CT images alongside computer generated dose calculations, most effectively treat the unique three-dimensional shape of a tumor. This method allows for increased precision in the administration of high dose radiation while preserving the surrounding tissue.[403]

In 2007, *Varian Medical Systems* introduced a new IMRT treatment technique called *RapidArc,*[TM404] which delivers a radiation dose over a single rotation and utilizes a new software algorithm that can simultaneously control three parameters of treatment: (1) the *speed* of the gantry rotation; (2) the *shape and position* of the aperture created by the movement of *multileaf collimator (MLC)* leaves; and (3) the *dose* rate of delivery.[405] *RapidArc*[TM] uses *volumetric modulated arc* therapy, which allows treatment to be delivered in a single dose to the entire volume of the cancerous cell, in contrast to slice by slice. *RapidArc*[TM] is able to deliver a precise 3D dose distribution with a single 360-degree rotation and with treatments times two to eight times faster than typical IMRT techniques.[406]

Stereotactic Radiosurgery

Stereotactic radiosurgery is a nonsurgical procedure involving the single, high-dose delivery of targeted gamma-ray or x-ray beams typically used to treat various areas of the brain. It serves as an increasingly preferred alternative to invasive surgery for soft tissue tumors (e.g., brain tumors).[407] Most frequently, stereotactic radiosurgery is administered in one session; however, physicians may recommend fractionated stereotactic surgery (two to five treatments) or stereotactic radiotherapy (more than five treatments) in circumstances in which tumors are larger than an inch in diameter.[408] Linear accelerators, proton beams or heavy-charged particle beams, and gamma knives are all used to perform stereotactic procedures.[409]

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400 "Intensity-Modulated Radiation Therapy (IMRT)" By Radiological Society of North America, RadiologyInfo, June 10, 2009, http://www.radiologyinfo.org/en/info.cfm?PG=imrt (Accessed 6/26/09).
401 "Dose Variation During Hypofractionated Image-Guided Radiotherapy for Prostate Cancer: Planned Versus Delivered" By Vedang Murthy, et al., Journal of Cancer Research and Therapeutics, Vol. 7, No. 2 (April-June 2011), p. 162.
402 "Intensity –Modulated Radiation Therapy, Proton Therapy, or Conformal Radiation Therapy and Morbidity and Disease Control in Localized Prostate Cancer" By Nathan C. Sheets, et al., Journal of the American Medical Association, Vol. 307, No. 15 (April 18, 2012), p. 1611.
403 "Intensity-Modulated Radiation Therapy (IMRT)" By Radiological Society of North America, RadiologyInfo, June 10, 2009, http://www.radiologyinfo.org/en/info.cfm?PG=imrt (Accessed 6/26/09).
404 "Varian's New RapidArc Delivery: The Next Dimension in Speed and Precision" By Corey Zankowski, Centerline, October 2007, p. 1.
405 "Rapid Arc Volumetric Modulated Therapy Planning for Prostate Cancer Patients" By Flemming Kjaer-Kristoffersen, et al, Acta Oncologica, Vol. 48, No. 2 (2009), p. 227-232.
406 "Varian's New RapidArc Delivery: The Next Dimension in Speed and Precision" By Corey Zankowski, Centerline, October 2007, p. 1.
407 "Stereotactic Radiosurgery" By Radiological Society of North America, RadiologyInfo, June 10, 2009, http://www.radiologyinfo.org/en/info.cfm?PG=stereotactic, (Accessed 6/26/09).
408 Ibid.
409 Ibid.

Stereotactic radiotherapy has been used more recently to treat tumors located in areas other than the brain in procedures referred to as *stereotactic body radiotherapy*. The most common sites for which *stereotactic body radiotherapy* is currently being utilized include: (1) *lungs*; (2) *liver*; (3) *abdomen*; (4) *spine*; (5) *prostate*; and (6) the *head and neck*.[410]

Robotics and Surgical Technology

Trends in Robotics and Surgical Technology

Historical Developments in Minimally Invasive Surgery

Laparoscopy, a form of minimally invasive surgery, involves the insertion of a slender, tubular endoscope and other surgical instruments through the abdomen wall, allowing a practitioner direct internal visual navigation and control of a surgery.[411] Laparoscopy and other forms of minimally invasive surgery have evolved from continuous improvements in surgical technology to increase ease-of-use, comfort, and accuracy. In the early 1990s, countless attempts at robotic prototyping were made, namely in the area of laparoscopic surgical procedures, but nothing materialized.[412] The U.S. military, with the intention of designing a prototype to provide remote operative care in combat regions, actually pioneered the realm of surgical robotics. Introduced by Intuitive Surgical in 1996, this prototype came to be known as the da Vinci system; it was approved by the FDA in 2000. Simultaneously, Computer Motion released to the market the first laparoscopic camera holder, which it called Automated Endoscopic System for Optimal Positioning, or AESOP.[413]

Medical device manufacturers are consistently designing new *minimally invasive surgery* products to make surgery less invasive for the patient while still improving the surgeon's precision and visualization.[414] The main barrier to expanding the scope of *minimally invasive surgery technologies* may be providers' *lack of awareness* of, and *training in*, advanced laparoscopic techniques. To avoid the circumstance of manufacturers outpacing *efficient implementation* within the industry, manufacturers are focusing development on *ease of use* of new technologies, in addition to development of *innovative surgical techniques*.[415]

The availability of these newly developed *energy devices* has expanded the market for the utilization of *minimally invasive techniques* to include such devices as: (1) *electrosurgical generators*; (2) *instruments*; (3) *accessories*; and (4) *thermal ligature systems*, which allow for more *accurate* and *less invasive* procedures by advancing *dissecting*, *cutting*, *coagulating*, and *ligature creation* surgical procedures.[416] As of 2015, market reports predict that the

410 "Stereotactic Radiosurgery (SRS) and Stereotactic Body Radiotherapy (SBRT)" Radiological Society of North America and American College of Radiology, 2012, http://www.radiologyinfo.org/en/info.cfm?PG=stereotactic, (Accessed 11/1/12).
411 "Minimally Invasive Surgery" Mayo Clinic, 2009, http://www.mayoclinic.org/minimally-invasive-surgery/ (Accessed 4/6/09).
412 "Robotic Assisted Laparoscopic Radical Prostatectomy: A Review of the Current State of Affairs" By V.R. Patel, M. F. Chammas Jr., and S. Shah, International Journal of Clinical Practice, Vol. 61, No. 2 (February 2007), p. 309-314.
413 "Robotic Assisted Laparoscopic Radical Prostatectomy: A Review of the Current State of Affairs" By V.R. Patel, M. F. Chammas Jr., and S. Shah, Int. J. Clin. Pract, Vol. 61, No. 2 (February 2007), p. 309-314; "Robot-Assisted Surgery" Mayo Clinic, 2009, http://www.mayoclinic.org/robotic-surgery/ (Accessed 4/1/15).
414 "Trends in MIS, Part I: Pushing Surgical Boundaries" By Anne Staylor, Medtech Insight, Vol. 14, No. 5 (May 2012), p. 18.
415 "Trends in MIS, Part II" By Anne Staylor, Medtech Insight, Vol. 14, No. 6, June/July 2012, p. 18.
416 "Trends in MIS, Part I: Pushing Surgical Boundaries" By Anne Staylor, Medtech Insight, Vol. 14, No. 5 (May 2012), p. 18.

electrosurgical market will grow at an annual rate of roughly 5.9% through 2019, with the global market expected to reach approximately $4.0 billion.[417]

The da Vinci System Versus Laparoscopy

Minimally invasive procedures lessen many of the risks traditionally associated with surgery through the use of several small incisions to guide fiber-optic cameras to the area(s) of interest.[418] Some minimally invasive instruments, such as the da Vinci System, employ robotic equipment, which serves as an added benefit compared to laparoscopic methods due to increases in maneuverability, visibility, and precision. Laparoscopic techniques project a mirror image onto the screen, which has proven to be counterintuitive for physicians. Robotic technology features digital correction to cater to the physician's intuitive, natural tendencies, and thereby increases overall accuracy.[419]

The da Vinci System revolutionized minimally invasive surgery by overcoming the limitations of both traditional surgical procedures and conventionally implemented noninvasive laparoscopic technology. The procedure performed with this technology was originally limited to cardiac endoscopy, but it has expanded to include gastrointestinal, cardiothoracic, gynecologic, urologic, and other specialty surgical procedures.[420] The da Vinci system uses small incisions for the placement of robotic appendages, which result in fewer scars that require less healing time, decrease patient discomfort, shorten post-operative hospital stays, lower hospital costs, and decrease patient morbidity and mortality.[421] Further, effective use of the da Vinci system reduces total operative time while minimizing blood loss.[422]

The da Vinci System revolutionized minimally invasive surgery by overcoming the limitations of both traditional surgical procedures and conventionally implemented noninvasive laparoscopic technology.[423]

A keynote feature of the da Vinci system is its EndoWrist technology, which allows a surgeon to fully rotate his or her hand, therefore giving the surgeon the capacity to reach around, beyond, or behind. The EndoWrist technology provides the surgeon with seven *degrees of freedom* (that is, the number of different rotations by the robot "*hand*"), more than most other surgical robots on the market.[424]

417 "Electrosurgery Market worth $4.0 B by 2019" Markets and Markets, 2014, http://www.marketsandmarkets.com/PressReleases/electrosurgical-instruments-accessories.asp (Accessed 3/23/15).
418 "Minimally Invasive Surgery" Mayo Clinic, 2009, http://www.mayoclinic.org/minimally-invasive-surgery/ (Accessed 4/6/09).
419 "Robotic Surgery" Mayo Clinic, 2009, http://www.mayoclinic.org/robotic-surgery/ (Accessed 4/1/15).
420 "Robotic Surgery" By Joan Trombetti, DotMed News, January 7, 2009, http://www.dotmed.com/news/story/7463 (Accessed 07/06/09) (as noted on the DotMed webpage, "This article originally appeared in the December 2008 issue of DOTmed Business News."); "Minimally Invasive and Robotic Surgery" By Michael J. Mack, MD, Journal of the American Medical Association, Vol. 285 No. 5 (2001), p. 568; "Robot-Assisted Surgery" Mayo Clinic, 2009, http://www.mayoclinic.org/robotic-surgery/ (Accessed 4/1/15).
421 "Minimally Invasive and Robotic Surgery" By Michael J. Mack, MD, Journal of the American Medical Association, Vol. 285, No. 5 (2001), p. 568; "Robotic Surgery" Mayo Clinic, 2009, http://www.mayoclinic.org/robotic-surgery/ (Accessed 4/1/15).
422 "Robotics in Vascular Surgery" By Bernardo Martinez & Catherine Wiegand, The American Journal of Surgery, Vol. 188, No. 4A (Supplement to October 2004), p. 58s.
423 "Robotic Surgery," By Joan Trombetti, DotMed News, January 7, 2009, www.dotmed.com/news/story/7463 (Accessed July 6, 2009) (as noted on the DotMed webpage, "This article originally appeared in the December 2008 issue of DOTmed Business News").
424 "Endoscopic Coronary Artery Bypass Grafting with the Aid of Robotic Assisted Instruments" By Didier Loulmet, et al., The Journal of Thoracic and Cardiovascular Surgery, Vol. 118 (1999), p. 5-6.

A fairly recent sojourn in minimally invasive surgery, robotic-assisted laparoscopic prostatectomy, combines da Vinci robotics with laparoscopy and "allow[s] for greater surgical precision . . . [leading] to improvements in cancer control, potency, and urinary function." The da Vinci system has also been used to treat small and complex renal tumors.[425]

Despite its proven benefits in the field, the system has its limitations. Surgeons struggle with the lack of tactile feedback. This would be remedied by strain sensor feedback, which is under development for implementation in future models. Additionally, the size and complexity of robotic appendages still limit the extent to which accurate movement can be controlled.[426] Further, the system requires a significant amount of space—something that many hospitals and facilities cannot spare.[427]

Demand for Robotic Surgery

Despite the difficulties associated with robotic surgery, minimally invasive technologies are replacing traditional methods as quickly as the technology will allow. The global market was valued at an estimated $25.03 billion in 2012; it is expected to reach $50.6 billion by 2019.[428]

During the past twenty years, the number of general surgical, gastrointestinal, gynecological, neurosurgical, orthopedic, pediatric, radiosurgical, and urological procedures that employ either robotically assisted or robotically controlled capabilities has grown steadily, most frequently through adoption of the da Vinci system.[429] As of December 2014, 3,266 da Vinci units had been installed internationally, 2,223 of which belong to facilities in the United States.[430] In 2014 Intuitive Surgical, who manufactures the da Vinci system, saw its net income and revenue drop by 37% ($418.8 million) and 6% ($2.13 billion) respectively, though reported procedures using the units rose 10%.[431] Until recently, the da Vinci system was the only approved system on the market; however, in early 2009, CUREXO Technology Corporation announced FDA clearance of its robotic orthopedic surgical device, ROBODOC, for total hip arthroplasty.[432]

The CBO's 2007 report, *The Long-Term Outlook for Healthcare Spending*, predicted that the United States would see a rise in total healthcare spending from 16% of GDP as of March 2007 to 25% in 2025, 37% in 2050, and 49% in 2082.[433] More recent CBO estimates put near-term projections for healthcare spending around 19.3% of GDP in 2023 however.[434] These projections

425 "Robotic Surgery" By Joan Trombetti, DotMed News, January 7, 2009, http://www.dotmed.com/news/story/7463 (Accessed 07/06/09) (as noted on the DotMed webpage, "This article originally appeared in the December 2008 issue of DOTmed Business News").
426 "Recent Trends in Minimally Invasive Cardiac Surgery" By Alan P. Kypson, Cardiology, Vol. 107 (2007), p. 156.
427 "Robotic Technology in Surgery: Past, Present, and Future" By David B. Camarillo, Thomas M. Krummel, and J. Kenneth Salisbury, The American Journal of Surgery, Vol. 188, No. 4A (Supplement to October 2004), p. 11S.
428 "Global Minimally Invasive Surgery Market to Expand at a 10.5% CAGR During the Forecast Period 2013 - 2019 Due to Rising Expenditure on Healthcare" Transparency Market Research, May 19, 2015, http://www.transparencymarketresearch.com/pressrelease/minimally-invasive-surgery-market.htm (Accessed 7/2/2015).
429 "Robotic Surgery" By Joan Trombetti, DotMed News, January 7, 2009, http://www.dotmed.com/news/story/7463 (Accessed 07/06/09) (as noted on the DotMed webpage, "This article originally appeared in the December 2008 issue of DOTmed Business News").
430 "Investor FAQ" Intuitive Surgical, 2015, http://phx.corporate-ir.net/phoenix.zhtml?c=122359&p=irol-faq (Accessed 3/23/15).
431 "Intuitive Surgical Earnings Dampened by Robotic Surgery Debate" By Jaimy Lee, Modern Healthcare, January 22, 2015, http://www.modernhealthcare.com/article/20150122/NEWS/301229963/intuitive-surgical-earnings-dampened-by-robotic-surgery-debate (Accessed 3/23/15).
432 "CUREXO to Launch New Robotic Surgery Technology" By Diana Manos, Healthcare IT News, February 23, 2009, http://www.healthcareitnews.com/news/curexo-launch-new-robotic-surgery-technology (Accessed 6/30/09).
433 "The Long-Term Outlook for Health Care Spending" By Congressional Budget Office, November 2007, http://www.cbo.gov/ftpdocs/87xx/doc8758/11-13-LT-Health.pdf (Accessed 07/06/09).
434 "National Health Expenditure Projections 2013-2023: Forecast Summary" CMS, 2014, http://www.cms.gov/Research-Statistics-Data-and-Systems/Statistics-Trends-and-Reports/NationalHealthExpendData/Downloads/Proj2013.pdf (Accessed 3/23/15).

are fueled by the perpetual technological advancement, dynamic availability of the most accelerated technologies, fear of potential malpractice suits, and efforts to procure economic gain that support the necessary supply factors to perpetuate this inevitable expansion. Diagnostic and therapeutic technologies continue to emerge, replacing outdated and risky techniques with less invasive, yet more expensive, alternatives. This ongoing development of new technologies undoubtedly contributes to the role of the U.S. as the global leader in healthcare expenditures.[435]

In addition to the rising costs are the technical demands associated with the accumulating intricacies that make noninvasive procedures desirable. The required skill sets are challenging and demand extensive training, and improper use of these technologies can be more dangerous than the older alternatives.[436] Although the da Vinci system has been used successfully in an array of surgical procedures, many surgeons remain skeptical of its continued use in the medical profession. Due to the excessive start-up and per procedural costs of robotic surgery, as well as the complexity of many procedures, such as cardiac and thoracic surgeries, many institutions do not use the da Vinci robot as much as was expected, often utilizing it only for less complicated procedures (for example, urological surgery). Although minimally invasive technology is clearly a potential asset in the future of surgery, it is uncertain at what point and to what extent robotic surgery will become a regularly feasible procedure for many specialized and intensive surgical programs.[437]

A "tortuous learning curve," paired with economic barriers to use, necessarily indicates that surgeons proficient in robotic surgical procedures are scarce; however, surgeons and other medical professionals agree that this is bound to change.[438] With time, evolving criteria, perspectives, and credentials will foster a new "breed" of surgeons, trained to take full advantage of the benefits that robotic, noninvasive procedures provide.[439] Upon approving the da Vinci robot for cardiac procedures, the FDA mandated training of all surgical teams and professionals intending to use the product.[440] Surgeons who have pioneered the infusion of robotic technology into their programs believe that success is imminent with the right team; dedication to administrative and clinical commitment; a properly devised curriculum targeted at surgeons, their teams, and other members of their departments; multispecialty training; and patience.[441] As more institutions and surgical teams follow in their footsteps, a new tier of surgical competition will lead to different expectations in medical care.

435 "Economics Issues in Medical Care" in "Goldman Cecil Medicine, 23rd Edition" By Lee Goldman, MD and Dennis Arthur Ausiello, MD, Saunders, 2008, http://www.mdconsult.com.ezp.slu.edu/das/book/body/1301180599-5/826126389/1492/28.htm (Accessed April 4, 2008).

436 "Economics Issues in Medical Care" in "Goldman Cecil Medicine, 23rd Edition" By Lee Goldman, MD and Dennis Arthur Ausiello, MD, 2008, http://www.mdconsult.com.ezp.slu.edu/das/book/body/1301180599-5/826126389/1492/28.htm (Accessed April 7, 2008).

437 "Robotic Cardiac Surgery: Time Told!" By Francis Robicsek, Journal of Thoracic Cardiovascular Surgery, Vol. 135 (2008), p. 245.

438 "Minimally Invasive Surgery: Continued Growth Opens New Doors" By Michelle Beaver, Surgistrategies, 2009, http://www.surgistrategies.com/articles/751feat3.html (Accessed 4/7/08).

439 Ibid.

440 "Robotic Surgical Training in an Academic Institution" By W. Randolph Chitwood et al., Annals of Surgery, Vol. 234 No. 4 (October 2001), p. 478.

441 "Building a Surgical Robotics Program" By Wiley Nifong and Randolph Chitwood, The American Journal of Surgery, Vol. 188, No. 4A (2004), p. 16S.

Regulatory and Reimbursement

Although each insurance company differs in what procedures it reimburses, Medicare covers most laparoscopic and thoracoscopic procedures.[442] Currently, reimbursement for procedures that use robotic technologies is limited to the agreed-upon reimbursement for the baseline procedure.[443] However, as more studies show that noninvasive cardiac technology is improving patient outcome metrics and policymakers move toward incentive-based programs that improve the quality of robotically assisted procedures, robotic procedures may procure higher reimbursement.[444]

HOME HEALTH TECHNOLOGY

Home care patients represented approximately 3.8 percent of the U.S. population as of 2008, an increase from 2.5 percent in 2000.[445] Additionally, the growing segment of older Americans will invariably contribute to the increased use of home infusion therapies. Although the Bureau of Health Professions predicted in 2006 that, between 2000 and 2020, the U.S. population would increase by 18 percent, the number of Americans aged sixty-five and older is anticipated to reach 88.5 million in 2050, with the "oldest old," those 85 and older, expected to triple from "6.3 million in 2015 to 17.9 million in 2050, accounting for 4.5% of the total population."[446] Approximately 69 percent of those receiving home care services are older than age sixty-five.[447] In addition, the aging *baby boomer* population, the first cohort of which reached eligibility in 2011, will continue to inflate the number of candidates for home healthcare.[448]

Trends in Home Infusion Therapy

According to *The Braff Group*, a healthcare M&A firm, *home infusion therapy* experienced a 60% increase in transactional market activity between 2010 and 2011.[449] According to *Braff*, with 16 deals in 2011 (11 of which had different buyers), the home infusion therapy market posted its highest transaction volume since 2008.[450]

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442 "Bariatric surgery, Medicare.gov, http://www.medicare.gov/coverage/bariatric-surgery.html (Accessed 3/30/15); "2014 Thoracic Medicare Reimbursement Coding Guide: Effective January 1, 2014" Covidien, http://www.covidien.com/imageServer.aspx/doc265365.pdf?contentID=43864&contenttype=application/pdf (Accessed 3/30/15), p. 1.

443 Note: The baseline procedure is denoted by HCPCS Code S2900.

444 "Superior Financial and Quality Metrics with Robotically-Assisted (DaVinci) Coronary Artery Revascularization" By Robert S. Poston, American Surgeon Association, 2008, http://www.americansurgical.info/abstracts/2008/26.cgi (Accessed 4/7/09); "ASA: Robotic CABG Paint Cost-Effective Benefits for Patients" By Crystal Phend, 2008, MedPage Today, http://www.medpagetoday.com/Cardiology/CoronaryArteryDisease/9254 (Accessed 4/7/09); "ASA: Robotic CABG Paint Cost-Effective Benefits for Patients" By Crystal Phend, 2008, MedPage Today, http://www.medpagetoday.com/Cardiology/CoronaryArteryDisease/9254 (Accessed 4/7/09).

445 "Basic Statistics About Home Care, Updated 2010" By The National Association for Home Care & Hospice, Washington, DC: National Association for Home Care & Hospice, 2010, http://www.nahc.org/assets/1/7/10HC_Stats.pdf (Accessed 3/23/15), p. 1, 6; "Interactive Population Map, U.S. Census Bureau, http://www.census.gov/2010census/popmap/ (Accessed 3/30/15).

446 "Long-Term Care Services in the United States: 2013 Overview" By Lauren Harris-Kojetin, Manisha Sengupta, Eunice Park-Lee, and Roberto Valverde, Hyattsville, MD: National Center for Health Statistics, December 2013, http://www.cdc.gov/nchs/data/nhsr/nhsr052.pdf (Accessed 3/23/15), p. 3.

447 "Basic Statistics About Home Care, Updated 2010" National Association for Home Care & Hospice, Washington, DC: National Association for Home Care & Hospice, 2010, http://www.nahc.org/assets/1/7/10HC_Stats.pdf (Accessed 3/23/15), p. 6.

448 "The Nation's Health Care Conundrum: Where Do We Go From Here" By David Kroitz, The Concord Coalition, May 15, 2009, http://www.concordcoalition.org/issue-briefs/2009/0515/nations-health-care-conundrum-where-do-we-go-here (Accessed 12/10/09).

449 "4 Perspectives: 2011 Fourth Quarter" The Braff Group, 2011, http://www.thebraffgroup.com/Articles/articlespdfs/perspectives/Q42011.pdf (Accessed 9/28/12), p. 2, 6.

450 "Market Watch 2012: Pharmacy Services" The Braff Group, 2012, http://www.thebraffgroup.com/Articles/articlespdfs/MarketWatch/MW_Pharmacy_Service.pdf (Accessed 9/28/12), p. 2.

Infusion therapy, growing in popularity, involves the administration of medications, nutrients, or other solutions *intravenously*, *subcutaneously*, *enterally*, or *epidurally* (into the bloodstream, under the skin, into the digestive system, or into the membranes surrounding the spinal cord). Specific home infusion therapies include anti-infectives, chemotherapy, pain management, parenteral and enteral nutrition, hydration therapy, and immunotherapy.[451] By 2030, it is expected that approximately 20%, or 72 million, of Americans will be older than the age of 65, twice as many as the 65 and older population in 2000,[452] which will lead to an increase in the demand for home- and community-based services. Skilled nursing services are the most commonly used by home healthcare patients 65 and older, with infusion therapy being one of the primary services performed.[453]

The implementation in 1983 of the Prospective Payment System (PPS) for inpatient hospital services with its diagnosis-related group (DRG) payment system touched off a number of dramatic changes in the healthcare field.[454] These changes affected not only inpatient hospital care, but also virtually every aspect of the U.S. healthcare delivery system. As a result of the DRG payment methodology, traditional indicators of inpatient hospital utilization showed substantial changes. Between 1980 and 1990, the number of hospitals and hospital beds declined, admissions and average daily census fell, and average length of stay decreased. Combined, these indicators of inpatient utilization pointed the way to a dramatic shift in the way healthcare services would be delivered. The types of services provided, as well as the location of service delivery, began to shift from the inpatient to the outpatient setting. As length of stay for Medicare patients shortened in the early 1980s, the percentage of Medicare patients discharged to home health increased from 9.1% in 1981 to 17.9% in 1985.[455]

In June 2012, the *Medicare Payment Advisory Commission* (MedPAC) submitted its report to Congress regarding the feasibility of expanding Medicare to include *home-based infusion therapy*, in addition to the infusion therapy performed in inpatient, outpatient, hospice, and *skilled nursing facility* settings.[456] About 36,000 *Medicare Part B* beneficiaries and about 100,000 *Medicare Part D* beneficiaries received home infusion therapy in 2009.[457] Both Medicare spending on home infusion therapy drugs and the number of beneficiaries receiving these drugs increased rapidly between 2006 and 2009, with the number of Part D enrollees receiving Part D-covered home infusion drugs increasing at a rate of 21% per year, as compared to a growth rate of five percent per year for the overall Part D population.[458] Additionally, Medicare *fee-for-service* spending for Part B-covered home infusion therapy drugs increased at an average rate of 17% per year, as compared to an average growth rate of six percent in the number beneficiaries using Part B home infusion drugs.[459] *Home infusion antibiotics* covered by

451 "Home Infusion Therapy" BlueCross BlueShield of Illinois, BlueCross BlueShield of Illinois, 2008 http://www.bcbsil.com/PDF/providermanual/home_infusion_therapy.pdf, (Accessed 10/2/09).
452 "Older Americans 2012: Key Indicators of Well-Being" By Federal Interagency Forum on Aging-Related Statistics, Washington, DC: U.S. Government Printing Office, June 2012, p. 2.
453 "National Health Statistics Reports: Characteristics and Use of Home Health Care by Men and Women Aged 65 and Over" By Adrienne L. Jones, Lauren Harris-Kojetin, Roberto Valverde, Hyattsville, MD: National Center for Health Statistics, No. 52, April 18, 2012, p. 3; "Option Care, Inc. Form 10K for Fiscal Year Ending December 31, 2005, Securities Exchange Commission, p. 8.
454 See Chapter 2 for further discussion of the PPS and DRG payment system.
455 "Basic Statistics About Home Care, Updated 2010" By The National Association for Home Care & Hospice, Washington, DC: National Association for Home Care & Hospice, 2010, http://www.nahc.org/assets/1/7/10HC_Stats.pdf (Accessed 3/23/15), p. 6.
456 "Report to the Congress: Medicare and the Health Care Delivery System" Medicare Payment Advisory Commission, Washington, DC, June 2012, p. 169-207.
457 Ibid, p. 177-178.
458 Ibid, p. 178.
459 Ibid, p. 177-178.

Part D accounted for the greatest number of users of Medicare covered home infusion drugs, followed by *immune globulin* and *alpha-1-proteniase inhibitor* drugs, and several drugs used to treat *rheumatoid arthritis*.[460] Similarly, *antibiotics* were the most common type of home infusion therapy drug covered by commercial insurers.[461]

The decrease of traditional inpatient utilization led to a virtual explosion of healthcare services in other areas, both on the hospital campus and in freestanding facilities located in the community. However, the location of service delivery also moved into the most convenient location possible—the patient's home.[462] Despite adequate patient access to home health services, the number of providers continues to grow, exceeding the growth rate of Medicare enrollees.[463] As of 2009, more than 10,000 active home health agencies participated in the Medicare payments program for home healthcare, with nearly 85% of the agencies being freestanding centers.[464]

Regulatory and Reimbursement

Medicare and Medicaid remain the largest single payors of home healthcare services, paying roughly 43 percent and 37 percent respectively, of all home health expenditures in 2012, although private insurance represented a small portion of home health payments (7 percent).[465] *Out-of-pocket* spending growth decreased from 5.2 percent in 2005 to 3.8 percent in 2006, largely due to the introduction of Medicare Part D[466] and has stayed relatively stable in that time with most recent 2013 NHE data showing a growth rate of 3.2 percent.[467] In fact, total out-of-pocket spending declined from 14 percent in 2001[468] to 12 percent in 2013.[469] However, it is estimated that the rate of out-of-pocket expenditures will increase and peak at roughly 6 percent by 2020.[470] This would bring parity to the ratio of out-of-pocket spending to private health insurance spending.[471]

Although Medicare Part D covers both the ingredient costs and dispensing fees associated with home infusion therapy, it excludes any costs associated with equipment, supplies, and professional services.[472] Due to regulatory action in 2014, home health reimbursement will be cut by $60 million, or 0.3%, in 2015 as a part of a four-year phase-in of lower payment rates for home health services, which the National Association for Homecare & Hospice has estimated to

460 Ibid, p. 178.
461 Ibid.
462 "Report to the Congress: Home Health Services" Medicare Payment Advisory Commission, March 2008, p. 171.
463 "Home Health Care Services Payment System" Medicare Payment Advisory Commission, October 2008, p. 171.
464 "Home Health Study Report" By Judy Goldberg Dey, et al., To Centers for Medicare & Medicaid Services, Baltimore, MD: L&M Policy Research, January 11, 2011, p. 12.
465 "Health Care Costs 101: Slow Growth Persists" California Healthcare Foundation, July 2014, http://www.chcf.org/~/media/MEDIA%20LIBRARY%20Files/PDF/H/PDF%20HealthCareCosts14.pdf (Accessed 3/23/15).
466 "Basic Statistics About Home Care" National Association for Home Care and Hospice, 2008, http://www.nahc.org/facts/08HC_Stats.pdf (Accessed 4/28/09).
467 "NHE Fact Sheet" Centers for Medicare & Medicaid Services, 2014, http://www.cms.gov/Research-Statistics-Data-and-Systems/Statistics-Trends-and-Reports/NationalHealthExpendData/NHE-Fact-Sheet.html (Accessed 3/23/15).
468 "Trends in U.S. Health Care Spending, 2001" By Katharine Levit, Cynthia Smith, Cathy Cowan, Helen Lazenby, Art Sensenig, and Aaron Catlin, Health Affairs, Vol. 22 No. 1 (2003), p. 162.
469 "NHE Fact Sheet" Centers for Medicare & Medicaid Services, 2014, http://www.cms.gov/Research-Statistics-Data-and-Systems/Statistics-Trends-and-Reports/NationalHealthExpendData/NHE-Fact-Sheet.html (Accessed 3/23/15).
470 "National Health Expenditure Projections 2013-2023: Forecast Summary" CMS, 2014, http://www.cms.gov/Research-Statistics-Data-and-Systems/Statistics-Trends-and-Reports/NationalHealthExpendData/Downloads/Proj2013.pdf (Accessed 3/23/15).
471 "Basic Statistics About Home Care" National Association for Home Care and Hospice, 2008, http://www.nahc.org/facts/08HC_Stats.pdf, (Accessed 04/28/09).
472 "Memorandum to All Part D Sponsors from Gary Bailey, Deputy Director, Center for Beneficiary Choices Regarding Home Infusion Therapy" By Center for Beneficiary Choices, CMS, March 10, 2006, p. 1.

result in a nearly 14% reimbursement cut by 2017.[473] Despite the relatively stable reimbursement environment, numerous attempts have been made by both the House of Representatives and the Senate to pass legislation for the reimbursement of equipment, supplies, and professional services. Senators proposed bills in 2007 and 2008 (S 870 and S 3505, respectively) that were not passed.[474] Additionally, in 2006 and 2007, the House of Representatives unsuccessfully proposed HR 5791 and HR 2567.[475] Most recently in 2009, Eliot Engel (D-NY) proposed *The Medicare Home Infusion Therapy Coverage Act of 2009* (HR 574), proposed that Part D coverage of home infusion services include equipment, supplies, and professional services.[476] However, the bill was never enacted and a subsequent attempt to introduce the bill in 2011 also failed.[477]

CONCLUSION

Over the course of human history, healthcare trends have been driven by advances in our medical capabilities, which are largely dependent on our technological progress. Current total spending on healthcare is 17.4% of GDP and grew at a rate of 3.6 percent in 2013 to an estimated $2.9 trillion.[478] This growth is driven in part by the *perpetual technological advancement*; *dynamic availability* of the most *accelerated technologies*; fear of potential *malpractic*e suits; and efforts to procure *economic gain* that support the necessary supply factors to perpetuate this invincible expansion. With the current market demand for both chronic and acute services undergoing continuous growth, available technologies, as well as future technological developments, will augment the healthcare practice with the clinical and administrative tools necessary to provide efficient, effective, and affordable healthcare services.

473 "CMS Finalizes 2015 Payment Cuts to Home Healthcare Agencies" By Paul Demko, Modern Healthcare, October 31, 2014, http://www.modernhealthcare.com/article/20141031/NEWS/310319961 (Accessed 3/23/15).

474 "S. 3505 Medicare Home Infusion Therapy Coverage Act of 2008" 110th Congress, September 17, 2008, http://www.govtrack.us/congress/bill.xpd?bill=s110-3505 (Accessed 5/05/09); "S. 870: Medicare Home Infusion Therapy Consolidated Coverage Act of 2007" 110th Congress, March 14, 2007, http://www.opencongress.org/bill/110-s870/show (Accessed 5/05/09).

475 "H.R. 2567 Medicare Home Infusion Therapy Consolidated Coverage Act of 2007" 110th Congress, June 12, 2007, http://www.govtrack.us/congress/bill.xpd?bill=h110-2567 (Accessed 5/05/09); "H.R. 5791 Medicare Home Infusion Therapy Consolidated Coverage Act of 2006" 110th Congress, August 1, 2006, http://www.govtrack.us/congress/bill.xpd?bill=h109-5791 (Accessed 5/05/09).

476 "H.R. 574 Medicare Home Infusion Therapy Consolidated Coverage Act of 2009" 111th Congress, January 15, 2009.

477 "All Bill Information (Except Text) for H.R. 2195 - Medicare Home Infusion Therapy Coverage Act of 2011" United States Congress, 2011, https://www.congress.gov/bill/112th-congress/house-bill/2195 (Accessed 3/23/15).

478 "National Health Expenditures 2013 Highlights" Centers for Medicare & Medicaid Services, 2014, http://www.cms.gov/Research-Statistics-Data-and-Systems/Statistics-Trends-and-Reports/NationalHealthExpendData/downloads/highlights.pdf (Accessed 3/23/15).

Key Sources

Key Source	Description	Citation	Website
"Electronic Health Records Overview"	Overview of EHR.	"Electronic Health Records Overview" National Institutes of Health: National Center for Research Resources, April 2006, p. 1.	n/a
"To Err is Human: Building a Safer Health System"	The first study to show the need for Computerized Physician Order Entry (CPOE). Gained national attention and is still quoted today as reasoning for CPOE implementation.	"To Err is Human: Building a Safer Health System" Institute of Medicine, Nov. 1999, p. 1.	n/a
Leapfrog Hospital Survey Results	Leapfrog is a voluntary program aimed at mobilizing employer purchasing power to alert America's health industry that big leaps in healthcare safety, quality, and customer value will be recognized and rewarded.	"Leapfrog Hospital Survey Results" The Leapfrog Group, 2008, p. 3.	www.leapfroggroup.org
"Inpatient Computerized Provider Order Entry (CPOE): Findings from the AHRQ Health IT Portfolio"	A study of CPOE benefits and statistics resulting in the Agency for Healthcare Research and Quality's promotion of CPOE implementation.	"Inpatient Computerized Provider Order Entry (CPOE): Findings from the AHRQ Health IT Portfolio" By Brian E. Dixon and Atif Zafar, U.S. Department of Health and Human Services, Agency for Healthcare Research and Quality, January 2009, http://healthit.ahrq.gov/ahrq-funded-projects/emerging-lessons/computerized-provider-order-entry-inpatient/inpatient-computerized-provider-order-entry-cpoe (Accessed 4/1/15), p. 1.	n/a
"Computerized Physician Order Entry Usage in North America: The Doctor is In"	Statistics regarding levels of hospital integration of CPOE systems.	"Computerized Physician Order Entry Usage in North America: The Doctor is In" By Stacilee Oakes Whiting and Adam Gale, HIT Report from KLAS, Healthcare Quarterly, Vol. 11, No. 3 (2008), p. 94.	n/a
"U.S. Adoption of Computerized Physician Order Entry Systems"	Statistics and trends about the United States' adoption of CPOE systems.	"U.S. Adoption of Computerized Physician Order Entry Systems" By David M. Cutler, Naomi E. Feldman and Jill R. Horitz, Health Affairs, Vol. 24, No. 6 (November/December 2005), p. 1660.	n/a
"Saving Lives, Saving Money: The Imperative for Computerized Physician Order Entry In Massachusetts Hospitals"	The ramifications and necessity of CPOE use in hospitals. Also a highly quoted and comprehensive study regarding CPOE use in Massachusetts' hospitals.	"Saving Lives, Saving Money: The Imperative for Computerized Physician Order Entry In Massachusetts Hospitals" By Mitchell Adams et al., Massachusetts Technology Collaborative, New England Healthcare Institute, February 2008.	n/a

(continued)

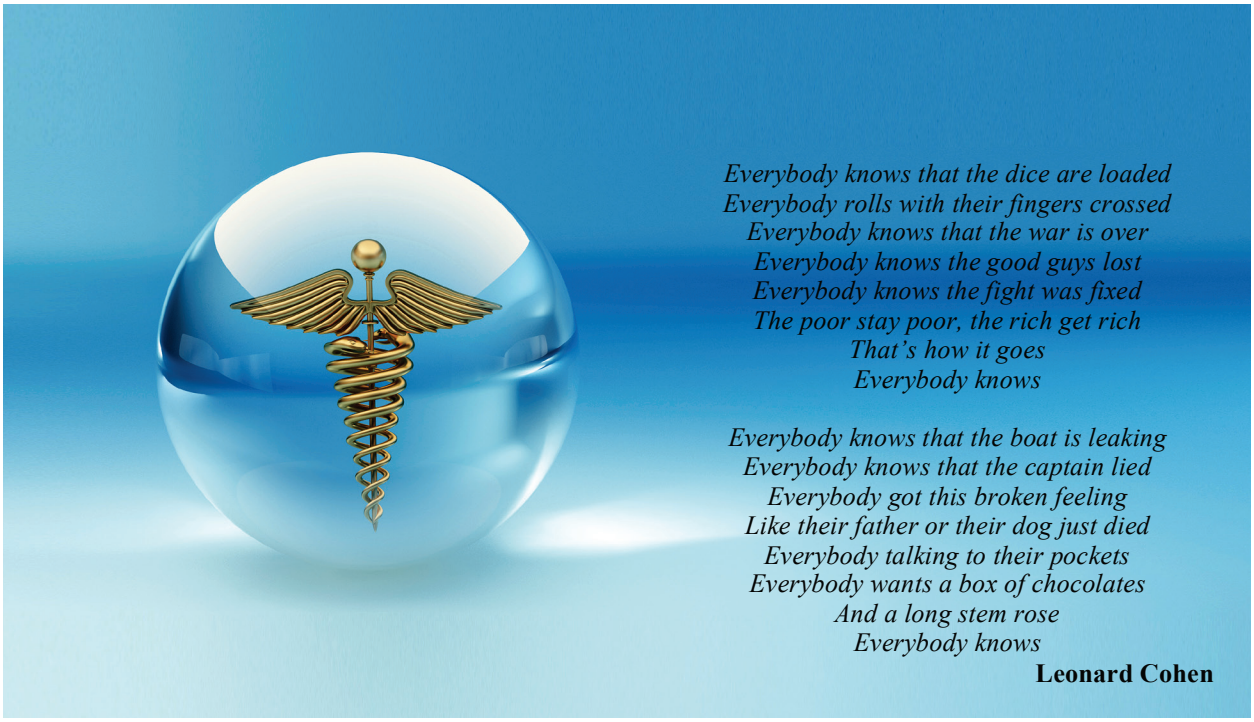
Key Source	Description	Citation	Website
"Biopharmaceutical benchmarks 2006: The rate of biopharmaceutical approvals has leveled off, but some milestones bode well for the future"	Information regarding the biopharmaceutical market.	"Biopharmaceutical Benchmarks 2006: The rate of biopharmaceutical approvals has leveled off, but some milestones bode well for the future" By Gary Walsh, Nature Biotechnology, Vol. 24, No. 7 (July 2006), p. 769–776.	n/a
"Rx Watchdog Report, Trends in Manufacturer Prices of Specialty Prescription Drugs Used by Medicare Beneficiaries, 2004-2007"	Trends in biopharmaceutical pricing.	"Rx Watchdog Report, Trends in Manufacturer Prices of Specialty Prescription Drugs Used by Medicare Beneficiaries, 2004-2007" By Stephen W. Schlondelmeyer, Leigh Purvis, and David J. Gross, American Association of Retired Persons, September 2008, http://assets.aarp.org/rgcenter/health/2008_15_specialty_q407.pdf (Accessed 4/1/15).	n/a
"Report to the Congress: Medicare Payment Policy"	MedPac report with Chapter 9 Dedicated to Home Health Care Services	"Report to the Congress: Medicare Payment Policy" Medicare Payment Advisory Commission, March 2014, Chapter 9: Home Health Care Services.	n/a
National Institutes of Health	A resource for stem cell research.	"Stem Cell Information: Stem Cell Basics" National Institutes of Health Resource for Stem Cell Research, April 28, 2009, http://stemcells.nih.gov/info/basics/ (Accessed 4/1/15).	http://stemcells.nih.gov

Associations

Type of Association	Name	Description	Citation	Contact Information
International	The International Radiosurgery Association (IRSA)	The IRSA provides information on current radiation therapy technologies.	"About Us" International Radiosurgery Association, www.irsa.org/about_us.html (Accessed 4/1/15).	The International Radiosurgery Association P.O. Box 5186 Harrisburg, PA 17110 Phone: 717-260-9808 www.irsa.org
International	Radiological Society of North America (RSNA)	Founded in 1915, RSNA is a membership of medical imaging professionals committed to patient care through education and research. RSNA hosts the world's largest annual radiological meeting.	"About RSNA" Radiological Society of North America, http://www.rsna.org/AboutRSNA.aspx (Accessed 4/1/15).	Radiological Society of North America, Inc. 820 Jorie Blvd. Oak Brook, IL 60523 Phone: 630-571-2670, 800-381-6660 Fax: 630-571-7837 www.rsna.org
National	American Telemedicine Society (ATA)	The ATA is the leading resource and advocate promoting access to medical care for consumers and health professionals by way of telecommunications technology.	"Who is ATA?" American Telemedicine Association, http://www.americantelemed.org/about-ata/who-is-ata#.VRxW7vnF91Y (Accessed 4/1/15).	American Telemedicine Association 1100 Connecticut Avenue, NW Suite 540 Washington, DC 20036 Phone: 202-223-3333 Fax: 202-223-2787 E-mail: info@americantelemed.org www.americantelemed.org

Chapter 6

Healthcare Reform: Past as Prologue to the Future



Everybody knows that the dice are loaded
Everybody rolls with their fingers crossed
Everybody knows that the war is over
Everybody knows the good guys lost
Everybody knows the fight was fixed
The poor stay poor, the rich get rich
That's how it goes
Everybody knows

Everybody knows that the boat is leaking
Everybody knows that the captain lied
Everybody got this broken feeling
Like their father or their dog just died
Everybody talking to their pockets
Everybody wants a box of chocolates
And a long stem rose
Everybody knows

Leonard Cohen

KEY TERMS

Alternative Payment Models (APMs)
Benefit Enhancement Tools
Bundled Payments
Death Spiral
Exchanges
Full Performance Risk Arrangement
Grandfathered Health Plan
Next Generation Accountable Care Organization
Small Business Health Options Programs (SHOPs)

Key Concept	Definition	Citation	Concept Mentioned on Page #
Alternative Payment Models (APMs)	Methods by which providers of healthcare services may be reimbursed for said services, that deviate from the traditional fee-for-service reimbursement model. APMs include: (1) payment models under the Center for Medicare and Medicaid Innovation; (2) Accountable Care Organizations (ACOs); or, (3) demonstrations of payment models under certain federal laws.	"Medicare Access and CHIP Reauthorization Act of 2015" Pub. L. No. 114-10, § 101, 129 Stat. 87, 121 (April 16, 2015); "Center for Medicare and Medicaid Innovation" Letter to Senator Tom Coburn, From Jim Hahn, Congressional Research Service, February 24, 2012, http://www.law.umaryland.edu/marshall/crsreports/crsdocuments/022412B_04242012.pdf (Accessed 4/22/2015), p. 1.	409
Benefit Enhancement Tools	Practices that are designed to improve patient engagement with ACOs, including: (1) a process by which beneficiaries may enroll with Next Generation ACOs; (2) improved access to home visits, telehealth services, and skilled nursing facilities; (3) financial rewards for beneficiaries who receive care from ACOs; and (4) collaboration between CMS and Next Generation ACOs to improve communication with beneficiaries regarding their ACOs, and the potential benefits of receiving care from their ACOs.	"Next Generation ACO Model Frequently Asked Questions" Centers for Medicare & Medicaid Services, March 10, 2015, http://innovation.cms.gov/Files/x/nextgenacofaq.pdf (Accessed 3/18/2015), p. 1.	413
Bundled Payments	A method of reimbursement that combines institutional and professional charges into a single payment.	"The Managed Health Care Handbook" By Peter R. Kongstvedt, 3rd Ed., Aspen Publishers, Inc., 1996, p. 187.	412
Death Spiral	An economic phenomenon that can occur in health insurance markets, wherein the healthiest people drop out of the market due to price concerns, thus raising the average healthcare expenditures per capita in the market. In response, health insurance companies raise premiums, which in turn drives more healthy people out of the market. This creates a perpetual loop that drives up health insurance premiums and the share of the population that is uninsured.	"David King et al. v. Sylvia Mathews Burwell et al." Case No. 14-114 (SCOTUS 2015), Oral Argument, p. 15; "Will concern for states' rights win out in subsidies battle? Today's argument in Plain English" By Amy Howe, SCOTUSblog, March 4, 2015, http://www.scotusblog.com/2015/03/will-concern-for-states-rights-win-out-in-subsidies-battle-todays-argument-in-plain-english/ (Accessed 3/18/2015).	441
Health Insurance Exchange	An online marketplace created by the ACA, which is intended to reduce the cost associated with health insurance and ease the process of selecting a health insurance plan by providing a single place for consumers to: (1) search for and compare health plans; (2) ask questions regarding coverage; (3) check eligibility for programs and tax credits; and (4) ultimately enroll in a health plan.	"Affordable Insurance Exchanges" U.S. Department of Health and Human Services, August 23, 2012, http://www.healthcare.gov/law/features/choices/exchanges/index.html (accessed March 20, 2012); "Patient Protection and Affordable Care Act" Pub. L. No. 111-148, § 1311(b), 124 Stat. 119, 173 (March 23, 2010).	436
Full Performance Risk Arrangement	A risk model that is available to Next Generation ACOs, wherein the Next Generation ACO reaps 100% of any generated savings or losses, capped at 15% of the Next Generation ACO's financial benchmark.	"Next Generation ACO Model: Model Overview Presentation" Centers for Medicare & Medicaid Services, March 17, 2015, http://innovation.cms.gov/Files/slides/nextgenaco-odf1slides.pdf (Accessed 3/20/2015), p. 14.	412

Key Concept	Definition	Citation	Concept Mentioned on Page #
Grandfathered Health Plan	Any group health plan or individual coverage that was effective on March 23, 2010, the date of the ACA's enactment. These plans are not subject to some of the ACA's provisions.	"'Grandfathered' Plans Spared Some Reform Mandates" By Paul M. Hamburger and James R. Napoli, Society for Human Resource Management, April 9, 2010, http://www.shrm.org/hrdisciplines/benefits/Articles/Pages/GrandfatheredPlans.aspx (Accessed 4/15/2010); "Patient Protection and Affordable Care Act" Pub. L. No. 111-148, § 1251, 124 Stat. 119, 161 (March 23, 2010).	428
Next Generation Accountable Care Organization	A new model of ACOs announced by CMS in March of 2015, which may utilize new reimbursement models (other than fee-for-service, as used by standard Medicare ACOs) and feature a higher degree of shared savings and losses.	"Next Generation ACO Model" Centers for Medicare & Medicaid Services, http://innovation.cms.gov/initiatives/Next-Generation-ACO-Model/ (Accessed 3/18/2015).	412
Small Business Health Options Programs (SHOPs)	A sub-set of the ACA's Exchanges, which offer health insurance options for small employers.	"Patient Protection and Affordable Care Act; Establishment of Exchanges and Qualified Health Plans; Exchange Standards for Employers" Federal Register 77, No. 59 (March 27, 2012), p. 18310-18311; "Affordable Insurance Exchanges: Choices, Competition and Clout for States" U.S. Department of Health and Human Services, July 11, 2011, http://www.healthcare.gov/news/factsheets/2011/07/exchanges07112011a.html (Accessed August 7, 2012).	436

OVERVIEW

Motivated by the current economic conditions, trends in the reimbursement, regulatory, competitive, and technology aspects of the healthcare environment have facilitated the emergence of a historical reform initiative. In March of 2010, sweeping changes in federal healthcare policy were enacted, following months of partisan controversy, political drama, and often rancorous debates. The *Patient Protection and Affordable Care Act*, HR 3590, was signed into law on March 23, 2010, and one week later, President Barack Obama signed the *Health Care and Education Reconciliation Act of 2010*, HR 4872, into law. As singular and perhaps as chaotic as these events may seem to have been, they should not have been totally unexpected within the context of the history of healthcare reform efforts.

A HISTORICAL PERSPECTIVE ON HEALTHCARE REFORM

Political and legislative initiatives related to U.S. healthcare reform date back to the early 1900s. President Theodore Roosevelt and the Progressive movement were among the first major political parties to endorse the idea of health insurance, and President Franklin D. Roosevelt (FDR) continued to support efforts for national health reform, mainly with the *Social Security Act*, which was passed by the United States Congress in 1935. Healthcare reform efforts continued through the late 1930s and early- to mid-1940s with the establishment of the Department of Health and Human Services (HHS) in 1939 and other national efforts to support a national health insurance plan. Early healthcare reform efforts also faced significant opposition, however. Following his election to a full term, President Harry S. Truman attempted to pass FDR's healthcare reform program, but it was defeated as a result of strong opposition, some of which equated national health insurance to communism.[1]

Healthcare reform reached a major milestone with the creation of the Medicare and Medicaid programs, which President Lyndon B. Johnson signed into law in 1965. However, as growing healthcare expenditures began to raise concern throughout the 1970s, cost-containment efforts replaced national healthcare coverage initiatives as the main focus of lawmakers. This emphasis on cost savings and the corresponding lack of support for healthcare reform initiatives continued through President William J. Clinton's administration. His healthcare reform initiatives, led by First Lady Hilary Clinton, ultimately failed to garner adequate support for passage of the *Health Security Act of 1993*.[2]

1 "Timeline: History of Health Reform in the U.S." The Henry J. Kaiser Family Foundation, 2010, http://healthreform.kff.org/flash/health_reform-print.html (Accessed 4/2/2010).
2 Ibid.

THE AFFORDABLE CARE ACT AND HEALTHCARE REFORM

The 2010 healthcare reform legislation marks the beginning of a new era in the long history of healthcare reform. The 2010 healthcare reform will substantially affect many, if not all, aspects of the delivery of healthcare in the United States by affecting healthcare providers, insurers, employers, and individual citizens.

Figure 6-1 provides an overview of key historical healthcare reform events that paved the way for the current 2010 healthcare reform legislation.

Figure 6-1: Healthcare Reform Historical Timeline—1912–**1939**

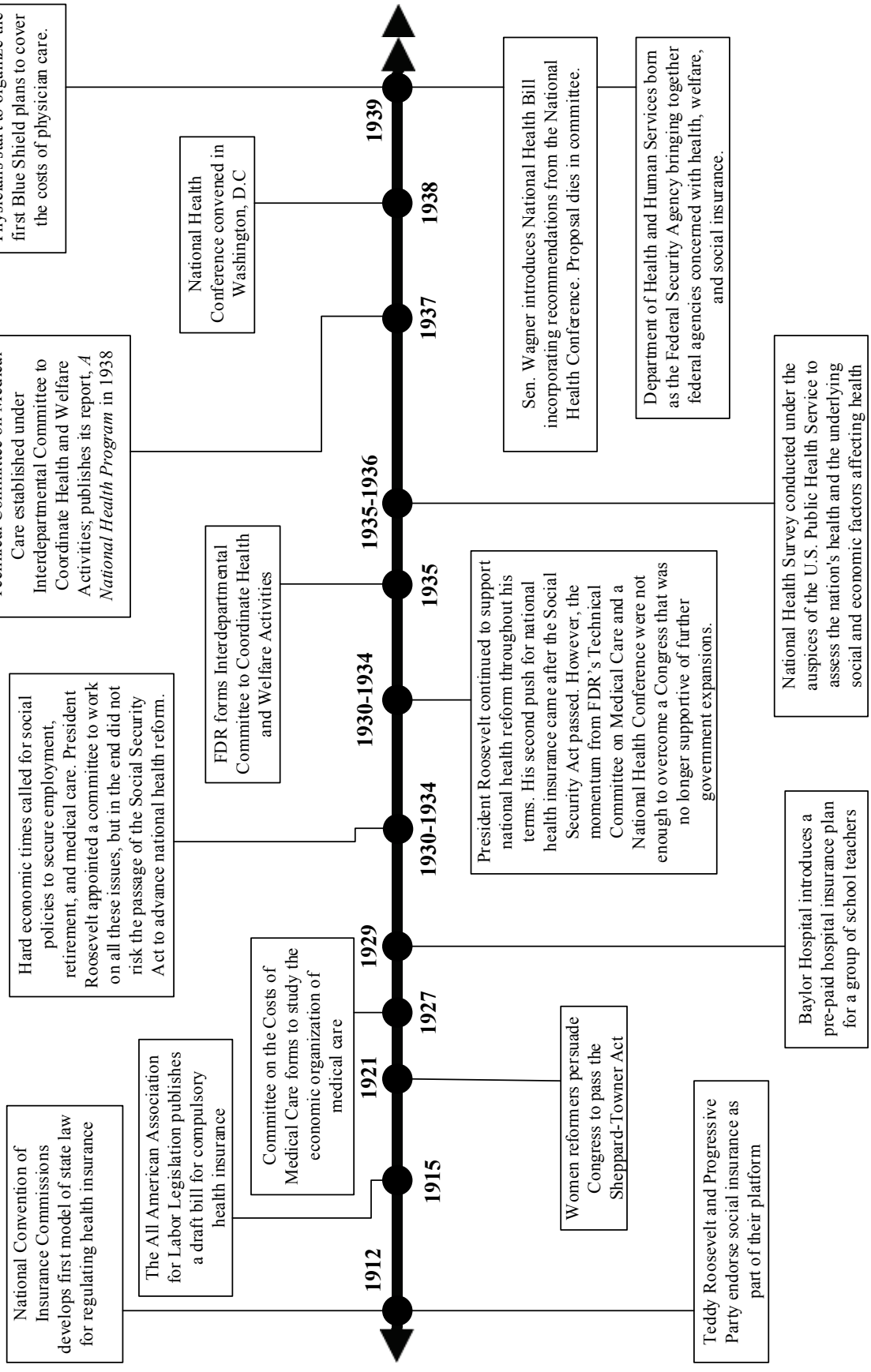


Figure 6-1: Healthcare Reform Historical Timeline—1940–1959

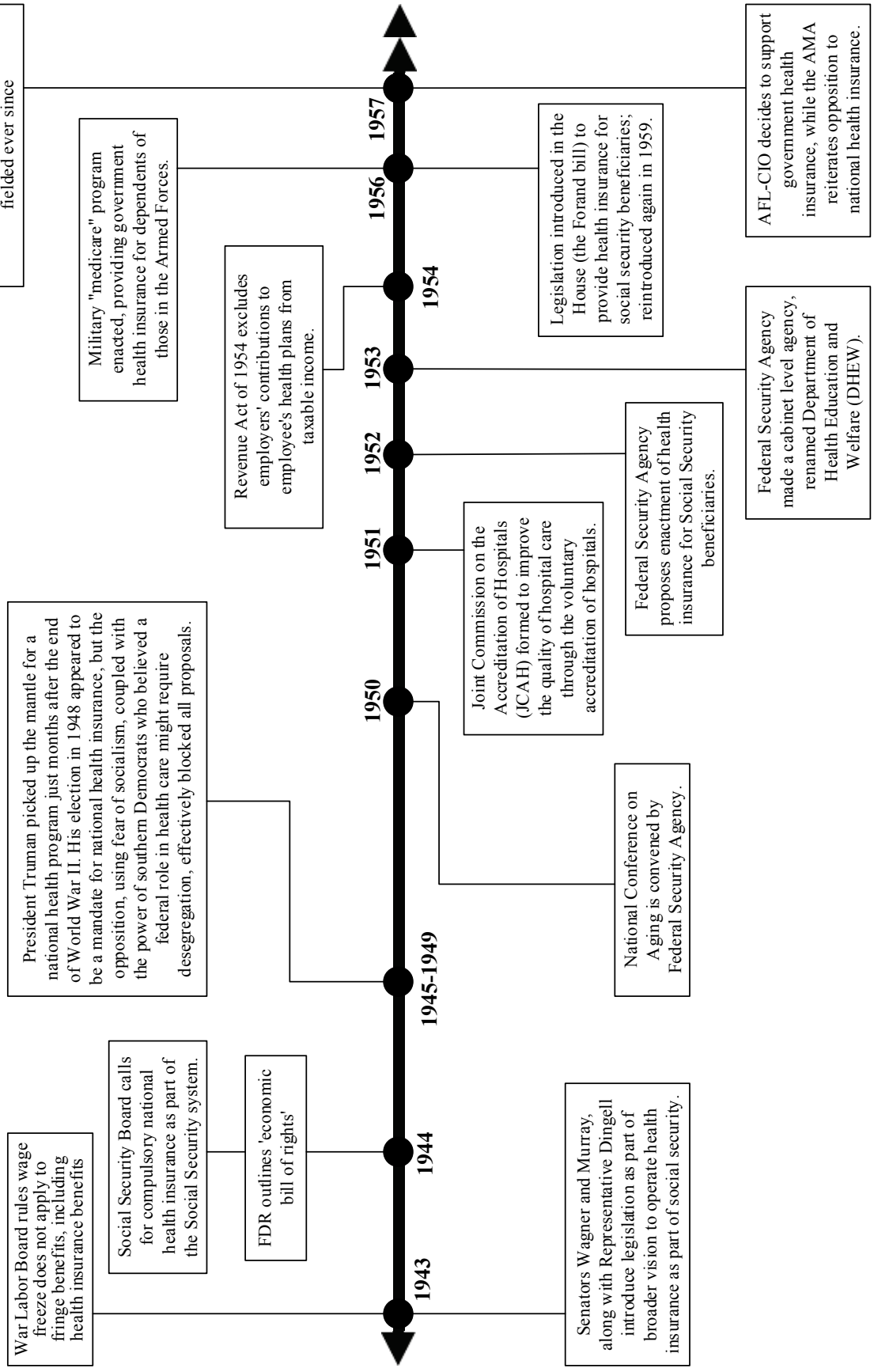


Figure 6-1: Healthcare Reform Historical Timeline— 1960-1986

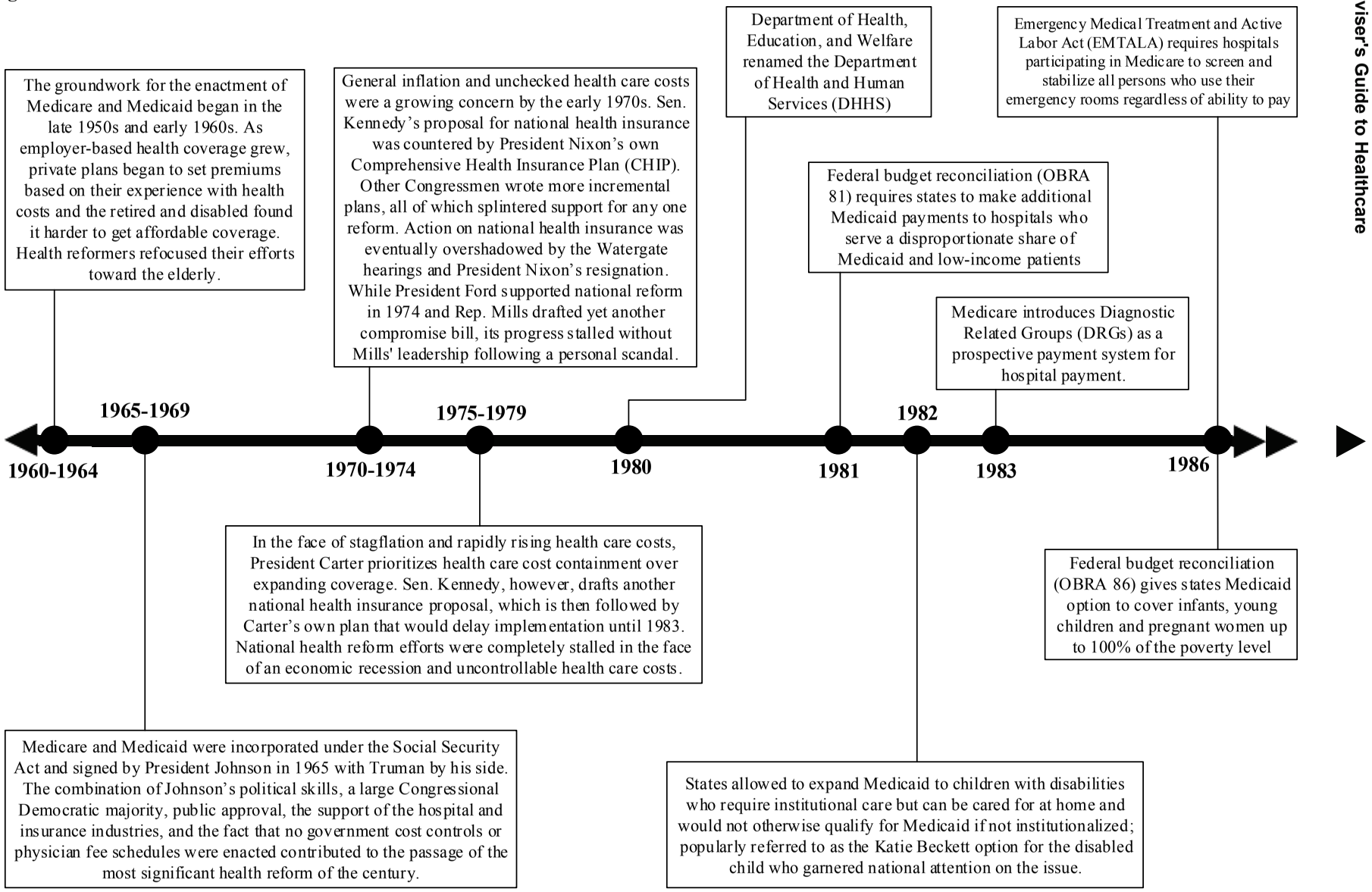
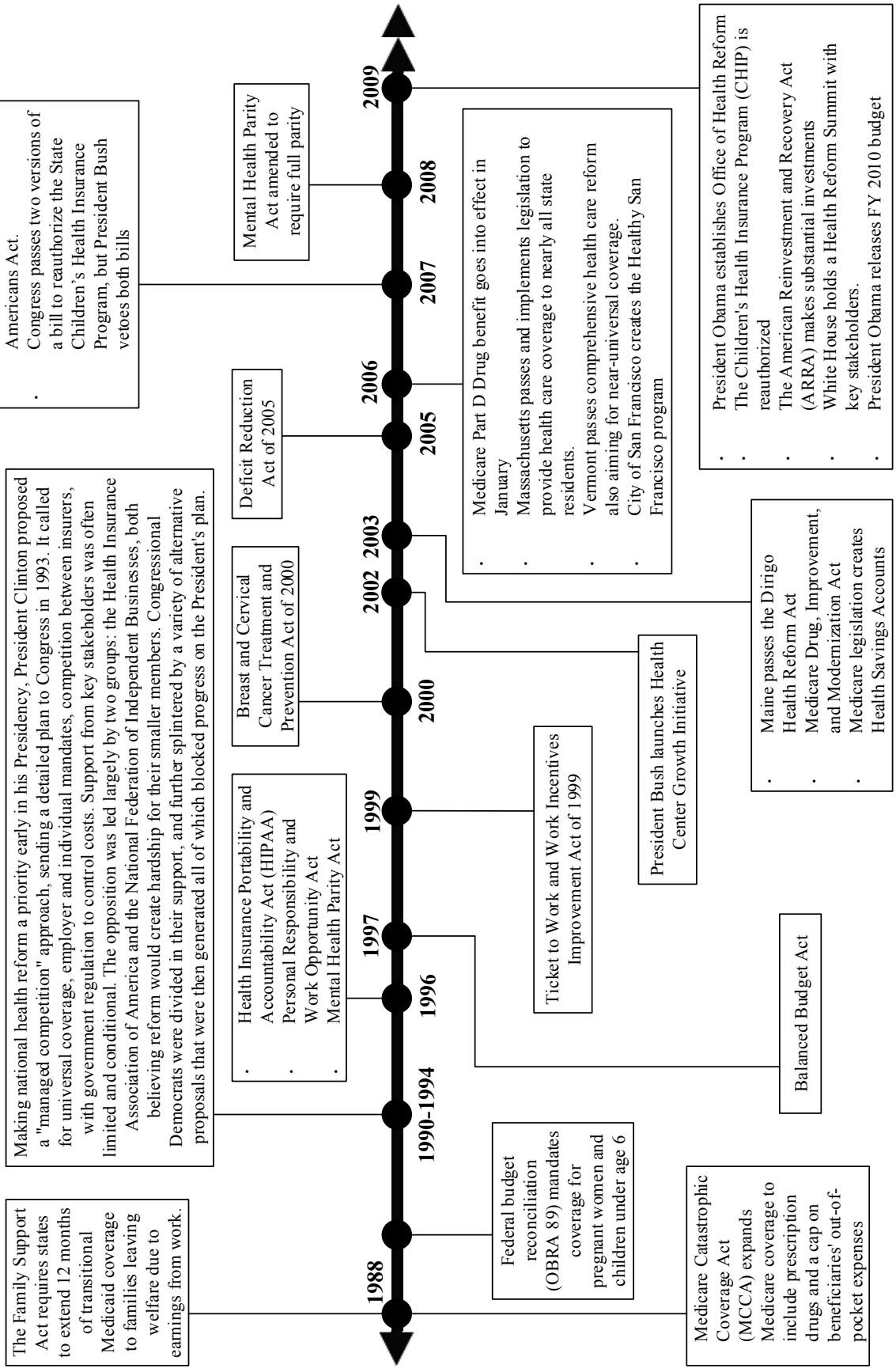


Figure 6-1: Healthcare Reform Historical Timeline— 1987-2009



WHAT IS DRIVING HEALTHCARE REFORM?

The continued rise in healthcare expenditures, which may soon impose an unsustainable economic burden on the United States' economy, served as one of several catalysts that precipitated the need for the most recent national healthcare reform initiatives. Widespread lack of access to care, the aging baby-boomer population, declining reimbursement for physician services and provider manpower shortages, as well as increasing public concern with the quality of healthcare services are also forces which helped to drive national healthcare reform. So long as these circumstances persist, they may continue to fuel real changes to the current system of healthcare delivery in the United States. Furthermore, future implementation of healthcare reform may be molded by the recent economic recession, an unprecedented intensity in political discourse regarding U.S. government deficits and debt, and increasing political polarization and governance, especially related to an ardent renewal of asserting states' rights in opposing federal initiatives.

EXPLODING TIME BOMB: CHANGING PATIENT POPULATION DEMOGRAPHIC

As mentioned throughout this *Guide*, the changing patient population demographic is one of the major factors driving healthcare reform. The changing age and ethnic distribution of the population substantially affects the demand for healthcare reform, and the projected growth of the U.S. elderly population plays an important role in the anticipated demand for healthcare services. The population over the age of sixty-five is projected to grow from an estimated 47.8 million in 2015 to 98.1 million in 2060, an increase from 14.9% to 23.6% of the total population.[3] Due to the fact that the elderly population typically has a greater per capita utilization of healthcare services when compared to younger populations,[4] this demographic shift will likely result in greatly increased demand for healthcare services for the next several decades.

The ethnicity of the U.S. patient population is also changing, with the 2015 to 2060 projections figures indicating an increasing degree of racial and ethnic diversity.[5] Perhaps best illustrating this change is the fact that in 2012 the number of minority births surpassed the number of Caucasian births in the United States for the first time in history.[6] The healthcare industry may need to adjust its practices in response to this shift in the country's ethnic demographic composition. Recent research has suggested that linguistic minorities (i.e., non-English speaking

3 "Table 3. Projections of the Population by Sex and Selected Age Groups for the United States: 2015 to 2060 (NP2014-T3)" U.S. Census Bureau, Population Division, December 2014, http://www.census.gov/population/projections/data/national/2014/summarytables.html (Accessed 3/4/15). Share of population calculated using data presented in source. 2015 share of population over the age of 65 = 47,830,000 / 321,369,000 = 14.9%. 2060 share of population over the age of 65 = 98,164,000 / 416,795,000 = 23.6%.

4 "US Health Spending Trends By Age And Gender: Selected Years 2002-10" By David Lassman et al., Health Affairs, Vol. 33, No. 5, May 2014, http://content.healthaffairs.org/content/33/5/815.full.pdf (Accessed 8/6/2014), p. 820.

5 "Table 10. Projections of the Population by Sex, Hispanic Origin, and Race in the United States: 2015 to 2060 (NP2014-T10)" U.S. Census Bureau, Population Division, December 2014, http://www.census.gov/population/projections/data/national/2014/summarytables.html (Accessed 3/4/15). Data in source shows that share of population that is "one race" and "white" drops from 77% in 2015 (248,369,000 out of 321,369,000) to 68% in 2060 (285,314,000 out of 416,795,000).

6 "Whites Account for Under Half of Births in U.S." By Sabrina Tavernise, New York Times, May 17, 2012, http://www.nytimes.com/2012/05/17/us/whites-account-for-under-half-of-births-in-us.html?pagewanted=all (Accessed June 8, 2012).

populations) often experience reduced access to healthcare services.[7] As such, the healthcare delivery system will need to identify disparities in access to care and differences in culture that impact the provision of care in order to adjust the availability of services, so as to adequately meet the healthcare needs of this growing segment of the U.S. population.[8]

HEALTHCARE EXPENDITURES

Rising healthcare expenditures as a percentage of gross domestic product (GDP) may continue to drive healthcare reform efforts. In 2013, total national health expenditures (NHE) in the United States grew to $2.9 trillion, a 3.6 percent increase from 2012.[9] Although this growth rate is slow compared to historical trends,[10] NHE growth is projected to accelerate to an annual rate of nearly 6 percent between the years of 2013 to 2023.[11] This rate, which is faster than the anticipated annual growth for the GDP, is projected to drive NHE from 17.2 percent of GDP in 2012 to 19.3 percent of GDP by 2023.[12] A 2009 study published in *Health Affairs* found that the greatest contributor to rising personal healthcare expenses (a subset of NHE) is growing medical prices.[13]

INCREASED SCRUTINY OF FRAUD AND ABUSE

In addition to the goals for increased and affordable healthcare coverage, the 2010 healthcare reform legislation also responds to concerns related to fraud and abuse in the healthcare system. The legislation includes significant initiatives aimed at reducing fraud and increasing transparency in the Medicare and Medicaid programs, through such efforts as implementing transparency requirements for pharmaceutical and medical device manufacturers and amending various federal enforcement tools, including the federal Anti-Kickback Statute (AKS), the False Claims Act (FCA), and the federal physician self-referral law (Stark law).[14]

The healthcare reform legislation incorporates extensive reporting and public disclosure of financial arrangements between certain provider customers (e.g., physicians) and medical product manufacturers in the form of the *Physician Payments Sunshine Act* (Sunshine Act).[15] This disclosure is intended to encourage voluntary avoidance of conflicts of interest that

7 "Disparities in Rates of Inpatient Mortality and Adverse Events: Race/Ethnicity and Language as Independent Contributors" By Anika L. Hines et al., International Journal of Environmental Research and Public Health, Vol. 11, No. 12, December 12, 2014, p. 13018, 13026.

8 "Changing Demographics: Implications for Physicians, Nurses, and Other Health Workers" Health Resources and Services Administration, 2003, p. 37-38.

9 "NHE Fact Sheet" Centers For Medicare & Medicaid Services, December 3, 2014, http://www.cms.gov/Research-Statistics-Data-and-Systems/Statistics-Trends-and-Reports/NationalHealthExpendData/NHE-Fact-Sheet.html (Accessed 1/29/15).

10 "Table 1: National Health Expenditures; Aggregate and Per Capita Amounts, Annual Percent Change and Percent Distribution: Selected Calendar Years 1960-2012" in "National Health Expenditures Data" Centers for Medicare & Medicaid Services, May 5, 2014, http://www.cms.gov/Research-Statistics-Data-and-Systems/Statistics-Trends-and-Reports/NationalHealthExpendData/ (Accessed 12/8/2014).

11 "NHE Fact Sheet" Centers For Medicare & Medicaid Services, December 3, 2014, http://www.cms.gov/Research-Statistics-Data-and-Systems/Statistics-Trends-and-Reports/NationalHealthExpendData/NHE-Fact-Sheet.html (Accessed 1/29/15).

12 Ibid.

13 "Health Spending Projections Through 2019: Recession Effects Add Uncertainty to the Outlook" By Christopher J. Truffer et al., Health Affairs, Vol. 28, No. 2 (February 24, 2009), p. 526.

14 "Patient Protection and Affordable Care Act" Pub. L. 111-148, § 6001, §1128J, 124 Stat. 119, 684, 755, 759 ; "Health Care Reform: Substantial Fraud and Abuse and Program Integrity Measures Enacted" McDermott Will & Emery, April 12, 2010, p. 2.

15 "Patient Protection and Affordable Care Act" Pub. L. 111-148, § 6002, 124 Stat. 119, 689; "Health Policy Brief: The Physician Payments Sunshine Act" Health Affairs, October 2, 2014, http://healthaffairs.org/healthpolicybriefs/brief_pdfs/healthpolicybrief_127.pdf (Accessed 3/25/2015), p. 1.

potentially can jeopardize the quality, integrity, and safety of clinical care, biomedical and academic research, and medical education, as well as lead to violations of federal fraud and abuse regulations.[16]

In addition to the new transparency and disclosure requirements, the healthcare reform legislation amends various fraud and abuse enforcement activities. One new requirement is that overpayments made by Medicare or Medicaid must be reported within sixty days after the date the recipient identified the overpayment. The requirement further states that failure to make a timely repayment gives rise to liability under the FCA.[17]

The healthcare reform legislation also makes two changes to the intent standards relating to fraud and abuse. First, the legislation amends the AKS by stating that a person need not have actual knowledge of, or specific intent to, commit a violation of the statute for the government to prove a kickback violation.[18] Second, the ACA provides that "…a claim that includes items or services resulting from a violation [of the AKS] constitutes a false or fraudulent claim for purposes…" of the FCA, which results in a law that any violation of the AKS is sufficient to state a claim under the FCA.[19]

The ACA also significantly changes the FCA by eliminating the jurisdictional bar for allegations based on publicly disclosed information and by relaxing the requirements for a qui tam action to be eligible as an "original source."[20] These changes have the potential to increase providers' FCA exposure by allowing for a greater number of whistleblowers to bring a claim.[21] Alternatively, the ACA also requires the secretary of HHS to set up a Stark law self-referral disclosure protocol, which will permit HHS to receive payment lower than the full Stark law measure of damages in appropriate circumstances. This initiative will potentially provide considerable monetary relief for certain providers.[22]

In Chapter 3, *Regulatory Environment,* we addressed the current regulatory environment of the healthcare industry and provided a more detailed analysis of the additional fraud and abuse initiatives that have evolved during the era of healthcare reform. These efforts have resulted in increased scrutiny regarding the regulation of the healthcare industry. Recent reports suggest that this is well worth the investment, as recoveries on fraud and abuse investigations are currently

16 Ibid.

17 "Patient Protection and Affordable Care Act" Pub. L. 111-148, § 1128J, 124 Stat. 119, 755 ; "Health Care Reform: Substantial Fraud and Abuse and Program Integrity Measures Enacted" McDermott Will & Emery, April 12, 2010, p. 3.

18 "Patient Protection and Affordable Care Act" Pub. L. No. 111-148, § 10606, 124 Stat. 119, 1008 (March 23, 2010).

19 "Patient Protection and Affordable Care Act" Pub. L. 111-148, § 1128J, 124 Stat. 119, 759; "Health Care Reform: Substantial Fraud and Abuse and Program Integrity Measures Enacted" McDermott Will & Emery, April 12, 2010, p. 3.

20 "Patient Protection and Affordable Care Act" Pub. L. 111-148, § 1303, 124 Stat. 119, 901; "KABOOM! The Explosion of Qui Tam False Claims Under the Health Reform Law" By Beverly Cohen, Penn State Law Review, Vol. 116, No. 1 (2011), http://www.pennstatelaw review.org/116/1/116%20Penn%20St.%20L.%20Rev.%2077.pdf (Accessed 3/25/2015), p. 78-79.

21 "KABOOM! The Explosion of Qui Tam False Claims Under the Health Reform Law" By Beverly Cohen, Penn State Law Review, Vol. 116, No. 1 (2011), http://www.pennstatelawreview.org/116/1/116%20Penn%20St.%20L.%20Rev.%2077.pdf (Accessed 3/25/2015), p. 78-79.

22 "Patient Protection and Affordable Care Act" Pub. L. No. 111-148, § 6409. 124 Stat. 119, 772-773 (March 23, 2010); "Self-Referral Disclosure Protocol" Centers for Medicare & Medicaid Services, December 27, 2011 https://www.cms.gov/PhysicianSelfReferral/98_Self_Referral_Disclosure_Protocol.asp#TopOfPage (Accessed 02/10/12).

yielding $7.70 (on average) for every dollar spent pursuing fraud cases,[23] up from 4 to 1 in 2009.[24]

HEALTHCARE PROVIDER MANPOWER: SUPPLY AND DEMAND

As discussed in several other sections in this *Guide*, recent reports have indicated that the United States will face a growing physician manpower shortage, especially in primary care. A 2015 projection estimated a shortage of 46,000 to 90,000 physicians by 2025, of which approximately one third will be primary care providers.[25] One of the primary drivers of this projected shortage is the growth in the number of insured individuals due to the healthcare reform provisions under the ACA.[26] Projections of the shortage of physicians include the impact of younger physicians working fewer hours, as well as retirement patterns of current physicians (over 240,000 of whom were older than 65 in 2013).[27] Adding to the increased population with insurance coverage under the ACA, younger physicians are more interested in obtaining a sustainable work-life balance than the older generation, thereby reducing the average hours worked for physicians,[28] and increasing the demand on the physician workforce. However, the dynamic change and the versatility of non-physician providers (e.g., nurse practitioners and physician assistants) as to their scope of practice has been growing to accommodate the changing reimbursement, regulatory, competitive, and technological aspects of an evolving healthcare industry.[29] The Association of American Medical Colleges (AAMC) has indicated that solving the predicted physician shortage will not only depend on training more physicians, but also on reconfiguring healthcare delivery and increasing efficiency.[30]

The 2010 healthcare legislation responds to this projected shortage in physician manpower by: (1) increasing the number of graduate medical education training positions; (2) giving priority to primary care and general surgery fields and to those states with the lowest resident physician-to-patient population; (3) increasing workforce supply and support by providing health

23 "Departments of Justice and Health and Human Services Announce Record-breaking Recoveries Resulting from Joint Efforts to Combat Health Care Fraud" Department of Health and Human Services, February 26, 2014, http://www.hhs.gov/news/press/2014pres/02/20140226a.html (Accessed March 4, 2015).

24 "Departments of Justice and Health and Human Services announce over $27.8 billion in returns from joint efforts to combat health care fraud" U.S. Department of Health and Human Services, March 19, 2015, http://www.hhs.gov/news/press/2015pres/03/20150319a.html (Accessed 4/28/2015); "Annual Report of the Departments of Health and Human Services and Justice: Health Care Fraud and Abuse Control Program FY 2014" U.S. Department of Health and Human Services and U.S. Department of Justice, March 19, 2015, http://oig.hhs.gov/publications/docs/hcfac/FY2014-hcfac.pdf (Accessed 6/30/15), p. 8; "Sebelius: New Fraud Prevention Team Will Turn Up HEAT" By Ben Amirault, Health Leaders Media, May 21, 2009, http://www.healthleadersmedia.com/content/233446/topic/WS_HLM2_FIN/Sebelius-New-Fraud-Prevention-Team-will-Turn-up-Heat.html (Accessed May 21, 2009).

25 "The Complexities of Physician supply and Demand: Projections from 2013 to 2025—Final Report" IHS, Inc., March 2015, p. v-vi. Source projects a shortage of 12,500 to 31,100 primary care physicians by 2025, representing 27-35% (12,500 / 46,000 to 31,100 / 90,000) of the total shortfall.

26 "The Complexities of Physician supply and Demand: Projections from 2013 to 2025—Final Report" IHS, Inc., March 2015, p. vi. See the Healthcare Reform Impact on the Future of U.S. Healthcare Delivery section for a discussion on the ACA's provisions, many of which are aimed at increasing the number of individuals with health insurance coverage.

27 "The Complexities of Physician supply and Demand: Projections from 2013 to 2025—Final Report" IHS, Inc., March 2015, p. 6-8; "Physician Characteristics and Distribution in the US" 2015 Edition, American Medical Association, 2014, p. 9.

28 "Wanting it All: A New Generation of Doctors Places Higher Value on Work-Life Balance" By Eve Glicksman, Association of American Medical Colleges, May 2013, https://www.aamc.org/newsroom/reporter/336402/work-life.html (Accessed 3/30/2015).

29 "Coming Together, Moving Apart: A History of the Term Allied Health in Education, Accreditation, and Practice" By Fred G. Donini-Lenhoff, Journal of Allied Health Vol. 37, no. 1, 2008, p. 47; "Interprofessional Healthcare: A Common Taxonomy to Assist with Understanding" By Alice B. Aiken and Mary Ann McColl, Journal of Allied Health Vol. 38, No. 3, 2009, p. e-92.

30 "GME Funding: How to Fix the Doctor Shortage" Association of American Medical Colleges, https://www.aamc.org/advocacy/campaigns_and_coalitions/fixdocshortage/ (Accessed 3/25/2015).

professionals with training-related scholarships and loans; (4) increasing the capacity for nurse education, the support for nurse training programs, and the number of loan repayment and retention grants; (5) creating a career ladder to nursing; and (6) establishing a Prevention and Public Health Fund for prevention, wellness, and public health activities.[31]

RESTRUCTURING REIMBURSEMENT

The continuing controversy regarding physician reimbursement levels and the sustainable growth rate (SGR) formula for determining the annual conversion factor (CF) under the Medicare physician fee schedule are partial drivers of the efforts that have supported the progression of healthcare reform initiatives under the Obama administration. At the same time, the movement from a capitated fee reimbursement system to a fee-for-service (FFS) and managed care payment system has facilitated an increase in NHE. This growth in NHE during the past several years has prompted recent efforts to downshift reimbursement for physician services (for example, by way of bundled payments) in an effort designed to contain healthcare costs.

Repeal of the Sustainable Growth Rate (SGR)

The SGR method replaced the Medicare Volume Performance Standard (MVPS) provision in 1997 to provide annual target updates to the physician fee schedule for Medicare Part B. The SGR formula is designed to control aggregate growth in Medicare expenditures by raising or lowering the proposed payment target to reflect actual cumulative expenditures.[32] The calculation of SGR relies upon four factors, according to the Centers for Medicare & Medicaid Services (CMS):[33]

(1) The estimated percentage change in fees for physicians' services.
(2) The estimated percentage change in the average number of Medicare fee-for-service beneficiaries.
(3) The estimated 10-year average annual percentage change in real gross domestic product (GDP) per capita.
(4) The estimated percentage change in expenditures due to changes in law or regulations.

The SGR was intended to predictably control federal spending on Medicare Part B.[34] Since its enactment, actual Medicare expenditures remained below target expenditures through 2001. However, every year since 2002, actual expenditures have exceeded target expenditures, with the discrepancy growing annually.[35] Because of actual expenditures exceeding target expenditures,

31 "Summary of The Affordable Care Act" The Henry J. Kaiser Family Foundation, April 23, 2013, https://kaiserfamilyfoundation.files.wordpress.com/2011/04/8061-021.pdf (Accessed 3/28/15), p. 10, 12.
32 "Estimated Sustainable Growth Rate and Conversion Factor, for Medicare Payments to Physicians in 2015" Centers for Medicare & Medicaid Services, November 2014, https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/SustainableGRatesConFact/Downloads/SGR2015f.pdf (Accessed 3/19/2015), p. 1.
33 Ibid.
34 "Reform Medicare Physician Payent Formula" American College of Emergency Physicians, http://www.acep.org/workarea/DownloadAsset.aspx?id=48579 (Accessed 3/25/2015), p. 1.
35 "Medicare Physician Payment Updates and the Sustainable Growth Rate (SGR) System" By Jim Hahn, Congressional Research Service, June 12, 2014, http://greenbook.waysandmeans.house.gov/sites/greenbook.waysandmeans.house.gov/files/R40907_gb.pdf (Accessed 3/13/2015), p. 5.

the SGR formula dictated a reduction in the fee schedule.[36] Despite this, Congressional action to suspend the impending cuts to payments for physician services every year since 2003 has resulted in a widening gap between the cumulative spending and cumulative target each year the proposed cuts were overridden.[37] A January 2015 projection by the Congressional Budget Office (CBO) estimated that a Congressional override of the scheduled reductions to physician payments would result in approximately $6.0 billion in increased Medicare outlays.[38] However, in April of 2015, Congress passed legislation that significantly reformed the methodology for updating physician payments. This legislation had its own associated costs, which are described in the following section below.

Medicare Access and CHIP Reauthorization Act of 2015

For years, many healthcare industry stakeholders including the American Medical Association, the American Hospital Association, and the Medicare Payment Advisory Committee urged for the repeal of the SGR.[39] After multiple failed attempts,[40] in April 2015, Congress passed the *Medicare Access and CHIP Reauthorization Act of 2015* (MACRA), which President Obama signed into law on April 16, 2015.[41] Among its provisions, MACRA repeals the SGR, replacing it with a series of pre-determined updates to the MPFS, which are modified based on a given provider's utilization of certain *alternative payment models* (APMs), as opposed to traditional fee-for-service payments.[42]

According to the text of the statute, APMs include models under section 1115A (i.e., the Center for Medicare and Medicaid Innovation),[43] accountable care organizations (ACOs), or demonstrations under section 1866C or another federal law.[44] In general, to qualify as an APM participant, a provider must meet certain thresholds, i.e.:[45]

(1) 2019-2020: At least 25% of payments through an eligible alternative payment entity;
(2) 2021-2022: At least 50% of payments through an eligible alternative payment entity; and,
(3) 2023 forward: At least 75% of payments through an eligible alternative payment entity.

36 "Reform Medicare Physician Payent Formula" American College of Emergency Physicians, http://www.acep.org/workarea/DownloadAsset.aspx?id=48579 (Accessed 3/25/2015), p. 2.
37 Ibid.
38 "The Budget and Economic Outlook: 2015 to 2025" Congressional Budget Office, January 2015, https://www.cbo.gov/sites/default/files/cbofiles/attachments/49892-Outlook2015.pdf (Accessed 3/28/2015), p. 24-26.
39 "Doc associations rip Medicare pay deal" By Jessica Zigmond, Modern Healthcare, February 15, 2012, http://www.modernhealthcare.com/article/20120215/NEWS/302159974/doc-associations-rip-medicare-pay-deal (Accessed 2/16//2012); "Hospitals hit too hard in SGR deal: AHA" By Jessica Zigmond, Modern Healthcare, February 16, 2012, http://www.modernhealthcare.com/article/20120216/NEWS/302169948/hospitals-hit-too-hard-in-sgr-deal-aha (Accessed 2/17/2012); "Moving forward from the Sustainable Growth Rate System" By Cristina Boccuti, et al., Medicare Payment Advisory Commission, September 15, 2011, http://interactive.snm.org/docs/MedPAC%20SGR%20sept%202011%20handout.pdf (Accessed 02/23/2012).
40 "AMA Pushes Lame Duck Congress for SGR Repeal" By John Commins, HealthLeaders Media, November 19, 2014, http://www.healthleadersmedia.com/page-1/PHY-310470/AMA-Pushes-Lame-Duck-Congress-for-SGR-Repeal (Accessed 4/28/2015).
41 "Summary: H.R.2—114th Congress (2015-2016)" Congress.gov, https://www.congress.gov/bill/114thcongress/housebill/2 (Accessed 4/22/2015); "Medicare Access and CHIP Reauthorization Act of 2015" Pub. L. No. 114-10, § 101 et seq., 129 Stat. 87 (April 16, 2015).
42 "Summary: H.R.2—114th Congress (2015-2016)" Congress.gov, https://www.congress.gov/bill/114thcongress/housebill/2 (Accessed 4/22/2015).
43 "Center for Medicare and Medicaid Innovation" Letter to Senator Tom Coburn, From Jim Hahn, Congressional Research Service, February 24, 2012, http://www.law.umaryland.edu/marshall/crsreports/crsdocuments/022412B_04242012.pdf (Accessed 4/22/2015), p. 1.
44 "Medicare Access and CHIP Reauthorization Act of 2015" Pub. L. No. 114-10, § 101, 129 Stat. 87, 121 (April 16, 2015).
45 Ibid, .129 Stat. 87, 118-121. See the text of the statute for specific requirements for each period.

Furthermore, an alternative payment entity is defined as an entity that:[46]

(1) Participates in an APM and meets the following requirements;
    a. requires participants in the model to use certified EHR technology and
    b. provides for payment based on certain quality measures;
(2) Bears financial risk for material monetary losses under the APM; or
(3) Is a medical home.

If a provider qualifies as an APM participant, they are eligible for certain financial incentives. First, providers that qualify as APM participants between 2019 and 2024 receive a 5% bonus payment for services furnished to Medicare beneficiaries paid in an annual lump sum.[47] Furthermore, beginning in 2026, the annual update to Medicare payments to providers who *do not* qualify as APM participants is 0.25%, while the annual update to Medicare payments for qualifying APM participants is 0.75%.[48]

It is worth noting that, although many were happy to see the SGR repealed,[49] there is a significant cost associated with replacing the update methodology. Indeed, the Office of the Actuary of CMS estimates that MACRA will cost just over $100 billion between 2015 and 2025. The greatest annual costs are concentrated in the early stages of implementation, with 2016 and 2017 costs at $13.1 billion and $15.7 billion, respectively. The greatest component of the cost of MACRA is, in fact, the physician payment update reform at $150.5 billion, followed by the reforms to Medicaid and CHIP at $25.0 billion. These costs are offset by savings in other areas of Medicare (savings of $62.2 billion) and savings in the health insurance marketplaces (savings of $10.5 billion).[50]

Downshifting Reimbursement

As Medicare reimbursement has remained stagnant or has decreased for the professional component of healthcare reimbursement since the 1990s, physicians have looked to the ancillary services and technical component (ASTC) revenue stream to supplement their income, by way of ownership investment in ambulatory surgical centers, independent diagnostic testing facilities, and specialty or surgical hospitals. However, legislative and regulatory opposition at the federal and state levels to limit physician ownership of or investment in ASTC revenue stream enterprises have served to restrict physicians in private practice to receiving only professional fee component revenues. This is viewed by some as relegating physicians to the status of *sharecroppers* or *hired help* or compelling many physicians to acquiesce by accepting employee status under the substantial control of hospital systems or large corporate players.

46 Ibid, 129 Stat. 87, 121-122.
47 "Medicare Access and CHIP Reauthorization Act of 2015" Pub. L. No. 114-10, § 101, 129 Stat. 87, 121-122 (April 16, 2015).
48 Ibid, 129 Stat. 87, 90.
49 "May the Era Of Medicare's Doc Fix (1997-2015) Rest In Peace. Now What?" By Billy Wynne, Health Affairs Blog, April 14, 2015, http://healthaffairs.org/blog/2015/04/14/may-the-era-of-medicares-doc-fix-1997-2015-rest-in-peace-now-what/ (Accessed 4/22/2015).
50 "Estimated Financial Effects of the Medicare Access and CHIP Reauthorization Act of 2015 (H.R. 2)" By Paul Spitalnic, Chief Actuary, Office of the Actuary, Centers for Medicare & Medicaid Services, April 9, 2015, http://www.cms.gov/Research-Statistics-Data-and-Systems/Research/ActuarialStudies/Downloads/2015HR2a.pdf#sthash.ONGV8hcB.dpuf (Accessed 4/22/2015), p. 1.

The reduction in reimbursement levels for physicians may have had more widespread effects than adversely affecting physician revenue and income levels. A study published in the *Journal of the American Medical Association* in February 2010 found that a sample of more than 40,000 physicians reported that their hours worked have decreased an average of 7.2 percent from the periods 1996–98 through 2006–08 (from an average of 54.9 to 51 hours per week).[51] Additionally, the authors found that inflation-adjusted physician fees had decreased by approximately 25 percent between 1996 and 2006, which coincided with the decrease in physician hours worked, suggesting that the decrease in physician work hours may have been partially a result of decreasing incentives due to reduced levels of reimbursement.[52] In light of the impending physician shortage, these trends may be particularly troubling.[53]

The continuing two-pronged attack on niche providers pertains to both specialty physicians and physician owners of practices and specialty hospitals. It includes: (1) increasing the reduction of reimbursement yield, most notably for traditionally high-reimbursement yield specialty procedures (for example, echocardiography, nuclear imaging, etc.) and (2) the continued attack on physicians sharing in the ownership of the ASTC revenue stream, as evidenced by the provisions restricting physician ownership of specialty hospitals in the 2010 healthcare reform legislation.

These changes limit revenue streams available to physicians and give rise to several current trends, such as the rise of hospital acquisitions of physician practices and employment of physicians, especially for more profitable specialties that are well-suited to provide services in a hospital-based setting (for example, cardiology, orthopedics, radiology, etc.). While this attack on niche providers persists, these trends are likely to continue.

Experts predict that competitive pressure, as well as newly adopted and pending revenue cycle management regulations, will force providers to assess their revenue cycle management systems. This assessment will likely result in providers making system upgrades and purchasing new systems.[54] Providers with older revenue cycle management systems could possibly upgrade these systems to improve patient satisfaction and convenience, as well as to realize certain government financial incentives.[55] Furthermore, providers will likely benefit from new systems that improve efficiency. These systems are capable of (1) easily checking payors' rules to ensure that the services to be performed are covered; (2) automatically creating bills from patients' electronic medical records; (3) bypassing clearinghouses and submitting claims directly to payors, which enables providers to receive electronic funds transferred directly from payors to the provider's bank; and (4) allowing providers to integrate their financial and clinical data.[56] Nonetheless, the

51 "Trends in the Work Hours of Physicians in the United States" By Douglas O. Staiger et al., Journal of the American Medical Association, Vol. 303, No. 8 (February 24, 2010), p. 750.

52 Ibid, p. 751.

53 Discussed in the Healthcare Provider Manpower: Supply and Demand section above

54 "Revenue Cycle Management - Storm Clouds on the Horizon" By Mike Davis, Future Healthcare, 2007, http://www.futurehealthcareus.com/?mc=revenue-cycle&page=fin-viewresearch (Accessed 5/17/2010); "Meaningful Use Regulations" HealthIT.gov, http://www.healthit.gov/policy-researchers-implementers/meaningful-use-regulations (Accessed 3/28/15).

55 "Essentials of the U. S. Hospital IT Market" HIMSS Analytics, 4th Ed., 2009, http://www.himssanalytics.org/docs/4thEditionEssentialsNGRCMfinal.pdf (5/17/ 2010), p. 18-2; "Meaningful Use Regulations" HealthIT.gov, http://www.healthit.gov/policy-researchers-implementers/meaningful-use-regulations (Accessed 3/28/15).

56 "Revenue Cycle Management - Storm Clouds on the Horizon" By Mike Davis, Future Healthcare, 2007, http://www.futurehealthcareus.com/?mc=revenue-cycle&page=fin-viewresearch (Accessed 5/17/2010).

significant changes to the reimbursement landscape lay an unsteady and uncertain foundation for the future of reimbursement for providers.

Bundling Payments

Bundling is a method of reimbursement that combines institutional and professional charges into a single payment.[57] Despite the various industry stake holder opinions, in January of 2013, CMS launched the three year *Bundled Payments for Care Improvement* (BPCI) initiative.[58] Providers in this program may enter into payment bundling agreements with CMS, selecting from one of four models of care that define episodes of care and payment arrangements around inpatient stays in acute care hospitals (the four models available under the BCPI are discussed in more detail in Chapter 2: *Reimbursement Environment*).[59] An analysis of preliminary data from the BPCI initiative indicates that a hospital could achieve up to $900,000 in cost savings across 300 episodes of care.[60]

Next Generation ACOs

In March of 2015, CMS announced a new classification of ACOs, called the *Next Generation* model. Compared to current models (which are described in Chapter 2: *Reimbursement Environment*), Next Generation ACOs feature a higher degree of shared savings or losses.[61] Specifically, Next Generation ACOs may opt for an arrangement with risk sharing rates of 80% (which grows to 85% after three years) or a *Full Performance Risk* arrangement, wherein the Next Generation ACO bears 100% of the risk for their savings or losses.[62] In both of these arrangements, savings and losses are subject to a cap (set at 15% of the Next Generation ACO's financial performance benchmark), and Next Generation ACOs are not responsible for the costs of beneficiaries who are beyond the 99th percentile of medical expenditures.[63]

Next Generation ACOs also set their financial benchmarks differently from previous models. In addition to utilizing the ACO's previous financial performance adjusted based on the risk characteristics of the ACO's population of beneficiaries, benchmarks for Next Generation ACOs also incorporate projected regional trends in expenditures and are discounted based on: (1) the Next Generation ACO's performance on quality metrics; (2) the Next Generation ACO's expenditures relative to regional FFS expenditures; and (3) the Next Generation ACO's

57 "The Managed Health Care Handbook" By Peter R. Kongstvedt, 3rd Ed., Aspen Publishers, Inc., 1996, p. 187.
58 "Bundled Payments for Care Improvement (BPCI) Initiative: General Information" Centers for Medicare & Medicaid Services, http://innovation.cms.gov/initiatives/bundled-payments/ (Accessed 3/25/2015).
59 Ibid.
60 "BPCI: First Results and Fresh Insights" By John Harris and Idette Elizondo, Healthcare Financial Management Association, November 12, 2014, https://www.hfma.org/Content.aspx?id=26012 (Accessed 3/25/2015). The hospital analyzed in the source utilized Model 2 under the BCPI, defining an episode of care as a patient's inpatient hospital stay as well as 90 days of post-discharge outpatient care.
61 "Next Generation ACO Model" Centers for Medicare & Medicaid Services, http://innovation.cms.gov/initiatives/Next-Generation-ACO-Model/ (Accessed 3/18/2015).
62 "Next Generation ACO Model: Model Overview Presentation" Centers for Medicare & Medicaid Services, March 17, 2015, http://innovation.cms.gov/Files/slides/nextgenaco-odf1slides.pdf (Accessed 3/20/2015), p. 14.
63 "Next Generation ACO Model: Request for Applications" Centers for Medicare & Medicaid Services, http://innovation.cms.gov/Files/x/nextgenacorfa.pdf (Accessed 3/20/2015), p. 13.

expenditures relative to national FFS expenditures.[64] Notably, this discount will replace the minimum savings rate (MSR) that is utilized by previous models of ACOs.[65]

In addition to these modifications to previous risk sharing arrangements, Next Generation ACOs introduce several elements that are distinct from those present in current models of ACOs. For example, Next Generation ACOs may elect to use four different payment mechanisms, including: (1) normal FFS payments; (2) per-beneficiary per-month (PBPM) infrastructure payments in addition to normal FFS payments, which must be repaid to CMS; (3) an arrangement in which the Next Generation ACO's providers receive reduced FFS payments, and in return, CMS gives the Next Generation ACO a monthly payment based on the projected aggregate annual reduction in FFS payments; and (4) capitation, beginning in 2017.[66]

Aside from new payment methodologies, the Next Generation ACO model also incorporates provisions that are designed to improve patient engagement. These *"benefit enhancement tools"* include: (1) a process by which beneficiaries may enroll with Next Generation ACOs; (2) improved access to home visits, telehealth services, and skilled nursing facilities; (3) financial rewards for beneficiaries who receive care from ACOs; and (4) collaboration between CMS and Next Generation ACOs to improve communication with beneficiaries regarding their ACOs, and the potential benefits of receiving care from their ACOs.[67] ACOs have noted the lack of an ability to engage with patients in the past, which these provisions may help to address.[68] If successful, this improved level of patient engagement may help a Next Generation ACO to have a greater ability to control their patient's medical costs.

DEMAND FOR QUALITY IMPROVEMENTS

Patient concerns regarding the quality of healthcare delivered in the United States, in relation to the high costs associated with such healthcare services, were another significant driver of healthcare reform.[69] Although the United States spends a relatively large share of its GDP per capita on healthcare compared to other developed countries, the United States is ranked very low in terms of health status, due in part to poor access to care, poor health behaviors (e.g. abuse of drugs and alcohol), and high levels of socioeconomic inequality.[70]

64 "Methodology for Determining Shared Savings and Losses under the Medicare Shared Savings Program" Centers for Medicare & Medicaid Services, April 2014, http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/sharedsavingsprogram/Downloads/ACO_Methodology_Factsheet_ICN907405.pdf (Accessed 3/20/2015), p. 3-4; "Next Generation ACO Model: Request for Applications" Centers for Medicare & Medicaid Services, http://innovation.cms.gov/Files/x/nextgenacorfa.pdf (Accessed 3/20/2015), p. 11-12.

65 "Next Generation ACO Model: Request for Applications" Centers for Medicare & Medicaid Services, http://innovation.cms.gov/Files/x/nextgenacorfa.pdf (Accessed 3/20/2015), p. 12.

66 "Next Generation ACO Model: Model Overview Presentation" Centers for Medicare & Medicaid Services, March 17, 2015, http://innovation.cms.gov/Files/slides/nextgenaco-odf1slides.pdf (Accessed 3/20/2015), p. 15-18.

67 "Next Generation ACO Model Frequently Asked Questions" Centers for Medicare & Medicaid Services, March 10, 2015, http://innovation.cms.gov/Files/x/nextgenacofaq.pdf (Accessed 3/18/2015), p. 1.

68 "CMS preps 'next generation' ACO model" By Melanie Evans, Modern Healthcare, March 10, 2015, http://www.modernhealthcare.com/article/20150310/NEWS/150319994?template=print (Accessed 3/18/2015).

69 "Americans Speak on Health Reform: Report on Health Care Community Discussions" U.S. Department of Health and Human Services, March 2009, http://wwwhealthreform.gov/reports/hccd/concernsd.html (Accessed July 2, 2012), p. 48.

70 "U.S. Health in International Perspective: Shorter Lives, Poorer Health" Institute of Medicine, January 2013, http://www.iom.edu/~/media/Files/Report%20Files/2013/US-Health-International-Perspective/USHealth_Intl_PerspectiveRB.pdf (Accessed 3/24/2015), p. 1-2 (This report compares the U.S. to sixteen other high income "peer" countries on measures of life expectancy and various health areas related to illness and injury ,e.g., infant mortality, prevalence of various chronic diseases, etc.); "Mirror, Mirror on the Wall" By Karen Davis et al., The Commonwealth Fund, June 2014, http://www.commonwealthfund.org/~/media/files/publications/fund-report/2014/jun/1755_davis_mirror_mirror_2014_exec_summ.pdf (Accessed 7/8/215), p. 3 (This report compares the U.S. to 11 other developed countries on measures of quality of care, access to care, efficiency, equity, healthy lives, and health expenditures per capita).

Such discrepancies in cost and quality outcomes, in conjunction with limited data on healthcare enterprises quality metrics, have resulted in increased demands for *transparency* and *accountability* in healthcare, two issues addressed in the 2010 reform legislation.

PASSAGE OF THE PATIENT PROTECTION AND AFFORDABLE CARE ACT AND THE HEALTH CARE AND EDUCATION RECONCILIATION ACT OF 2010

LEGISLATIVE EVENTS LEADING TO THE PASSAGE OF HEALTHCARE REFORM

With the Obama administration in the White House and a Democratic majority in both the Senate and the House of Representatives, the favorable time to approach healthcare reform appeared imminent to some. After a long and heated debate regarding the content of potential healthcare reform initiatives to be included in the proposed legislation, the Patient Protection and Affordable Care Act, HR 3590 (PPACA), and the Health Care and Education Reconciliation Act of 2010, HR 4872 (HCRA), collectively referred to as the ACA, were enacted on March 23, 2010 and March 25, 2010, respectively. Although the 2010 healthcare reform legislation may not satisfy those who sought a single payor healthcare system, it did mark the beginning of a new era in the long march toward U.S. *healthcare reform.* Indeed, this reform may result in a changed paradigm for the way in which healthcare services are delivered and paid for in the United States. The reform's most recent initiatives have already modified or improved several aspects of the healthcare delivery system, including, for example: (1) increased regulatory scrutiny aimed at combating fraud and abuse and antitrust violations; (2) health plan regulation; (3) addressing physician shortages; (4) access to, and quality of, care initiatives; and (5) increased attention to public health/wellness activities, among others.[71]

Summary of Key Provisions

The ACA will continue to result in significant changes to the country's healthcare landscape. Table 6-1 provides a brief overview of the various entities and sectors of the healthcare industry that are affected by provisions included in the 2010 healthcare reform legislation.

71 "Health Care that Works for Americans" The White House, https://www.whitehouse.gov/healthreform/healthcare-overview (Accessed 3/24/2015).

Table 6-1: Chart of Key Provisions of the ACA[72]

Target for Reform	Provision	Effective Date
Insurance Industry	Insurance market rules	September 23, 2010
Insurance Industry	Grandfathered Plans - Eliminate preexisting condition exclusions for children	September 23, 2010
Insurance Industry	Provide dependent coverage for adult children up to age 26 for all individual and group policies	2010
Insurance Industry	National Association of Insurance Commissioners must establish uniform definitions and standard methodologies	December 31, 2010
Insurance Industry	Simplify health insurance administration by adopting a single set of rules for eligibility verification and claims status	January 1, 2013
Insurance Industry	Consumer Operated and Oriented Plans (CO-OPs)	July 1, 2013
Insurance Industry	Grandfathered Plans - Eliminate preexisting condition exclusions for adults	2014
Insurance Industry	Limit deductibles for health plans in the small group market to $2,000/individual and $4,000/family	2014
Insurance Industry	Health insurance exchanges for individual states	January 1, 2014
Insurance Industry	Deadline for all health plans to document compliance with the new rules (penalty for noncompliance is $1 per covered life)	April 1, 2014
Individuals and Employers	Provide grants for up to five years for small businesses that establish wellness programs	2011
Individuals and Employers	All individuals required to obtain health insurance coverage	March 1, 2014
Individuals and Employers	Employers with 100 or more employees that do not offer coverage assessed tax penalties	2015
Individuals and Employers	Employers with fewer than 50 employees that offer insurance receive tax credits and exemption from tax penalties	2015
Individuals and Employers	Employers with 50-99 employees that do not offer coverage assessed tax penalties	2016
Medicare	Ban new physician-owned hospitals in Medicare (and require hospitals to have a provider agreement in effect by 12/31/10)	2010
Medicare	Improve care coordination for dual eligible by creating the Federal Coordinated Health Care Office	2010
Medicare	50% discount from pharmaceutical manufacturers on brand-name prescriptions filled in the Medicare Part D coverage gap	2011
Medicare	Prohibit higher cost-sharing requirements for some Medicare benefits than is required under the traditional FFS program	2011
Medicare	Restructure payments to Medicare Advantage plans	2011
Medicare	Freeze income threshold for income-related Medicare Part B premiums at 2010 levels	2011, effective through 2019
Medicare	Provide a 10% Medicare bonus payment to primary care physicians	2011, effective through 2015
Medicare	Provide a 10% Medicare bonus payment to general surgeons practicing in areas lacking in health professionals	2011, effective through 2015
Medicare	Make Medicare Part D cost-sharing for full-benefit dual-eligible beneficiaries receiving home or community-based care services equal to the cost-sharing for those receiving institutional care	2012
Medicare	Allow ACOs to share in the cost savings that they achieve for the Medicare program	2012
Medicare	Reduce rebates for Medicare Advantage plans	2012
Medicare	Provide bonus payments to high-quality Medicare Advantage plans	2012
Medicare	Begin phasing in federal subsidies for brand-name prescriptions filled in the Medicare Part D coverage gap	2013
Medicare	Establish a national Medicare pilot program	2013

(continued)

72 "Health Reform Implementation Timeline" The Henry J. Kaiser Family Foundation, http://kff.org/interactive/implementation-timeline/ (Accessed 4/1/15).

Target for Reform	Provision	Effective Date
Medicare	Reduce Medicare Disproportionate Share Hospital (DSH) payments	2014
Medicare	Reduce the out-of-pocket amount required to qualify for catastrophic coverage	2014
Medicare	Establish an Independent Payment Advisory Board (IPAB)	2014
Medicare	Restrictions on revenue spending for Medicare Advantage plans	2014
Medicare	Reduce Medicare payments to certain hospitals by 1% for certain hospital-acquired conditions	2015
Medicare	Reduce the gap between generic and brand-name drugs	2020
Medicaid	Create a state option to cover childless adults through a Medicaid state plan amendment	2010
Medicaid	Establish the State Balancing Incentive Program	2011
Medicaid	Create a new state plan option to permit enrollees with: (a) at least two chronic conditions; (b) one condition and a risk of developing another; or (c) at least one serious mental health condition	2011
Medicaid	Create new demonstration projects	Begin 2012
Medicaid	Increase payments for primary care services	2013 and 2014
Medicaid	Increase Federal CHIP matching to states by 23%	October 1, 2015
Tax Provisions	Provide a sliding scale tax credit to small employers with fewer than 25 full-time equivalent employees	2010
Tax Provisions	Impose additional requirements on non-profit hospitals, for which failure to comply will result in a $50,000 tax per year of noncompliance	2010
Tax Provisions	Limit the deductibility of executive and employee compensation to $500,000 per individual for health insurance providers	2010
Tax Provisions	10% tax on indoor tanning services implemented	2010
Tax Provisions	Impose new annual fees on pharmaceutical manufacturers	2012
Tax Provisions	Increase the threshold for the itemized deduction for the for unreimbursed medical expenses from 7.5% adjusted gross income (AGI) to 10% AGI for regular tax purposes	2013
Tax Provisions	Increase the Medicare Part A tax rate on wages by 0.9%	2013
Tax Provisions	Excise tax on taxable medical devices	2013
Tax Provisions	Provide a refundable credit for coverage under a qualified health plan	January 1, 2014
Tax Provisions	Tax penalty assessed on individuals who do not obtain coverage by March 31, 2014	2014
Tax Provisions	Tax penalty assessed on large employers (more than 100 employees) that do not offer coverage	2015
Tax Provisions	Tax penalty assessed on mid-sized employers (50-99 employees) who do not offer coverage	2016
Tax Provisions	Excise Tax on high-cost "*Cadillac*" insurance plans	2018
Prevention and Wellness	Establish the National Prevention, Health Promotion, and Public Health Council to improve overall national health	2011
Prevention and Wellness	Create a personalized prevention plan that provides incentives to Medicare and Medicaid beneficiaries to complete behavior modification systems	2011
Prevention and Wellness	Provide Medicare beneficiaries access to a comprehensive health risk assessment	2011
Prevention and Wellness	Allow employers to offer employees rewards of up to 30% (and increasing to 50%, if appropriate) of the cost of coverage for participation in a wellness program and meeting certain wellness-related standards	2014
Prevention and Wellness	Coordination of federal prevention, wellness, and public health activities	2014
Prevention and Wellness	Create the Prevention and Public Health Fund	2014
Prevention and Wellness	Create task forces on Preventive Services and Community Preventive Services	2014
Fraud and Abuse	Streamline Medicare prepayment medical review limitations and additional funds for programs focusing on reducing healthcare fraud	Implementation dates will vary

The various entities and sectors of the healthcare industry that are affected by provisions included in the 2010 healthcare reform legislation include:

(1) **Insurance industry.** The 2010 healthcare reform legislation subjects the insurance industry to increasing restrictions regarding expanding coverage requirements.[73]
(2) **Individual states.** All states are required to establish an American Health Benefit Exchange to facilitate the purchase of qualified health plans and a Small Business Health Options Program (SHOP) that will assist small employers (fewer than 100 employees) in obtaining coverage for employees.[74]
(3) **Individuals.** Perhaps the most controversial mandate is that individuals are required to obtain or provide some minimum level of health insurance coverage. The healthcare legislation requires all individuals to obtain health insurance coverage or pay penalties. Exemptions will be granted for financial hardship, religious objections, American Indians, those without coverage for less than three months, undocumented immigrants, incarcerated individuals, those for whom the lowest cost plan option exceeds 8% of individual income, and those whose individual (or household) income was below the tax filing thresholds.[75]
(4) **Employers.** Although the 2010 healthcare reform legislation does not require employers to offer health coverage to employees, employers can face significant penalties if they choose not to do so.[76]
(5) **Medicare.** The program is required to provide, among other topics, a productivity adjustment and reductions to market basket updates for many providers; make several concessions to expand primary care, coordinated care, and delivery system reform; support quality, transparency, and fraud and abuse enforcement initiatives; provide a rebate for Medicare Part D beneficiaries required to pay out-of-pocket for prescription drug coverage in 2010; enforce provisions to continuously reduce the gap between generic and brand-name drugs by 2020; add restrictions on revenue spending for Medicare Advantage plans; update Disproportionate Share Hospital (DSH) payments; address the impact of physician ownership; and control the diagnostic imaging utilization rate.[77]
(6) **Medicaid.** Reform initiatives related to Medicaid were phased in between 2010 and 2014 and include several provisions related to expanding enrollee eligibility, prescription drug coverage, and primary care and preventive services coverage, among others. Additionally, Medicaid will be required to designate new matching payments for eligible individuals and increase Medicaid payment rates for primary care physicians.[78]

73 "Patient Protection and Affordable Care Act" Pub. L. No. 111-148, §§ 1101, 1102, 1201, 1251, 124 Stat. 119, 119-120. (March 23, 2010).
74 "Patient Protection and Affordable Care Act" Pub. L. No. 111-148, §§ 1321, 1322, 1331, 1332, 1333, 124 Stat. 119, 120. (March 23, 2010).
75 "Patient Protection and Affordable Care Act" Pub. L. No. 111-148, § 1501, 124 Stat. 119, 242 et seq. (March 23, 2010).
76 "Patient Protection and Affordable Care Act" Pub. L. No. 111-148, §§ 1511, 1512, 1513, 1514, 1515, 124 Stat. 119, 121. (March 23, 2010).
77 "Patient Protection and Affordable Care Act" Pub. L. No. 111-148, §§ 3133, 3135, 3201, 3301, 3401, 5501, 6001, 6402, 124 Stat. 119, 119-130. (March 23, 2010).
78 "Patient Protection and Affordable Care Act" Pub. L. No. 111-148, §§ 2001, 2501, 2502, 2503, 124 Stat. 119, 119-130. (March 23, 2010).

(7) **Public health.** The ACA also supports public health workforce training and expansion, as well as support for prevention and wellness initiatives.[79] Additionally, ACA establishes the National Prevention, Health Promotion, and Public Health Council to coordinate federal prevention, wellness, and public health activities, as well as the creation of a Prevention and Public Health fund to expand funding for prevention and public health programs. Further, the legislation creates task forces related to preventive services and community preventive services for the purpose of developing, updating, and disseminating evidence-based recommendations on the use of clinical and community prevention services.[80]

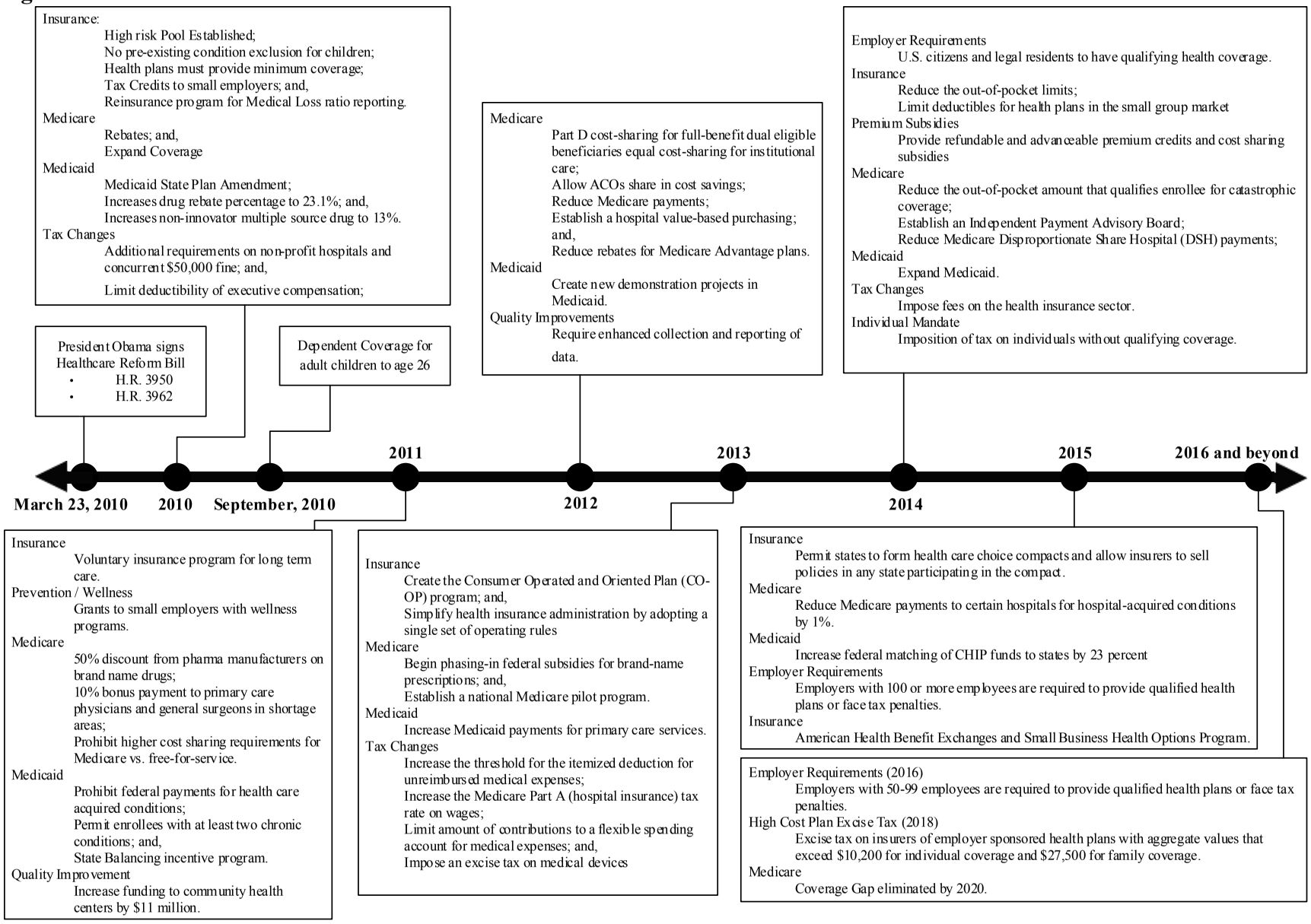
(8) **Tax payers.** The ACA contains certain tax provisions, including the provision of a refundable credit for coverage under a qualified health plan, effective January 1, 2011, as well as a sliding-scale tax credit to small employers (those with fewer than twenty-five employees and average annual wages of less than $50,000) that purchase health insurance for their employees. Funding mechanisms to support the implementation of these reform initiatives include imposing a tax on high-cost insurance (that is, insurance that exceeds a maximum premium payment level while increasing premiums for those in high-risk professions). The legislation additionally expands the Medicare tax base for taxpayers with higher income revenue provisions.[81]

TIMELINE FOR IMPLEMENTATION OF THE ACA

Figure 6-2 provides an overview of the implementation timeline related to certain key healthcare reform initiatives.

79 "Patient Protection and Affordable Care Act" Pub. L. No. 111-148, §§ 4001, 4002, 4103, 4104, 5204, 5307, 5314, 124 Stat. 119, 124-125 (March 23, 2010).
80 "Patient Protection and Affordable Care Act" Pub. L. No. 111-148, §§ 4001, 4002, 4003, 4105, 124 Stat. 119, 124-125 (March 23, 2010).
81 "Patient Protection and Affordable Care Act" Pub. L. No. 111-148, §§ 1421, 9001, 9015, 124 Stat. 119, 119-130. (March 23, 2010).

Figure 6-2: A Brief Primer on Healthcare Reform —Healthcare Reform Timeline P.L. 111-148 • P.L. 111-152



OBSTACLES TO THE IMPLEMENTATION OF HEALTHCARE REFORM

The continued success of the implementation of the healthcare reform timeline will depend largely on the continued political and fiscal support for the measures proposed in the ACA, and although the current political environment on the federal level may support the bill, individual states are responsible for much of its implementation, leaving ample room for delays created by lack of aggressive oversight or support.[82] The states' major implementation responsibilities include establishing the insurance exchanges for small businesses and individuals, enforcing the new insurance requirements, and administering the new Medicaid expansion.[83] Without continued support of the Obama administration, Congress, other stakeholder groups, the media, and the public, the strides made in healthcare reform by the passage of the ACA may be countered, similar to when the *Medicare Catastrophic Coverage Act of 1988* was repealed slightly more than a year after its passage.[84] Recently, the ACA faced its second major test in the Supreme Court in *David King et al. v. Sylvia Mathews Burwell et al.* Although the court ruled in favor of the administration, preserving the ACA, there may still be other challenges to the ACA.[85]

After passage of the ACA, there remained heated opposition from the Republican Party regarding the content and implementation of the bill's provisions. Several of the attorneys general that were running for political office or up for re-election challenged the reform bill.[86] State attorneys general filed lawsuits in federal court within minutes of President Obama's signing of the healthcare reform legislation into law, each claiming that the healthcare reform legislation violates the United States Constitution.[87] One lawsuit, led by Florida Attorney General Bill McCollum, and joined by twelve other state attorneys general, claimed that the reform legislation exceeds Congress's power to regulate commerce, violated the 10th Amendment protection of state sovereignty, and imposed an unconstitutional direct tax.[88]

These states took legal action in *The State of Florida et al. v. United States Department of Health and Human Services et al.* (commonly referred to as Florida v. HHS), in which the 26 states disputed the constitutionality of the ACA's individual mandate provision and the constitutionality of the ACA itself.[89] The National Federation of Independent Business (NFIB) also filed a suit challenging the constitutionality of the ACA, questioning "whether the ACA must be invalidated in its entirety because it is non-severable from the individual mandate that

82 "The War Isn't Over" By Henry J. Aaron, and Robert D. Reischauer, New England Journal of Medicine, March 24, 2010, http://www.brookings.edu/~/media/research/files/opinions/2010/3/24-health-reform-aaron/0324_health_reform_aaron.pdf (Accessed 5/17/2010), p. 1-2.

83 "Implementation is Forever" By Drew Aultman, The Henry J. Kaiser Family Foundation, April 6, 2010, http://www.kff.org/pullingittogether/040610_altman.cfm (Accessed 5/17/2010).

84 "The War Isn't Over" By Henry J. Aaron, and Robert D. Reischauer, New England Journal of Medicine, March 24, 2010, http://www.brookings.edu/~/media/research/files/opinions/2010/3/24-health-reform-aaron/0324_health_reform_aaron.pdf (Accessed 5/5/2010), p. 1-3.

85 See the Future of the ACA section below, for a further discussion related to challenges to the ACA.

86 "Democratic, Republican Attorneys General Continue Health Reform Lawsuit Battle" Kaiser Health News, April 1, 2010, http://www.kaiserhealthnews.org/daily-reports/2010/april/01/thursday-state-lawsuits-health-reform.aspx (Accessed 5/5/2010).

87 "15 State Attorneys General to Sue to Block Health Care Reform Law" By Joanne Dechenaux, Society for Human Resource Management, March 31, 2010, http://www.shrm.org/LegalIssues/EmploymentLawAreas/Pages/15StateAttorneysGeneral.aspx (Accessed 5/5/2010).

88 Ibid.

89 "State of Florida et al. v. United States Department of Health and Human Services, et al." Case No. 11-398 (SCOTUS 2011), Petition for Writ of Certiorari, p. I.

exceeds Congress' limited and enumerated powers under the Constitution."[90] After a series of opposing circuit court decisions, the Supreme Court of the U.S. (SCOTUS) decided to combine the cases and issue one ruling for both of the underlying cases.

In March of 2012, two years after the passage of the ACA, SCOTUS began hearing oral arguments to consider four key questions related to the ACA: (1) whether the individual mandate was a "*tax*" or a "*penalty*," thereby addressing the question of the "*ripeness*" necessary for a constitutional challenge; (2) whether the individual mandate was a violation of the U.S. Constitution's Commerce Clause; (3) whether the individual mandate provision was severable from the rest of the law; and (4) whether the federal requirement that states expand Medicaid coverage was a violation of the U.S. Constitution's Supremacy Clause.[91]

On June 28, 2012, SCOTUS issued a ruling that passed over issues of ripeness and chose to uphold the constitutionality of the individual mandate. Despite agreeing with the argument that the individual mandate violated the U.S. Constitution's Commerce clause, SCOTUS reasoned that the individual mandate was an exercise of the Federal taxing power.[92] SCOTUS held that the "*penalty*" mandated against those individuals that do not purchase insurance under the individual mandate was a tax, because it: (1) is paid upon filing an annual income tax return; (2) only applies to those individuals who pay federal income tax; (3) takes into account similar factors as taxes, for example, number of dependents, joint filing status, and taxable income; and (4) is codified in the Internal Revenue Code and enforced by the *Internal Revenue Service* (IRS).[93] Chief Justice Roberts stated in his opinion that, "the Constitution permits such a tax, it is [therefore] not our role to forbid it, or to pass upon its wisdom or fairness."[94] With regards to the Medicaid expansion, the Court limited Congress's attempt to "pressure" states into participating, comparing the termination of all Medicaid funding to those states that chose not to participate to a "gun to the head."[95] Under the SCOTUS ruling, Congress could attempt to entice states to expand Medicaid by offering additional funding, but could not withdraw existing funds. Additionally, SCOTUS noted that a lack of participation by any number of the states did not invalidate the entire Medicaid expansion provision, thus upholding its constitutionality within the ACA.[96]

In addition to political obstacles to the enactment of healthcare reform, some consider physicians a potential barrier to certain reform initiatives, namely, cost-containment measures.[97] Research studies have shown that the regional variance in healthcare spending is correlated with physician recommendation of additional tests of discretionary or uncertain benefit to the patient, and that

90 "National Federation of Independent Businesses et al. v. Kathleen Sebelius et al." Case No. 11-393 (SCOTUS 2011), Petition for a Writ of Certiorari, p. i.
91 "Supreme Court Review of the Healthcare Reform Law" By Gregory D. Curfman, Brendan S. Abel and Renee M. Landers et al., New England Journal of Medicine, Vol. 366, Nno. 11, March 15, 2012, p. 978-979.
92 "National Federation of Independent Business et al. v. Sebelius et al." 132 S. Ct. 2566, 2600 (2012).
93 "National Federation of Independent Business et al. v. Sebelius et al." 132 S. Ct. 2566, 2653 (2012).
94 "National Federation of Independent Business et al. v. Sebelius et al." 132 S. Ct. 2566, 2600 (2012).
95 "National Federation of Independent Business et al. v. Sebelius et al." 132 S. Ct. 2566, 2604 (2012).
96 "National Federation of Independent Business et al. v. Sebelius et al." 132 S. Ct. 2566, 2607-08 (2012).
97 "Medicine's Ethical Responsibility for Health Care Reform—The Top Five List" By Howard Brody, New England Journal of Medicine, Vol. 362, No. 4 (January 28, 2010), p. 284.

reform efforts focused on reducing spending in high-cost regions (for example, limiting unnecessary visits, procedures, etc.) would greatly assist in cost-containment initiatives.[98]

PROPOSED SUPPLEMENTAL REFORM INITIATIVES

Despite the monumental passage of the ACA, one thing that remains clear amid the looming uncertainty regarding what this reform *means* is that healthcare reform must be viewed as a *process* rather than an *event*. In the months (and years) ahead, additional healthcare reform initiatives will be proposed and implemented. The implementation of the 2010 healthcare reform legislation has been and will be adaptive and possibly erratic, as its implementation not only depends on what is contained within the actual text of the legislation but also how it responds to outside factors, such as the public's support of the legislation; the changing political and economic landscape; the private sector's response; the healthcare professionals' real-life, day-to-day application of the law; and the governors', attorneys' general, and states' response to the reform. Accordingly, consultants advising individuals and businesses in these matters should keep abreast not only regarding the impact of the healthcare reform legislation that has been passed to date, but also forthcoming proposals and initiatives.

In this era of continuing healthcare reform, the future of the competitive landscape for the healthcare industry may prove difficult to predict. Features of this evolving landscape include:

(1) The emergence of health insurance exchanges;
(2) The growing role of value-based reimbursement and VBP initiatives, such as the recently announced Oncology Care Model;[99]
(3) The looming physician manpower shortage in the face of a growing demand from the anticipated influx of the newly insured under the ACA's individual mandate and Medicaid expansion, as well as the aging baby boomer demographic;[100] and
(4) The consolidation of healthcare providers,[101] as well as expanding numbers of physicians becoming employed by hospitals and health systems.[102]

These trends, together with the continuing advance toward the "*corporatization*" and "*Wal-martization*" of medicine,[103] have led to a restructuring of the very nature of healthcare competition. This restructuring is likely energized in part by the aggressive pursuit of measurable

98 "Discretionary Decision Making by Primary Care Physicians and the Cost of U.S. Health Care" By Brenda Sirovich et al., Health Affairs, Vol. 27, No. 3 (May/June 2008), p. 819; "Slowing the Growth of Health Care Costs—Lessons from Regional Variation" By Elliott S. Fisher, Julie P. Bynum, and Jonathan S. Skinner, New England Journal of Medicine, Vol. 360, No. 9 (February 26, 2009), p. 851-852.
99 "Oncology Care Model" Centers for Medicare & Medicaid Services, http://innovation.cms.gov/initiatives/Oncology-Care/ (Accessed 3/16/2015).
100 "The Complexities of Physician Supply and Demand: Projections from 2013 to 2025—Final Report" IHS, Inc., March 2015, p. v-vi.
101 "Hospital Consolidation Trend to Continue" By Rich Daly, Healthcare Financial Management Association, June 16, 2014, http://www.hfma.org/Content.aspx?id=23307 (Accessed 3/28/15).
102 "Understanding the Physician Employment 'Movement'" By Bonnie Darves, New England Journal of Medicine Career Center, July 23, 2014, http://www.nejmcareercenter.org/article/understanding-the-physician-employment-movement-/ (Accessed 3/28/15); "A Guide to Physician Integration Models for Sustainable Success" Chicago, IL: Health Research and Educational Trust and Kaufman, Hall & Associates, Inc., September 2012, http://www.hpoe.org/Reports-HPOE/guide_to_physician_integration_models_for_sustainable_success.pdf (Accessed 3/24/2015), p. 5.
103 "The Wal-Martization of Health Care" By William M. Sage, The Journal of Legal Medicine, Vol. 28, No. 4 (2007), p. 503-504.

enhancement of patient care outcomes by means of coordinated care efforts across medical specialties, treatment modalities, and facility types.[104]

PAYING FOR HEALTHCARE REFORM

Reforming healthcare in America may cost the government billions of dollars, which may be funded in a variety of ways including: (1) cutting waste, fraud, and abuse within existing government health programs; (2) removing large subsidies to insurance companies; and (3) increasing healthcare delivery efficiency through streamlining paper work and coordinating care.[105] The CBO has recently released an updated estimate of the budgetary effects of the insurance provisions of the ACA. The CBO projects the insurance provisions of the legislation will cost approximately $1,707 billion between 2016 and 2025, which will be partially offset by $499 billion in penalty payments and other sources, resulting in a net cost of approximately $1,207 billion over that time frame.[106] It should be noted that, under the CBO's normal procedures, the remaining budgetary effects of the ACA (i.e., those provisions that are not related to insurance) are not estimated. The CBO has stated that the remaining budgetary effects of the ACA would need to be compared to a "counterfactual benchmark that exclude[s] the ACA."[107] Furthermore, the CBO has described the creation of such a counterfactual benchmark as a highly complicated task that would result in a benchmark that is "…hugely uncertain and speculative."[108] Accordingly, those remaining budgetary effects have not been estimated since the CBO's initial projection of the budgetary effects of the ACA in its entirety. However, the CBO recently noted that it has no reason to suspect that its initial estimate of these remaining budgetary effects relating to the ACA is incorrect.[109]

Based on the CBO's 2010 estimate, the budgetary effects of the ACA's provisions that are not related to insurance (i.e., those provisions for which the CBO does not create regularly updated estimations) are projected to result in net savings of $931 billion.[110] However, this includes $70 billion in savings resulting from the Community Living Assistance Services and Supports

104 "When and how provider competition can improve health care delivery" By Penelope Dash, MD and David Meredith, McKinsey & Company, November 2010, http://www.mckinsey.com/insights/health_systems_and_services/when_and_how_provider_competition_can_improve_health_care_delivery (Accessed 3/24/2015); "Bringing Home the Continuum of Care" Amedisys, http://www.amedisys.com/delivering_new_models_of_care (Accessed 3/28/15), p. 3.

105 "Frequently Asked Questions about Health Insurance Reform" The White House, http://www.whitehouse.gov/realitycheck/faq#c1 (Accessed 8/7/2012).

106 "Insurance Coverage Provisions of the Affordable Care Act—CBO's March 2015 Baseline" Congressional Budget Office, March 2015, https://www.cbo.gov/sites/default/files/cbofiles/attachments/43900-2015-03-ACAtables.pdf (Accessed 3/28/15), table 1.

107 "Estimating the Budgetary Effects of the Affordable Care Act" By Doug Elmendorf, Congressional Budget Office, June 17, 2014, https://www.cbo.gov/publication/45447 (Accessed 3/28/2015).

108 "Estimating the Budgetary Effects of the Affordable Care Act" By Doug Elmendorf, Congressional Budget Office, June 17, 2014, https://www.cbo.gov/publication/45447 (Accessed 3/28/2015).

109 "Estimating the Budgetary Effects of the Affordable Care Act" By Doug Elmendorf, Congressional Budget Office, June 17, 2014, https://www.cbo.gov/publication/45447 (Accessed 3/28/2015).

110 "Estimate of Direct Spending and Revenue Effects of HR 3590 and HR 4872" By Douglas W. Elmendorf, Congressional Budget Office, Letter to Nancy Pelosi, U.S. House of Representatives, March 20, 2010, https://www.cbo.gov/sites/default/files/amendreconprop.pdf (Accessed 8/7/2012), p. 5.

(CLASS) program, which has been eliminated since the CBO conducted its original projection.[111]

Other sources of funding for the 2010 healthcare reform legislation may include (1) new annual fees paid by insurers, estimated to yield $60.1 billion from 2014 to 2019; (2) new annual fees paid by pharmaceutical manufacturers, estimated to raise $27 billion from 2013 to 2019; (3) a 2.9 percent excise tax on medical device manufacturers, estimated to raise $20 billion from 2013 to 2019; and (4) an excise tax on high-cost insurance plans, estimated to raise $32 billion from 2018 to 2019.[112]

HEALTHCARE REFORM IMPACT ON THE FUTURE OF U.S. HEALTHCARE DELIVERY

In June 2014, the CBO reiterated its 2010 estimate that the enactment of the *Patient Protection and Affordable Care Act* would reduce federal budget deficits by $150 billion from 2010 to 2019.[113] Combined with the CBO's 2010 estimate of the reduction of the federal deficit associated with the *Health Care and Education Reconciliation Act of 2010*, the federal deficit is estimated to be reduced by $175 billion.[114] In addition to the budgetary benefits of bill passage, the Office of the Assistant Secretary for Planning and Evaluation estimates that 16.4 million people have gained health insurance coverage as a result of the ACA, which has reduced the percentage of uninsured from 20.3 percent (in October of 2013) to 13.2 percent (in March of 2015).[115]

IMPACT ON INDIVIDUALS

The 2010 healthcare reform legislation requires U.S. citizens and legal residents to maintain minimum amounts of health insurance coverage, a controversial provision of the ACA that was upheld in *NFIB v. Sebelius*.[116] Minimum essential coverage includes government-sponsored programs, eligible employer-sponsored programs, plans in the individual market, grandfathered group health plans, as well as some other types of coverage.[117]

111 "Estimate of Direct Spending and Revenue Effects of HR 3590 and HR 4872" By Douglas W. Elmendorf, Congressional Budget Office, Letter to Nancy Pelosi, U.S. House of Representatives, March 20, 2010, https://www.cbo.gov/sites/default/files/amendreconprop.pdf Accessed 8/7/2012), Table 5; "Estimating the Budgetary Effects of the Affordable Care Act" By Doug Elmendorf, Congressional Budget Office, June 17, 2014, https://www.cbo.gov/publication/45447 (Accessed 3/28/2015).

112 "What Will Happen Under Health Reform- and What's Next?" The Commonwealth Fund, April 30, 2010, http://www.ca-ilg.org/sites/main/files/file-attachments/2010_cjr_insert_what_next_web_415.pdf (Accessed 3/24/2015).

113 "Estimating the Budgetary Effects of the Affordable Care Act" By Doug Elmendorf, Congressional Budget Office, June 17, 2014, https://www.cbo.gov/publication/45447 (Accessed 3/28/2015).

114 "Estimate of direct spending and revenue effects of H.R. 3590 and H.R. 4872" Congressional Budget Office, Letter to Nancy Pelosi, Speaker U.S. House of Representatives, March 20, 2010, p. 2-3; "Estimating the Budgetary Effects of the Affordable Care Act" By Doug Elmendorf, Congressional Budget Office, June 17, 2014, https://www.cbo.gov/publication/45447 (Accessed 3/28/2015).

115 "Health Insurance and the Affordable Care Act" Assistant Secretary for Planning and Evaluation, Department of Health and Human Services, March 16, 2015, http://aspe.hhs.gov/health/reports/2015/uninsured_change/ib_uninsured_change.pdf (Accessed 3/28/15), p. 1.

116 See the Obstacles to the Implementation of Healthcare Reform section above

117 "Requirement to Maintain Minimum Essential Coverage" 26 U.S.C. § 5000A(f) (2012).

To assist U.S. citizens in paying for this coverage, the legislation provides for refundable tax credits that eligible taxpayers may use toward health insurance premiums (for both the individual taxpayer and his or her family) for health insurance purchased through a state health benefit exchange.[118] Each individual enrolled in a plan offered through an exchange will be required to report his or her income to the exchange. Based on this information provided by the individual, the individual will receive a premium assistance credit by the treasury paying the credit directly to the insurance plan in which the individual is enrolled. The individual will then pay the difference between the credit amount and the total premium charged.[119] The legality of these tax credits was recently reviewed by the Supreme Court, as specified in the section on *King v. Burwell*, below. The Supreme Court concluded that the tax credits were, in fact, legal.

Individuals who fail to maintain this minimum essential coverage will be subject to the following excise taxes: $95 in 2014, $325 in 2015, and $695 in 2016 and years beyond.[120] This penalty also is applied to any dependents who do not maintain minimum essential coverage. Individuals who qualify for hardship or religious exemptions are excluded.[121]

Significant provisions of the initial healthcare reform legislation affecting individuals are related to the exclusion of pre-existing conditions by health plans and the extension of health insurance coverage for dependent children. Effective September 23, 2010, all health insurance plans are prohibited from excluding children on the basis of a pre-existing condition. Later, during the second half of 2010, a temporary national high-risk pool was created to permit adults with pre-existing conditions to obtain subsidized coverage with maximum cost sharing capped at the current health savings account limit. This high-risk pool was dissolved as of January 1, 2014, as all insurers and group health plans are prohibited from excluding persons with pre-existing conditions.[122] Additionally, beginning on January 1, 2011, health plans must report the proportion of premium dollars spent on clinical services and quality improvement and other costs, and provide rebates to consumers for any medical loss ratio less than 85% for large group plans and 80% for individual and small group plans.[123] In addition, in 2010, a process for reviewing increases in health plan premiums was established, which requires insurance companies to justify increases.[124]

Also effective September 23, 2010, insurance plans are required to provide dependent coverage for children up to age twenty-six for all individual and group policies.[125] Eligible children up to

118 "Eligibility for Premium Tax Credit" 26 C.F.R. § 1.36B-2 (2013).
119 "Tax Provisions in the Health Care Act" Journal of Accountancy, March 22, 2010, http://www.journalofaccountancy.com/Web/20102724.htm (Accessed April 10, 2010).
120 "Individual Mandate Under ACA" By Annie L. Mach, Congressional Research Service, August 12, 2014, http://fas.org/sgp/crs/misc/R41331.pdf (Accessed 3/25/2015), p. 2; "Requirement to Maintain Minimum Essential Coverage" 26 U.S.C. § 5000A (2012).
121 "Tax Provisions in the Health Care Act" Journal of Accountancy, March 22, 2010, http://www.journalofaccountancy.com/Web/20102724.htm (Accessed April 10, 2010); "Requirement to Maintain Minimum Essential Coverage" 26 U.S.C. § 5000A(f) (2012).
122 "Patient Protection and Affordable Care Act" Pub. L. No. 111-148, § 1101 124 Stat. 119, 141 (March 23, 2010).
123 "Minimum Medical Loss Ratio" 45 C.F.R. 158.210 (2015); "Patient Protection and Affordable Care Act" Pub. Law 111-148, § 2718, 124 Stat. 119, 886 (March 23, 2010).
124 "Rate Increases Subject to Review" 45 C.F.R. § 154.200 (2011).
125 "Summary of New Health Reform Law" The Henry J. Kaiser Family Foundation, April 21, 2010, http://www.kff.org/healthreform/upload/8061.pdf (Accessed 5/6/2010), p. 6; "Eligibility of Children until at least age 26" 29 C.F.R. § 2590.715-2714 (2011).

twenty-six years of age who do not qualify for other coverage must be covered under their parents' employer's plan.[126]

IMPACT ON SMALL AND MID-SIZED EMPLOYERS

The impact of the ACA is not limited to individuals. States were required to establish Affordable Insurance Exchanges by January 1, 2014.[127] These exchanges will facilitate the purchase of qualified health plans and establish a SHOP, which will assist small employers to obtain coverage for their employees.[128] Employers with 100 or fewer employees may enroll in the exchange. Effective 2017, employers with more than 100 employees may obtain coverage through an exchange at the discretion of the state.[129]

Beginning in 2010, an *eligible small employer* that purchases health insurance for its employees receives a tax credit for amounts spent on health insurance coverage for employees.[130] An eligible small employer meets the following conditions when: (1) it has no more than twenty-five full-time equivalent employees for the taxable year; (2) the average wages it pays during the taxable year do not exceed $50,000; and (3) it pays at least half of the premium cost.[131]

Between 2010 and 2013, small employers providing healthcare coverage for employees were eligible to receive a tax credit up to 35 percent of the employer's contribution toward its employees' health insurance premiums if the employer contributed at least 50 percent of the total premium cost of 50 percent of the benchmark premium.[132] In 2014, the applicable tax credit percentage increased to 50 percent.[133] Employers with ten or fewer employees and average wages of less than $20,000 will receive 100 percent of the credit.[134] Employers with fifty or fewer employees are exempt from penalties assessed for failure to either (1) offer no health coverage to full-time employees or (2) provide coverage to full-time employees that is not affordable.[135]

An estimated four million small businesses may be eligible for the tax credit if they provide healthcare to their employees.[136] Indeed, the Congressional Budget Office estimated that from

126 "Health Care Reform Memo: April 12, 2010" Deloitte Center for Health Solutions, April 12, 2010, http://www.deloitte.com/view/en_US/us/Insights/Browse-by-Content-Type/Newsletters/health-care-reform-memo/6a8e7661b62f7210VgnVCM100000ba42f00aRCRD.htm (Accessed 4/19/2010).
127 "Patient Protection and Affordable Care Act" Pub. L. No. 111-148, § 1311(b), 124 Stat. 119, 173 (March 23, 2010).
128 "Key Provisions of Comprehensive Health Care Reform Legislation" Sonnenschein Nath & Rosenthal, LLP, March 30, 2010, p. 3; "Patient Protection and Affordable Care Act" Pub. L. No. 111-148, § 1311(b), 124 Stat. 119, 173 (March 23, 2010).
129 "Patient Protection and Affordable Care Act" Pub. L. No. 111-148, § 1311, 124 Stat. 119, 184 (March 23, 2010).
130 "Patient Protection and Affordable Care Act" Pub. L. No. 111-148, § 45R, 124 Stat. 119, 238 (March 23, 2010); "Health Care Reform Legislation: Provisions Affecting Employer-Sponsored Group Health Plans," Sonnenschein Nath & Rosenthal, LLP, April 14, 2010.
131 Ibid.
132 "Summary of New Health Reform Law" The Henry J. Kaiser Family Foundation, April 21, 2010, http://www.kff.org/healthreform/upload/8061.pdf (Accessed 4/14/2010), p. 3; "Patient Protection and Affordable Care Act" Pub. L. No. 111-148, § 45R(g), 124 Stat. 119, 241 (March 23, 2010).
133 "Patient Protection and Affordable Care Act" Pub. L. No. 111-148, § 45R(b), 124 Stat. 119, 238 (March 23, 2010).
134 Ibid.
135 "Patient Protection and Affordable Care Act" Pub. L. No. 111-148, § 1513, 124 Stat. 119, 253 (March 23, 2010).
136 "A Helping Hand for Small Businesses" Families USA and Small Business Majority, July 2010, http://www.smallbusinessmajority.org/_pdf/tax_credit/Helping_Small_Businesses.pdf (Accessed 3/30/2015), p. 2.

2016 to 2025, the federal government will provide $11 billion in support to small businesses and organizations through the premium tax credit program.[137]

IMPACT ON ALL LARGER EMPLOYERS

Although the 2010 healthcare reform legislation does not require larger employers to offer healthcare coverage to employees, employers can face significant penalties if they choose not to do so. Employers with more than fifty employees must offer "*eligible employer sponsored plan*[s]" to their employees.[138] These eligible employer-sponsored plans consist of government-sponsored coverage, employer-sponsored coverage, grandfathered health plans, and plans offered in the individual market.[139] These health plans must:[140] (1) provide the essential health benefits package; (2) limit annual cost-sharing to the high-deductible health plan limit; (3) limit the annual deductible for small group market plans to $2,000 for individual and $4,000 for families; and (4) not require cost-sharing for preventive services or immunization.[141]

Additionally, an *applicable large employer* (defined as an employer that employs an average of at least fifty full-time employees during the preceding calendar year) that (1) does not provide coverage for all of its full-time employees, (2) provides minimum essential coverage that is unaffordable, or (3) provides minimum essential coverage that consists of a plan in which the plan's share of the total allowed cost of benefits is less than 60 percent is required to pay a penalty if any full-time employee is certified to the employer as having purchased health insurance through a state exchange with respect to which a tax credit or cost-sharing reduction is allowed or paid to the employee.[142] If an employer offers unaffordable coverage, that is, if the premium exceeds 9.5 percent of a family's income, the employer must pay a $3,000 penalty for each full-time employee who is given a government subsidy and purchases coverage through a health exchange.[143]

Originally, the 2010 healthcare reform legislation included a provision that required employers who offer health coverage to provide their employees with a voucher, such that they could choose their own health insurance plan.[144] However, this provision was repealed as part of a budget deal in April 2011.[145]

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137 "Insurance Coverage Provisions of the Affordable Care Act—CBO's March 2015 Baseline" Congressional Budget Office, March 2015, https://www.cbo.gov/sites/default/files/cbofiles/attachments/43900-2015-03-ACAtables.pdf (Accessed 3/28/15), table 1.

138 "Patient Protection and Affordable Care Act" Pub. L. No. 111-148, § 1513, 124 Stat. 119, 253 (March 23, 2010).

139 "Requirement to Maintain Minimum Essential Coverage" 26 U.S.C. § 5000A(f)(2) (2012).

140 "Patient Protection and Affordable Care Act" Pub. L. No. 111-148, § 1513, 124 Stat. 119, 253 (March 23, 2010).

141 "Key Provisions of Comprehensive Health Care Reform Legislation" Sonnenschein Nath & Rosenthal, LLP, March 30, 2010, p. 4; "Qualified Health Plan Defined" 42 U.S.C. § 18021 (2011); "Essential Health Benefits Requirements" 42 U.S.C. § 18022 (2011).

142 "Tax Provisions in the Health Care Act" Journal of Accountancy, March 22, 2010, http://www.journalofaccountancy.com/Web/20102724.htm (Accessed April 10, 2010); "Patient Protection and Affordable Care Act" Pub. L. No. 111-148, § 1513, 124 Stat. 114, 253 (March 23, 2010).

143 "Patient Protection and Affordable Care Act" Pub. L. No. 111-148, § 1513, 124 Stat. 119, 253 (March 23, 2010); "Shared Responsibility for Employers Regarding Health Coverage; Final Rule" Federal Register Vol. 79, No. 29 (February 12, 2014), p. 8544; "Questions and Answers on Employer Shared Responsibility Provisions Under the Affordable Care Act" Internal Revenue Service, February 18, 2015, http://www.irs.gov/Affordable-Care-Act/Employers/Questions-and-Answers-on-Employer-Shared-Responsibility-Provisions-Under-the-Affordable-Care-Act (Accessed 4/1/15).

144 "Lobbyists Won Key Concessions in Budget Deal" By Eric Lichtblau, New York Times, April 12, 2011, http://www.nytimes.com/2011/04/13/us/politics/13lobby.html?_r=0 (Accessed 3/16/2015).

145 Ibid.

It should be noted that the 2010 healthcare reform legislation provides special rules for grandfathered health plans. A *grandfathered health plan* is any group health plan or individual coverage that was effective on March 23, 2010, the date of the legislation's enactment.[146] The healthcare legislation allows an employer to maintain current health coverage for individuals that are already enrolled in plans and for subsequently enrolled family members and new hires, which will not negate the grandfathered status as long as the plan allowed for dependent or family coverage on March 23, 2010.[147] Collectively bargained agreements are grandfathered until the date on which the last of the collective bargaining agreements relating to the grandfathered coverage terminates.[148]

Effective in 2018, a 40 percent excise tax on high-cost employer-sponsored plans will be assessed to plans costing more than $10,200 for individual coverage or more than $27,500 for family coverage.[149] The tax percentage will be adjusted for certain factors such as age, gender, and high-risk professions.[150]

IMPACT ON INSURERS

The provisions of the ACA that have the greatest impact on health insurers may be those that regulate: (1) the benefits that must be included in health plans; (2) the individuals that may not be excluded from health plans; and (3) the individuals that are required to purchase a health insurance plan. For example, effective September 23, 2010, all health insurance plans: (1) are prohibited from excluding children under age 19 on the basis of a preexisting condition; (2) are required to provide dependent coverage for children up to age 26 for all individual and group policies; and (3) may not impose annual maximum benefit limits for "essential benefits," except those limits that may be permitted by regulations at a later date.[151] Furthermore, effective January 1, 2014, group health plans are prohibited from excluding *any* patient on the basis of preexisting conditions.[152] In addition, under the ACA, self-funded plans are required to provide covered individuals with the option to seek external independent medical review of certain claims, such as claims that are denied based on a purported lack of medical necessity.[153] Insurance plans also may not require prior authorization or increased cost sharing for emergency services, even if those services are provided out-of-network, and are prohibited from

146 "Patient Protection and Affordable Care Act" Pub. L. No. 111-148, § 1251, 124 Stat. 119, 161 (March 23, 2010).

147 "'Grandfathered' Plans Spared Some Reform Mandates" By Paul M. Hamburger and James R. Napoli, Society for Human Resource Management, April 9, 2010, http://www.shrm.org/hrdisciplines/benefits/Articles/Pages/GrandfatheredPlans.aspx (Accessed 4/15/2010); "Patient Protection and Affordable Care Act" Pub. L. No. 111-148, § 1251, 124 Stat. 119, 161 (March 23, 2010).

148 "Federal Health Care Reform: Impacts on Employers" Anthem, April 7, 2010, http://preferredinscenter.com/learn/Anthem-Employer-HealthcareAct-Full.pdf, (Accessed 4/14/2010), p. 2; "Patient Protection and Affordable Care Act" Pub. L. No. 111-148, § 1251, 124 Stat. 119, 162 (March 23, 2010).

149 "Tax Provisions in the Health Care Act" Journal of Accountancy, March 22, 2010, http://www.journalofaccountancy.com/Web/20102724.htm (Accessed April 10, 2010); "Patient Protection and Affordable Care Act" Pub. L. No. 111-148, § 9001, 124 Stat. 119, 124, 847 (March 23, 2010).

150 "Patient Protection and Affordable Care Act" Pub. L. No. 111-148, § 9001, 124 Stat. 119, 848 (March 23, 2010); "Tax Provisions in the Health Care Act" Journal of Accountancy, March 22, 2010, http://www.journalofaccountancy.com/Web/20102724.htm (Accessed April 10, 2010).

151 "Patient Protection and Affordable Care Act" Pub. L. No. 111-148, §§ 1302, 2714, 124 Stat. 119, 132, 163-164 (March 23, 2010); "Health Care Reform Memo: April 12, 2010" Deloitte Center for Health Solutions, April 12, 2010, http://www.deloitte.com/view/en_US/us/Insights/Browse-by-Content-Type/Newsletters/health-care-reformmemo/6a8e7661b62f7210VgnVCM100000ba42f00aRCRD.htm (Accessed May 19, 2010).

152 "Patient Protection and Affordable Care Act" Pub. L. No. 111-148, § 1101, 124 Stat. 119, 141-143 (March 23, 2010).

153 "Patient Protection and Affordable Care Act" Pub. L. No. 111-148, § 10101, 124 Stat. 119, 887-888 (March 23, 2010).

discriminating in favor of highly compensated employees.[154] Despite these limitations, payors may still be able to incentivize beneficiaries to lower health expenditures. For example, under the ACA, group health plans may increase incentives for *wellness program investments* from 20 percent to 30 percent of the cost of the insurance premium.[155]

As noted above, the ACA provides special rules for *grandfathered health plans*, i.e., any group health plan or individual coverage that was effective before the enactment of the ACA.[156] Although grandfathered plans may avoid many of the ACA's requirements pertaining to health insurers, they are still subject to the following key provisions: (1) dependent coverage; (2) elimination of coverage rescissions; (3) lifetime coverage limits; and (4) as of 2014, excessive waiting periods.[157]

Medicare

In addition to its impact on insurers in general, the ACA made substantial changes to the Medicare program, which is the largest health insurance program in the country.[158]

The ACA mandates that the Medicare program:[159]

(1) Reduce payments to many providers through the application of productivity adjustments to market basket updates;[160]
(2) Significantly enhance the provision of primary care, the coordination of care, and reform healthcare delivery systems;[161]
(3) Support quality, transparency, and fraud and abuse enforcement initiatives;[162]
(4) Add restrictions on revenue spending for Medicare Advantage plans in 2014;[163]
(5) Reduce payments to *disproportionate share hospitals* (DSHs);[164]
(6) Address the impact of physician ownership of healthcare facilities;[165]

154 "Patient Protection and Affordable Care Act" Pub. L. No. 111-148, § 10101, 124 Stat. 119, 888-889 (March 23, 2010).
155 "Patient Protection and Affordable Care Act" Pub. L. No. 111-148, § 1201, 124 Stat. 119, 156-159 (March 23, 2010); "Federal Health Care Reform: Impacts on Employers" Anthem, April 7, 2010, http://preferredinscenter.com/learn/Anthem-Employer-HealthcareAct-Full.pdf (accessed April 14, 2010), p. 6.
156 "Patient Protection and Affordable Care Act" Pub. L. No. 111-148, § 1251, 124 Stat. 119, 887-888 (March 23, 2010).
157 "Grandfathered Health Insurance Plance" Healthcare.gov, https://www.healthcare.gov/health-care-law-protections/grandfathered-plans/ (Accessed 3/30/2015); "'Grandfathered' Plans Spared Some Reform Mandates" Paul M. Hamburger and James R. Napoli, Society for Human Resource Management, April 9, 2010, http://www.shrm.org/hrdisciplines/benefits/Articles/Pages/GrandfatheredPlans.aspx (accessed April 15, 2010); "FAQ: Grandfathered Health Plans" By Sarah Bar, Kaiser Health News, November 13, 2013, http://kaiserhealthnews.org/news/grandfathered-plans-faq/ (Accessed 4/1/15); "FAQs about Grandfathered Health Plans for 2014" United Benefit Advisors, Society for Human Resource management, August 26, 2013, http://www.shrm.org/hrdisciplines/benefits/articles/pages/faqs-grandfathered-plans.aspx (Accessed 4/1/15).
158 "Health Policy Brief: Health Reform's Changes in Medicare" By Amanda Cassidy, Health Affairs, May 20, 2010, p. 1; "CMS Press Toolkit" Centers for Medicare & Medicaid Services, http://www.cms.gov/Newsroom/PressToolkit.html (Accessed 3/30/2015).
159 "Summary of Key changes to Medicare in 2010 Health Reform Law" The Henry J. Kaiser Family Foundation, www.kff.org/healthreform/upload/7948-02.pdf (Accessed 8/24/2010); "Closing the Coverage Gap—Medicare Prescription Drugs are Becoming More Affordable" Centers for Medicare & Medicaid Services, January 2015, https://www.medicare.gov/Pubs/pdf/11493.pdf (Accessed 3/30/2015), p. 6.
160 "Patient Protection and Affordable Care Act" Pub. L. No. 111-148, § 3401, 124 Stat. 119, 480-488 (March 23, 2010).
161 "Patient Protection and Affordable Care Act" Pub. L. No. 111-148, §§ 3022, 5501 et seq., 124 Stat. 119, 395-399, 652 et seq. (March 23, 2010).
162 "Patient Protection and Affordable Care Act" Pub. L. No. 111-148, §§ 6002, 6003, 6004, 124 Stat. 119, 689-698 (March 23, 2010).
163 "Patient Protection and Affordable Care Act" Pub. L. No. 111-148, § 3201 et seq., 124 Stat. 119, 442 et seq. (March 23, 2010).
164 "Patient Protection and Affordable Care Act" Pub. L. No. 111-148, § 2551, 124 Stat. 119, 312-314, (March 23, 2010).
165 "Patient Protection and Affordable Care Act" Pub. L. No. 111-148, § 6001, 124 Stat. 119, 684-689. (March 23, 2010).

(7) Enact programs to incentivize hospitals to reduce unnecessary readmissions and hospital-acquired conditions;[166]
(8) Reduce the costs of prescription drugs for Medicare Part D beneficiaries in the coverage gap;[167] and
(9) Reduce the coverage gap between generic and brand-name drugs through 2020.[168]

The ACA includes several provisions that requires Medicare to reform the manner by which providers are reimbursed, in many cases reducing payments to facilities. For example, the ACA applies a productivity adjustment to the market basket updates for inpatient and outpatient hospitals, skilled nursing facilities, inpatient rehab facilities, long term care hospitals, and inpatient psychiatric facilities (as of 2012), as well as home health agencies (as of 2015).[169] Since their enactment, these productivity adjustments have reduced annual updates to the payment systems for these varied facilities by 0.5% to 1.0%.[170] Over the life of the program, market basket reductions may total more than $100 billon for hospitals alone.[171]

The ACA reduced Medicare payments to hospitals by other means—in addition to productivity adjustments—such as through the creation of a new payment structure for Medicare payments to DSH-qualifying hospitals. As of 2014, Medicare DSHs receive a base payment equal to 25 percent of the standard DSH allocation, as well as an additional payment, based on the prevalence of uncompensated care for a particular hospital, relative to uncompensated care provided by hospitals nationwide.[172] In total, reductions in Medicare DSH payments are projected at approximately $22 billion from 2014 to 2019.[173]

In addition to the reductions to hospital reimbursement created by productivity adjustments and reductions in DSH payments, the ACA also reduced Medicare payments to hospitals through value-based reimbursement (VBP) programs. For example, the ACA created the *Hospital Readmissions Reduction Program* (HRRP) to reduce Medicare payments to hospitals with excess readmissions for a specified set of conditions, such as acute myocardial infarction, heart failure, pneumonia, chronic obstructive pulmonary disease, and total hip or knee arthroplasty.[174] For fiscal year 2015, the maximum penalty for excess readmissions is three percent of the sum of a hospital's base operating *diagnosis-related group* (DRG) payments for all discharges.[175] In addition to the HRRP, in 2015, CMS implemented the *hospital acquired condition* (HAC) reduction program. The HAC program will reduce Medicare payments to hospitals whose

166 "Patient Protection and Affordable Care Act" Pub. L. No. 111-148, §§ 3008, 3025, 124 Stat. 119, 376-378, 408-413 (March 23, 2010).
167 "Patient Protection and Affordable Care Act" Pub. L. No. 111-148, § 3301, 124 Stat. 119, 461-468 (March 23, 2010).
168 "Patient Protection and Affordable Care Act" Pub. L. No. 111-148, § 3301, 124 Stat. 119, 461-468 (March 23, 2010).
169 "Actual Regulation Market Basket Updates" Centers for Medicare & Medicaid Services, http://www.cms.gov/Research-Statistics-Data-and-Systems/Statistics-Trends-and-Reports/MedicareProgramRatesStats/downloads/mktbskt-actual.pdf (Accessed 3/18/2015); "Patient Protection and Affordable Care Act" Pub. L. No. 111-148, § 3401, 124 Stat. 119, 480-488 (March 23, 2010).
170 "Actual Regulation Market Basket Updates" Centers for Medicare & Medicaid Services, http://www.cms.gov/Research-Statistics-Data-and-Systems/Statistics-Trends-and-Reports/MedicareProgramRatesStats/downloads/mktbskt-actual.pdf (Accessed 3/18/2015).
171 "Provider Reimbursement Changes in Healthcare Reform Law" By Eric D. Fader et al., Edwards, Angell, Palmer & Dodge, LLP, May 18, 2010, http://www.martindale.com/health-care-law/article_Edwards-Angell-Palmer-Dodge-LLP_1025278.htm (Accessed 5/25/2010).
172 "Disproportionate Share Hospital (DSH)" Centers for Medicare & Medicaid Services, Aug. 4, 2014, http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/AcuteInpatientPPS/dsh.html (Accessed 10/3/14).
173 "Medicare DSH Fact Sheet" American Hospital Association, March 11, 2015, http://www.aha.org/content/13/fs-dsh.pdf (Accessed 3/30/2015), p. 1.
174 "Readmissions Reduction Program" Centers for Medicare & Medicaid Services, Aug. 4, 2014, http://cms.gov/Medicare/Medicare-Fee-for-Service-Payment/AcuteInpatientPPS/Readmissions-Reduction-Program.html/ (Accessed 10/3/14).
175 Ibid. Note that the federal government's fiscal year runs from October 1 to September 30.

patients acquire certain conditions during their hospitals stay,[176] which may ultimately improve patient safety. To accomplish this, the HAC reduction program rates hospitals based upon certain quality standards that are composed of HAC measures.[177] Hospitals with the poorest performance (i.e., those in the top quartile for incidence of HACs) will have their inpatient Medicare payments reduced by 1.0 percent.[178]

Although the ACA reduces some Medicare payments (e.g., payments to hospitals and other facilities), it also includes provisions for a 10 percent bonus payment for primary care services that are delivered by primary care physicians, as well as certain nurse practitioners, clinical nurse specialists, and physician assistants.[179] Furthermore, the ACA provided that general surgeons practicing in health professional shortage areas received a 10% bonus payment from 2011 to 2015.[180]

Among the most significant changes to Medicare in the 2010 healthcare reform legislation are the changes to the *Medicare Advantage* (MA) Program. Although the majority of beneficiaries participate in traditional fee-for-service Medicare, over a quarter of Medicare beneficiaries receive coverage through the MA program.[181] The ACA reduces the federal payments made to the MA program over the next several years.[182] Prior to the passage of the ACA, Medicare payments per beneficiary were higher for beneficiaries covered by MA plans compared to traditional fee-for-service beneficiaries.[183] In an attempt to correct for this inequity, the 2010 healthcare reform restructures the payments made to MA plans, making their payments closer to the average costs of traditional Medicare beneficiaries.[184] These changes include: (1) revising the benchmarks used to calculate local payment rates; (2) altering the amount of money that may be paid as rebates to insurers; and (3) utilizing quality measures to adjust benchmarks that determine MA payment rates.[185]

Another reform to the Medicare program is given in Section 3403 of the ACA, which established an Independent Payment Advisory Board, comprised of 15 members who will be responsible for developing and submitting proposals to Congress in an effort to reduce excess cost growth and

176 "Fact Sheets: CMS Final Rule to Improve Quality of Care During Hospital Inpatient Stays" Centers for Medicare & Medicaid Services, 8/2/2013, http://www.cms.gov/newsroom/mediareleasedatabase/fact-sheets/2013-fact-sheets-items/2013-08-02-3.html (Accessed 6/11/2014).

177 Ibid.

178 "Fact Sheets: Fiscal Year 2015 Proposed Policy and Payment Changes for Inpatient Stays in Acute-Care Hospitals and Long-Term Care Hospitals" Centers for Medicare & Medicaid Services, 4/30/2014, http://www.cms.gov/Newsroom/MediaReleaseDatabase/Fact-sheets/2014-Fact-sheets-items/2014-04-30.html (Accessed 6/11/2014); "Fact Sheets: CMS Final Rule to Improve Quality of Care During Hospital Inpatient Stays" Centers for Medicare & Medicaid Services, 8/2/2013, http://www.cms.gov/newsroom/mediareleasedatabase/fact-sheets/2013-fact-sheets-items/2013-08-02-3.html (Accessed 6/11/2014).

179 "Patient Protection and Affordable Care Act" Pub. L. No. 111-148, § 5501, 124 Stat. 119, 652 (March 23, 2010).

180 "Summary of Key changes to Medicare in 2010 Health Reform Law" The Henry J. Kaiser Family Foundation, www.kff.org/healthreform/upload/7948-02.pdf (Accessed 8/24/2010); "Patient Protection and Affordable Care Act" Pub. L. No. 111-148, § 5501, 124 Stat. 119, 653 (March 23, 2010).

181 "Medicare Advantage 2013 Spotlight: Enrollment Market Update" The Henry J. Kaiser Family Foundation, 6/10/2013, http://kaiserfamilyfoundation.files.wordpress.com/2013/06/8448.pdf (Accessed 4/22/2014), p. 2.

182 "Summary of Key changes to Medicare in 2010 Health Reform Law" The Henry J. Kaiser Family Foundation, www.kff.org/healthreform/upload/7948-02.pdf (Accessed 8/24/2010); "Patient Protection and Affordable Care Act" Pub. L. No. 111-148, § 3201, 124 Stat. 119, 442 (March 23, 2010).

183 "Health Policy Brief: Health Reform's Changes in Medicare" By Amanda Cassidy, Health Affairs, May 20, 2010, p. 2-3.

184 "Summary of Key changes to Medicare in 2010 Health Reform Law" The Henry J. Kaiser Family Foundation, www.kff.org/healthreform/upload/7948-02.pdf (Accessed 8/24/2010), p. 2.

185 "Patient Protection and Affordable Care Act" Pub. L. No. 111-148, § 3201 et seq., 124 Stat. 119, 442 (March 23, 2010).

improve the quality of care for Medicare beneficiaries.[186] Under Section 10320 of the ACA, the Board must: (1) make annual recommendations to the President, Congress, and private entities regarding actions they can take to improve quality and constrain the rate of cost growth in the private sector; (2) make nonbinding recommendations to Congress in years in which Medicare expenditure growth is below the targeted growth rate; and (3) to specifically prohibit the Board from making recommendations that would reduce premium supports for low-income Medicare beneficiaries.[187]

Medicaid

The ACA also includes provisions to reform Medicaid. Certain provisions create state options to expand Medicaid coverage, such as:

(1) A state option to cover childless adults through a Medicaid State Plan Amendment;[188]
(2) A state option to provide coverage for family planning services to certain low-income individuals up to the highest level of eligibility for pregnant women;[189] and
(3) An option for states to provide *Children's Health Insurance Plan* (CHIP) coverage for children of state employees.[190]

Reforms to Medicaid also include several provisions targeting coverage of prescription drugs, such as:

(1) An increase in the drug rebate percentage for brand name drugs up to 23.1 percent;
(2) An increase in the drug rebate percentage for generic drugs up to 13 percent of the average manufacturer price; and
(3) Extension of the drug rebate to Medicaid managed care plans.[191]

Other revisions to Medicaid include providing additional funding for the Medicaid and CHIP Payment & Access Commission to include assessments of adult services (including those persons who are dually eligible for Medicare and Medicaid), and requiring the Secretary of HHS to issue regulations establishing a process for public notice and comment for Section 1115 waivers in Medicaid and CHIP.[192]

186 "Section-by-Section Analysis with Changes Made by Title X and Reconciliation included within Titles I-IX" Democratic Policy Committee, http://dpc.senate.gov/healthreformbill/healthbill96.pdf (Accessed 8/24/2010); "Patient Protection and Affordable Care Act" Pub. L. No. 111-148, § 3403, 124 Stat. 119, 489 (March 23, 2010).
187 "Section-by-Section Analysis with Changes Made by Title X and Reconciliation included within Titles I-IX" Democratic Policy Committee, http://dpc.senate.gov/healthreformbill/healthbill96.pdf (Accessed 8/24/2010); "Patient Protection and Affordable Care Act" Pub. L. No. 111-148, § 10320, 124 Stat. 119, 949-952 (March 23, 2010).
188 "Patient Protection and Affordable Care Act" Pub. L. No. 111-148, § 2001, 124 Stat. 119, 271-279 (March 23, 2010).
189 "Patient Protection and Affordable Care Act" Pub. L. No. 111-148, § 2303, 124 Stat. 119, 293-296 (March 23, 2010).
190 "Patient Protection and Affordable Care Act" Pub. L. No. 111-148, § 10203, 124 Stat. 119, 927-931 (March 23, 2010).
191 "Patient Protection and Affordable Care Act" Pub. L. No. 111-148, § 2501 et seq., 124 Stat. 119, 306 (March 23, 2010).
192 "Focus on Health Reform: Medicaid and CHIP Health Reform Implementation Timeline" The Henry J. Kaiser Family Foundation, April 12, 2010, http://kaiserfamilyfoundation.files.wordpress.com/2013/01/8064.pdf, (Accessed 3/5/2014), p. 1; "Patient Protection and Affordable Care Act" Pub. L. No. 111-148, § 2801, 124 Stat. 119, 328 (March 23, 2010).

Beginning in 2011, several Medicaid reform initiatives went into effect, including:[193]

(1) The prohibition of federal payments to states for Medicaid services related to healthcare acquired conditions;[194]
(2) The creation of a new Medicaid state plan option to permit certain high risk enrollees to designate a provider as a "*health home*";[195] and
(3) The establishment of the Medicaid *Community First Choice Option* to provide community-based attendant support services to certain people with disabilities.[196]

In addition to the provisions listed above, several ACA reforms modified Medicaid's operations. For example, through 2015, the ACA expanded Medicaid payments to institutions of mental disease for adult enrollees who require stabilization of an emergency condition (effective October 1, 2011).[197] In addition, the ACA created new demonstration projects (from 2012 to 2016) to evaluate the use of global payments for episodes of care that include hospitalization, as well as pediatric *Accountable Care Organizations*.[198]

Regarding CHIP, the ACA requires states to maintain current income eligibility levels for children in Medicaid and CHIP at 2010 levels, and extends funding levels for CHIP through 2015, with the CHIP benefit package and cost-sharing rules to continue under current laws.[199] As of 2015, states have the option to receive a 23 percent increase in the CHIP match rate up to a cap of 100 percent.[200] The *Medicare Access and CHIP Reauthorization Act of 2015* (i.e., MACRA) contains provisions that will preserve and extend CHIP funding through 2017.[201]

Following the SCOTUS decision that invalidated the ACA provisions that mandated states to expand their Medicaid programs or lose all matching federal funds, states were given the choice of whether to: (1) opt into the Medicaid expansion in exchange for significant federal assistance or (2) maintain their Medicaid program's status quo, which could deny access to potentially millions of poor and uninsured constituents. For states that choose to participate in Medicaid expansion, the federal government will pay 100 percent of the costs of the expansion for three years, gradually reducing its matching funds down to 90 percent of the cost of the expansion by 2020 and beyond.[202] Despite the fact that, beginning in 2017 states will become responsible for a percentage of the healthcare expenses for those adults who are newly-eligible under the expansion, as well as those adults who enroll in Medicaid as required by the ACA's individual

193 "The Patient Protection and Affordable Care Act as Passed: Section-by-Section Analysis with Changes Made by Title X and Reconciliation included within Titles I—IX, where Appropriate" Democratic Policy Committee, http://dpc.senate.gov/healthreformbill/healthbill53.pdf (Accessed 8/20/10), p. 19, 21, 24; See specified sections of "Patient Protection and Affordable Care Act" Pub. L. No. 111-148, 124 Stat. 119 (March 23, 2010).
194 "Patient Protection and Affordable Care Act" Pub. L. No. 111-148, § 2702, 124 Stat. 119, 318-319 (March 23, 2010).
195 "Patient Protection and Affordable Care Act" Pub. L. No. 111-148, § 2703, 124 Stat. 119, 319-323 (March 23, 2010).
196 "Patient Protection and Affordable Care Act" Pub. L. No. 111-148, § 2401, 124 Stat. 119, 297-301 (March 23, 2010).
197 "The Patient Protection and Affordable Care Actas Passed: Section-by-Section Analysis with Changes Made by Title X and Reconciliation included within Titles I—IX, where Appropriate" Democratic Policy Committee, http://dpc.senate.gov/healthreformbill/healthbill53.pdf (Accessed 8/20/10), p. 21; "Patient Protection and Affordable Care Act" Pub. L. No. 111-148, § 2707, 124 Stat. 119, 326 (March 23, 2010).
198 "Patient Protection and Affordable Care Act" Pub. L. No. 111-148, §§ 2705, 2706, 124 Stat. 119, 324 (March 23, 2010). See the Impact on Professional Practice Providers section below, for more detail on ACOs.
199 "Patient Protection and Affordable Care Act" Pub. L. No. 111-148, § 10203, 124 Stat. 119, 927 (March 23, 2010).
200 "Payments to States" 42 U.S.C. § 1397ee(b) (2012).
201 "Medicare Access and CHIP Reauthorization Act of 2015" Pub. L. No. 114-10, § 301, 129 Stat. 87, 154-158.
202 "Patient Protection and Affordable Care Act" Pub. Law 111-148, § 2001, 124 Stat. 119, 272 (March 23, 2010).

mandate;[203] states may stand to experience significant financial gain should they elect to expand their Medicaid programs. This is because the federal government would: (1) pay a significantly higher percentage of the healthcare costs incurred by certain currently-eligible adults; (2) provide coverage for poor and near-poor uninsured adults, which may decrease some of the non-Medicaid costs associated with these individuals; and (3) increase overall economic activity in the state as a result of the increased amount of federal matching funds.[204]

To further illustrate the impact of increased economic activity resulting from improved federal matching funds, consider the example of Missouri. One study found that the Medicaid expansion was expected to cost approximately $8.6 billion to implement in Missouri between 2014 and 2020 with approximately $8.2 billion of that cost borne by the federal government.[205] Despite these costs, the Medicaid expansion was expected to add $9.6 billion to the gross state product over the same time period[206] and result in coverage of an additional 161,281 individuals by 2020.[207]

As of March 6, 2015, 29 states, including the District of Columbia, have opted in to the Medicaid expansion, 9 states remain undecided about whether to expand their Medicaid programs, and 16 states have announced they will not move forward with Medicaid expansion at this time.[208] It is estimated that approximately 6.7 billion individuals will remain uninsured in the states that have not expanded Medicaid in 2016.[209] In addition, states that do not expand their Medicaid programs will increase the per-person cost to the federal government, in contrast to the per-person costs if those individuals were covered by Medicaid.[210] Further, many individuals will be rendered ineligible for both Medicaid and private insurance subsidies, which may leave them without health coverage at all.[211]

Private Insurers

In addition to reforming public payors, the ACA also created new rules to regulate the activity of commercial payors. For example, the ACA provides standards regarding certain risk shifting activities, which are necessary in the likely event of insurers targeting the healthiest patients and attempting to avoid high cost beneficiaries. First, the ACA's *risk adjustment* (RA) works to reduce the incentives for insurers to avoid enrolling individuals with high medical costs, and to

203 "Considerations in Assessing State-Specific Fiscal Effects of the ACA's Medicaid Expansion" By Stan Dorn, The Urban Institute Health Policy Center, August 20, 2012, p. 1; "Patient Protection and Affordable Care Act" Pub. Law 111-148, § 2001, 124 Stat. 119, 272 (March 23, 2010).

204 "Considerations in Assessing State-Specific Fiscal Effects of the ACA's Medicaid Expansion" By Stan Dorn, The Urban Institute Health Policy Center, August 20, 2012, p. 1.

205 "The Economic Impacts of Medicaid Expansion on Missouri" By University of Missouri School of Medicine—Department of Health Management and Informatics and Dobson DaVanzo & Associates, LLC, November 2012, http://www.mffh.org/mm/files/MUMedicaidExpansionReport.pdf (Accessed 3/30/15), p. 18.

206 Ibid.

207 Ibid, p. 7.

208 "Status of State Action on the Medicaid Expansion Decision" The Henry J. Kaiser Family Foundation, March 6, 2015, http://kff.org/health-reform/state-indicator/state-activity-around-expanding-medicaid-under-the-affordable-care-act/ (Accessed 3/16/2015).

209 "What is the Result of Not Expanding Medicaid" By Stan Dorn et al., Robert Wood Johnson Foundation, August 2014, http://www.rwjf.org/content/dam/farm/reports/issue_briefs/2014/rwjf414946 (Accessed 3/30/2015), p. 1.

210 "Estimates for the Insurance Coverage Provisions of the Affordable Care Act Updated for the Recent Supreme Court Decision" Congressional Budget Office, July 2012, p. 2.

211 Ibid.

force insurers to compete based upon the value and efficiencies of their plans.[212] The RA program requires health plans to assign individual risk scores to their enrollees based upon the individual's age, sex, and diagnoses. The average of these risk scores is then used to calculate the plans' predicted expenses.[213] Plans are compared to a baseline premium, and plans with lower actuarial risk will make payments to plans with higher actuarial risk, thus balancing some of the expenses associated with high cost health insurance.[214] In addition to the RA program, the *temporary reinsurance program* (TRP) works to stabilize individual market premiums by providing funding for insurers who have enrolled high cost individuals. Insurers across the U.S. contribute payments to the TRP, to a total of $10 billion in 2014, $6 billion in 2015, and $4 billion in 2016.[215] These payments are then transferred to insurers who meet certain cost thresholds relative to their covered benefits.[216] The TRP only applies to the individual market (which many small businesses will likely utilize when providing health benefits to employees), and will be in place from 2014 through 2016.[217] Finally, the *risk corridors* (RC) program protects against inaccurate rate settings due to lack of familiarity with rating the newly insured population.[218] The RC program creates conditions for plans in the individual market to receive additional reimbursement or pay charges to HHS based on how close its actual costs are from its targeted costs, and will be in effect from 2014 to 2016.[219]

In addition to regulations regarding risk shifting activities, the 2010 health reform legislation includes provisions that regulate certain aspects of health plans' premiums. As specified in the Impact on Individuals section above, health plans created on or after January 1, 2011 must report the proportion of premium dollars spent on clinical services and quality. If less than a given threshold (85 percent for large group plans and 80 percent for individual and small group plans) of the revenue generated from beneficiaries' premiums is spent on clinical services or quality initiatives, the plans must provide rebates for their consumers.[220] Furthermore, CMS has implemented rate review regulations, requiring an independent review of increases in premium rates of 10 percent or more.[221] In addition, insurance companies must provide simple, easily

212 "Fact Sheet: ACA Risk-Sharing Mechanisms," American Academy of Actuaries, 2013, http://www.actuary.org/files/ACA_Risk_Share_Fact_Sheet_FINAL120413.pdf (Accessed 4/27/2014), p. 1; "Explaining Health Care Reform: Risk Adjustment, Reinsurance, and Risk Corridors" The Henry J. Kaiser Family Foundation, 1/22/2014, http://kff.org/health-reform/issue-brief/explaining-health-care-reform-risk-adjustment-reinsurance-and-risk-corridors/ (Accessed 4/27/2014), p. 3; "Patient Protection and Affordable Care Act" Pub. Law 111-148, § 1343, 124 Stat. 119, 212 (March 23, 2010).

213 "Explaining Health Care Reform: Risk Adjustment, Reinsurance, and Risk Corridors" The Henry J. Kaiser Family Foundation, 1/22/2014, http://kff.org/health-reform/issue-brief/explaining-health-care-reform-risk-adjustment-reinsurance-and-risk-corridors/ (Accessed 4/27/2014), p. 3-4.

214 "Explaining Health Care Reform: Risk Adjustment, Reinsurance, and Risk Corridors" The Henry J. Kaiser Family Foundation, 1/22/2014, http://kff.org/health-reform/issue-brief/explaining-health-care-reform-risk-adjustment-reinsurance-and-risk-corridors/ (Accessed 4/27/2014), p. 4; "Patient Protection and Affordable Care Act" Pub. Law 111-148, § 1341, 124 Stat. 119, 208 (March 23, 2010).

215 "Patient Protection and Affordable Care Act; Standards related to Reinsurance, Risk Corridors and Risk Adjustment; Final Rule" Federal Register Vol. 77, No. 57 (March 23, 2012), p. 17246, 17248.

216 Ibid.

217 "In the Spotlight: Healthcare Reform and Risk Assessment" Blue Cross Blue Shield of North Carolina, 9/29/2011, www.bcbsnc.com/assets/hcr/pdfs/spotlight_risk.pdf (Accessed 4/27/2014), p. 1-2.

218 "In the Spotlight: Healthcare Reform and Risk Assessment," Blue Cross Blue Shield of North Carolina, 9/29/2011, www.bcbsnc.com/assets/hcr/pdfs/spotlight_risk.pdf (Accessed 4/27/2014), p. 2; "Patient Protection and Affordable Care Act" Pub. Law 111-148, § 1342, 124 Stat. 119, 211 (March 23, 2010).

219 "Patient Protection and Affordable Care Act; Standards related to Reinsurance, Risk Corridors and Risk Adjustment; Final Rule" Federal Register Vol. 77, No. 57 (March 23, 2012), p. 17251.

220 "Minimum Medical Loss Ratio" 45 C.F.R. 158.210 (2015); "Patient Protection and Affordable Care Act" Pub. Law 111-148, § 2718, 124 Stat. 119, 886 (March 23, 2010).

221 "Rate Increase Disclosure and Review; Final Rule" Federal Register Vol. 76, No. 99 (May 23, 2011), p. 29985; "Rate Increases Subject to Review" 45 C.F.R. § 154.200 (2011).

understood information to consumers about their reasons for any significant rate increases, and post such information on their website.[222]

Establishment of the Health Insurance Marketplace

According to the 2010 health reform legislation, states were required to have a state health insurance exchange (*Exchange*) in operation by the beginning of 2014.[223] These Exchanges are intended to reduce the cost associated with health insurance and ease the process of selecting a health insurance plan by providing a single place for consumers to: (1) search for and compare health plans; (2) ask questions regarding coverage; (3) check eligibility for programs and tax credits; and (4) ultimately enroll in a health plan.[224]

The final rule regarding *Exchanges* offers states significant flexibility in the design and operation of their *Exchanges* and provides states with more options through which to customize their *Exchanges* with respect to member eligibility, health plan participation, and the overall operation of the *Exchange.*[225] Flexibility is also a key part of a state's operation of the *Small Business Health Options Programs* (*SHOPs*), which offer health insurance options for small employers within state *Exchanges.*[226] Through SHOPs, employers may choose a level of coverage to offer to their employees. Furthermore, states may determine the size of the small group market that participates in SHOPs, thus improving the flexibility of individual states' SHOPs.[227]

IMPACT ON PROFESSIONAL PRACTICE PROVIDERS

In addition to the 2010 healthcare reform legislation's effect on individuals, employers, and payors, the recent reform efforts will have major implications for healthcare providers. For example, as stated in the Medicaid section above, primary care physicians (including family medicine, internal medicine, geriatric, and pediatric physician providers) whose Medicare charges for office, nursing facility, and home visits comprise at least 60 percent of their total Medicare charges will be eligible for a 10 percent bonus payment for services performed from

222 "The Center for Consumer Information & Insurance Oversight: State Effective Rate Review Programs" Center for Medicare & Medicaid Services, 1/1/2014, http://www.cms.gov/CCIIO/Resources/Fact-Sheets-and-FAQs/rate_review_fact_sheet.html (Accessed 4/27/2014).

223 "Patient Protection and Affordable Care Act" Pub. Law 111-148, § 1311, 124 Stat. 119, 173 (March 23, 2010).

224 "Affordable Insurance Exchanges" U.S. Department of Health and Human Services, August 23, 2012, http://www.healthcare.gov/law/features/choices/exchanges/index.html (accessed March 20, 2012); "Patient Protection and Affordable Care Act" Pub. L. No. 111-148, § 1311(b), 124 Stat. 119, 173 (March 23, 2010).

225 "Patient Protection and Affordable Care Act; Establishment of Exchanges and Qualified Health Plans; Exchange Standards for Employers" Federal Register Vol. 77, No. 59 (March 27, 2012), p. 18310-18311; "HIX Final Rule Released" By Margaret Dick Tocknell, Health Leaders Media, March 13, 2012, http://www.healthleadersmedia.com/page-1/HEP-277640/HIX-Final-Rule-Released (Accessed March 20, 2012).

226 "Patient Protection and Affordable Care Act; Establishment of Exchanges and Qualified Health Plans; Exchange Standards for Employers" Federal Register 77, No. 59 (March 27, 2012), p. 18310-18311; "Affordable Insurance Exchanges: Choices, Competition and Clout for States" U.S. Department of Health and Human Services, July 11, 2011, http://www.healthcare.gov/news/factsheets/2011/07/exchanges07112011a.html (Accessed August 7, 2012).

227 "Affordable Insurance Exchanges: Choices, Competition and Clout for States" U.S. Department of Health and Human Services, July 11, 2011, http://www.healthcare.gov/news/factsheets/2011/07/exchanges07112011a.html (Accessed August 7, 2012); "SHOP and the Small Group Market" Center for Consumer Information and Insurance Exchange, May 21, 2012, https://www.cms.gov/CCIIO/Resources/Presentations/Downloads/hie-shop-and-the-small-group-market-policies.pdf (Accessed 4/1/15), slide 13.

2011 through 2015.[228] Additionally, general surgeons who conduct major procedures in a designated health professional shortage area will be eligible for a 10 percent bonus payment for these services from 2011 to 2016.[229] Medicare also increased payment by 0.5 percent from 2012 to 2014 for voluntary participation in Medicare's Physician Quality Reporting Initiative (PQRI).[230] From 2015 forward, physician providers who do not successfully participate in the PQRI program will have their payments reduced by 1.5 percent in 2015 and 2 percent in subsequent years.[231]

While the ACA incorporates several provisions that are beneficial for primary care providers, it also places new restrictions on certain specialty providers, most notably physician-owned specialty hospitals. Having stymied similar restrictions in several other bills during the past decade or so, physician-owned specialty hospitals are now subject to new provisions the 2010 healthcare reform legislation, which places heavy restrictions on the growth or expansion of existing specialty hospitals with physician ownership.[232] Not only does this provision reduce the beneficial effects of healthcare provider competition and create a greater likelihood of potential for hospital and health system monopolies, as the current regulatory and reimbursement healthcare environments facilitate trends of hospital consolidation and practice roll-up, but it further sustains the two-pronged attack on niche providers.

Another reimbursement change for healthcare providers is related to the establishment of an ACO, which provides a framework for providers to work in a coordinated and efficient manner across the patient continuum of care. Under the ACO model, both hospital and physician providers will continue to bill Medicare under the current FFS reimbursement system, but they may be eligible to share in certain cost savings if the patient care delivered meets CMS quality standards and the cost of delivery (including both Medicare Part A and Medicare Part B expenditures) is below a predetermined threshold, as specified in Chapter 2: *Reimbursement Environment*.[233]

ACOs have already taken effect in both the federal market (under the *Medicare Shared Savings Program*) and the commercial market. In the month after the issuance of the final rule regarding the establishment of ACOs on November 2, 2011, CMS announced the names of 32 organizations that would participate in its *Pioneer ACO Model*, which began on January 1,

228 "How the Passage of Federal Health System Reform Legislation Impacts Your Practice" American Hospital Association, 2010, http://www.ama-assn.org/ama/pub/health-system-reform/hsr-impacts-practice.shtml (Accessed 4/19/2010), p. 1; "Patient Protection and Affordable Care Act" Pub. L. No. 111-148, § 5501, 124 Stat. 119, 652 (March 23, 2010).

229 "How the Passage of Federal Health System Reform Legislation Impacts Your Practice" American Hospital Association, 2010, http://www.ama-assn.org/ama/pub/health-system-reform/hsr-impacts-practice.shtml (Accessed 4/19/2010), p. 1; "Patient Protection and Affordable Care Act" Pub. L. No. 111-148, § 5501, 124 Stat. 119, 653 (March 23, 2010).

230 "How the Passage of Federal Health System Reform Legislation Impacts Your Practice" American Hospital Association, 2010, http://www.ama-assn.org/ama/pub/health-system-reform/hsr-impacts-practice.shtml (Accessed 4/19/2010), p. 1; "Physician Quality Reporting System (PQRS) Overview" Centers for Medicare & Medicaid Services, http://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/PQRS/Downloads/PQRS_OverviewFactSheet_2013_08_06.pdf (Accessed 3/30/15), p. 2.

231 "2013 Physician Quality Reporting System (PQRS): 2015 PQRS Payment Adjustment" Centers for Medicare & Medicaid Services, August 2013, http://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/PQRS/Downloads/2013MLNSE13__Avoiding PQRSPaymentAdjustment_083013.pdf (Accessed 3/30/15), p. 1.

232 "Patient Protection and Affordable Care Act" Pub. Law 111-148, § 6001, 124 Stat. 119, 684 et seq. (March 23, 2010).

233 "Provider Participation in ACOs May Hinge on HHS Regulations" By Robert Belfort, BNA Health Law Reporter, Vol. 19, No. 546 (April 15, 2010), http://news.bna.com/hlln/display/batch_print_display.adp (Accessed 4/15/2010).

2012.[234] By May of 2014, the total number of Medicare ACOs grew to 361, covering 5.6 million beneficiaries in 47 states, Washington, DC, and Puerto Rico.[235] Despite this rapid proliferation of ACOs across the country and general health policy support of the *accountable care* concept, the long-term clinical and economic feasibility of the ACO model have not yet been demonstrated by a robust body of research. However, preliminary indications may support the expectation that ACOs can reduce growth in healthcare expenditures. For example, a study published in November 2013 found that, on average, Medicare beneficiaries who were covered by Pioneer ACOs in 2011 and 2012 had modest reductions in the growth of healthcare expenditures.[236] Although most Pioneer ACOs performed similarly to traditional Medicare FFS in their regions, a select few had significant reductions in expenditure growth,[237] which may indicate the success potential of certain best practices.

Since the advent of the ACA 744 ACOs have been formed, over 400 of which are Medicare ACOs (with 404 ACOs in the MSSP and 19 ACOs in the Pioneer ACO program).[238] These ACOs provide care for an estimated 23.5 million patients in all 50 states, Washington, D.C., and Puerto Rico.[239]

As discussed above, states have the option to participate in an expansion of the Medicaid program, which expands Medicaid coverage to all non-Medicare eligible individuals under age 65 (including children, pregnant women, parents, and adults without dependent children) with incomes up to 133 percent of the federal poverty level.[240] Providers may be able to leverage such an expansion in Medicaid coverage into additional revenues by avoiding uncompensated care from these previously uninsured patients and capitalizing on increased state economic activity.[241]

Although there appears to be an increase in reimbursement for some physician services, other physician providers will face a decrease in reimbursement. As of July 2, 2012, Medicare reimbursement for the technical component of diagnostic imaging services has been reduced by

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234 "CMS Announces Pioneer ACO Participants" American Hospital Association News, December 19, 2011, http://www.ahanews.com/ahanews/jsp/display.jsp?domain=AHANEWS&dcrpath=AHANEWS/AHANewsNowArticle/data/ann_121911_ACOs (Accessed July 21, 2012).

235 "Fast Facts—All Medicare Shared Savings Program and Medicarae Pioneer ACOs" Centers for Medicare & Medicaid Services, May 2014, https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/sharedsavingsprogram/Downloads/PioneersMSSPCombinedFastFacts.pdf (Accessed 3/24/2015), p. 1.

236 "Evaluation of CMMI Accountable Care Organization Initiatives: Effect of Pioneer ACOs on Medicare Spending in the First Year" L&M Policy Research, LLC, Report for Centers for Medicare & Medicaid Services, November 3, 2013, http://innovation.cms.gov/files/reports/pioneeracoevalreport1.pdf (Accessed 3/18/2015), p. iv.

237 Ibid.

238 "Growth And Dispersion of Accountable Care Organizations in 2015" By David Muhlestein, Health Affairs, March 31, 2015, http://healthaffairs.org/blog/2015/03/31/growth-and-dispersion-of-accountable-care-organizations-in-2015-2/ (Accessed 7/8/2015); "Fast Facts—All Medicare Shared Savings Program and Medicarae Pioneer ACOs" Centers for Medicare & Medicaid Services, April 2015, https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/sharedsavingsprogram/Downloads/PioneersMSSPCombinedFastFacts.pdf (Accessed 7/8/2015), p. 1; "Growth and Dispersion of Accountable Care Organizations: June 2014 Update" By Matthew Peterson, et al., Leavitt Partners, June 2014, http://leavittpartners.com/wp-content/uploads/2014/06/Growth-and-Dispersion-of-Accountable-Care-Organizations-June2014.pdf (Accessed 9/4/2014), p. 3.

239 "Growth And Dispersion of Accountable Care Organizations in 2015" By David Muhlestein, Health Affairs, March 31, 2015, http://healthaffairs.org/blog/2015/03/31/growth-and-dispersion-of-accountable-care-organizations-in-2015-2/ (Accessed 7/8/2015); "Growth and Dispersion of Accountable Care Organizations: June 2014 Update" By Matthew Peterson, et al., Leavitt Partners, June 2014, http://leavittpartners.com/wp-content/uploads/2014/06/Growth-and-Dispersion-of-Accountable-Care-Organizations-June2014.pdf (Accessed 9/4/2014), p. 3.

240 "Eligibility" Centers for Medicare & Medicaid Services, http://www.medicaid.gov/AffordableCareAct/Provisions/Eligibility.html (Accessed 3/24/2015); "Focus on Health Reform: Health Reform Implementation Timeline" The Henry J. Kaiser Family Foundation, March 31, 2010, https://www.nln.org/governmentaffairs/health_care/pdf/timelineHCKFF0510.pdf (Accessed 3/24/2015), p. 4.

241 See the Medicaid section above.

25 percent for subsequent procedures on consecutive body parts.[242] Additionally, the market basket update for both inpatient and outpatient hospital services will be reduced by 0.25 percent for fiscal year (FY) 2010–11, 0.1 percent for FY 2012–13, 0.3 percent for FY 2014–15, 0.2 percent for FY 2015–6, and 0.75 percent for FY 2017–19.[243]

FUTURE OF THE ACA

Despite the June 2012 SCOTUS decision confirming the constitutionality of the ACA, there is still a considerable level of uncertainty as to the ultimate impact of the ACA's implementation and whether the ACA will remain intact as it currently stands. This is due in large part to repeated legislative and judicial attempts to revise or repeal the 2010 health reform legislation. For example, since the enactment of the ACA in 2010, various members of Congress have staged numerous votes to repeal, revise, or defund the legislation, with varying degrees of success.[244] In the future, the election of a Republican president or a Republican supermajority in Congress could lead to the defunding, undercutting, amendment, or repeal of the ACA. Future presidents of either party will be able to exercise extensive political leverage to attempt to modify the health reform law, either by pressuring Congress or by enacting changes through HHS.[245] Indeed, the ACA gives the President discretion in implementing many of its provisions, including employer contributions to *health savings accounts* (*HSAs*), quality improvement measures for providers who contract with private insurers, and CO-OP insurer tax-exempt status.[246]

Due to the fact that the ACA establishes its own budget authority within the law, any attempt to defund certain mandatory spending provisions would be impossible without a Senate super-majority (60 votes).[247] That said, defunding of the ACA's non-mandatory spending provisions is possible. For example, funding for the *Prevention and Public Health Fund* (*PPHF*) has already been cut by $5 billion over 10 years by the *Middle Class Tax Relief and Job Creation Act of 2012*.[248] Discretionary spending provisions for programs such as *Pediatric Accountable Care Organizations* and *Rural Hospital Flexibility Grants*, inter alia, are at more risk of defunding, as they are subject to annual budget appropriations review.[249]

KING V. BURWELL

In 2015, the SCOTUS heard arguments regarding a challenge to one of the major provisions of the ACA. In *David King et al. v. Sylvia Mathews Burwell et al.* (commonly referred to as *King v. Burwell*), the petitioners argued that the Internal Revenue Service (IRS) had mistakenly

242 "Pub 100-04 Medicare Claims Processing: Transmittal 2395" Centers for Medicare & Medicaid Services, January 26, 2012, https://www.cms.gov/Regulations-and-Guidance/Guidance/Transmittals/downloads/R2395CP.pdf (Accessed 11/21/2014), p. 3.
243 Ibid, p. 1-2.
244 "Legislative Actions to Repeal, Defund, or Delay the Affordable Care Act" By C. Stephen Redhead and Janet Kinzer, Congressional Research Service, March 2, 2015, http://fas.org/sgp/crs/misc/R43289.pdf (Accessed 3/17/2015), p. 1.
245 "The Supreme Court's PPACA Decision: Substance and Implications for HLS Clients" Oliver Wyman, June 28, 2012, p. 6.
246 Ibid, p. 9.
247 Ibid, p. 8.
248 Ibid, p. 8.
249 "Discretionary Spending in the Patient Protection and Affordable Care Act (ACA)" By C. Stephen Redhead et al., Congressional Research Service, May 18, 2012, p. 34–35.

interpreted the provision of the ACA that provides tax credits to individuals who purchase health insurance using Exchanges.[250] The IRS interpreted the statute to provide for these tax credits to individuals regardless of whether the Exchange that the individuals utilized was run by an individual state or the federal government.[251] However, the specific text of the statute states that the tax credit may be distributed to taxpayers who enrolled in a health plan "…through an Exchange ***established by the State****…"* (Emphasis added).[252] Based on this language, the petitioners argued that the tax credit should only apply to individuals who enrolled in health plans using Exchanges that their state established and should not apply to individuals who used the Exchange established by the federal government.[253] The respondents, in turn, argued that this reading of the statute is inappropriate, declaring such an interpretation to be "…contrary to the [ACA]'s text and structure and would render the Act unrecognizable to the Congress that passed it."[254] Furthermore, the respondents argued that an Exchange established and operated by HHS within a state (i.e., a federal Exchange) satisfied the ACA's legal definition of an Exchange established by the state.[255] Ultimately, the SCOTUS upheld the government's interpretation of the ACA. In the majority opinion, Chief Justice Roberts noted that the petitioners' reading of the statute would result in serious damage to the health insurance markets that the ACA was designed to reform,[256] as described further below.

Importantly, the SCOTUS interprets an agency's interpretation of a statute utilizing the Chevron doctrine, which first asks "whether a statute is ambiguous, and, if so, whether the agency's approach is reasonable."[257] However, in *King v. Burwell*, the SCOTUS declined to follow the Chevron doctrine, and instead stated that the case represented a situation where the SCOTUS should "hesitate before concluding that Congress has intended such an implicit delegation" of authority to the IRS and petitioners.[258] The SCOTUS reasoned that it was unlikely that Congress would have delegated such a health insurance policy to the IRS, which has "no expertise in crafting" such polices, and, accordingly, declined to follow the Chevron doctrine, allowing the SCOTUS to render its ultimate decision upholding the ACA.[259]

A SCOTUS decision in favor of the petitioners would have rendered IRS tax credits to millions of individuals who obtained health insurance through a federally operated exchange, living in 34 states that elected not to establish their own Exchange, to be illegal.[260] As of April 19, 2014, over 4.6 million people had received tax credits for signing up for a health plan using a federal Exchange,[261] and a 2015 projection estimated that this population will grow to over 13.4 million

250 "David King et al. v. Sylvia Mathews Burwell et al." Case No. 14-114 (SCOTUS 2014), Petition for a Writ of Certiorari, p. i.
251 "Health Insurance Premium Tax Credit" Federal Register Vol. 77, No. 100 (May 23, 2012), p. 30387. Note that the regulation identifies as eligible those individuals who "…enrolled in one or more qualified health plans through an Exchange…" without specifying whether the Exchange was run by a state or by the federal government.
252 "Patient Protection and Affordable Care Act" Pub. L. No. 111-148, § 1401, 124 Stat. 119, 213 (March 23, 2010).
253 "David King et al. v. Sylvia Mathews Burwell et al." Case No. 14-114 (SCOTUS 2015), Brief for Petitioners, p. 6.
254 "David King et al. v. Sylvia Mathews Burwell et al." Case No. 14-114 (SCOTUS 2015), Brief for the Respondents in Opposition, p. 12.
255 Ibid.
256 "King et al. v. Burwell, Secretary of Health and Human Services, et al" No. 14-114 (U.S. June 25, 2015), Slip Opinion, p. 21.
257 "King et al. v. Burwell, Secretary of Health and Human Services, et al" No. 14-114 (U.S. June 25, 2015), Slip Opinion, p. 8.
258 "King et al. v. Burwell, Secretary of Health and Human Services, et al" No. 14-114 (U.S. June 25, 2015), Slip Opinion, p. 8.
259 "King et al. v. Burwell, Secretary of Health and Human Services, et al" No. 14-114 (U.S. June 25, 2015), Slip Opinion, p. 8.
260 Ibid.
261 "Health Insurance Marketplace: Summary Enrollment Report for the Initial Annual Open Enrollment Period" Office of the Assistant Secretary for Planning and Evaluation, U.S. Department of Health and Human Services, June 18, 2014, http://aspe.hhs.gov/health/reports/2014/MarketPlaceEnrollment/Apr2014/ib_2014Apr_enrollment.pdf (Accessed 3/18/2015), p. 19.

people in 2016.[262] Furthermore, the tax credit in question accounts for an average 76 percent of the beneficiary's premium.[263] This indicates that, without the use of tax credits, a great number of people would be unable to afford health insurance. Accordingly, a SCOTUS decision in favor of the petitioners would have crippled the ACA's ability to provide coverage to health insurance to many Americans.

In addition, a SCOTUS decision in favor of the petitioners may have destabilized state health insurance markets. Such a decision may have deprived the ACA of the ability to compel individuals to purchase health insurance in states that did not provide their own Exchange, while insurers would still be required to offer health insurance to an increased number of individuals.[264] In such a situation, SCOTUS Justice Sonia Sotomayor described a "death spiral," wherein fewer healthy people would purchase health insurance, but sick people still would.[265] This would drive up the average cost of a health insurance plan, a cost that payors would pass on to consumers in the form of higher premiums. Higher prices would force more healthy consumers out of the market for health insurance, which would in turn drive the average cost of an insurance plan higher, which would once again raise premiums.[266] In preparation for such an outcome, several states proposed legislation to establish their own Exchanges, in an attempt to avoid significant damage to their health insurance markets.[267]

It is important to note that the majority opinion indicated that the hazards described above influenced the SCOTUS' conclusion. On June 25, 2015, the SCOTUS announced its decision to uphold the legality of health insurance subsidies for individuals participating in federally-run insurance exchanges.[268] In a 6 to 3 landmark decision, with the majority opinion written by Chief Justice Roberts, the Court upheld the federal government's interpretation of the ACA, allowing the IRS to issue tax credits, or subsidies, to participants who purchase insurance on federally-funded and run exchanges.[269] The SCOTUS concluded that the text of the statute was ambiguous, and thus relied on the *"…broader structure…"* of the law in order to make a decision.[270] In the majority opinion, Chief Justice Roberts stated, "*Congress passed the Affordable Care Act to improve health insurance markets, not to destroy them. If at all possible, we must interpret the Act in a way that is consistent with the former, and avoids the latter.*

262 "Map: How Many Amerians Could Lose Subisdies If the Supreme Court Rules for the Plaintiffs in King vs. Burwell?" The Henry J. Kaiser Family Foundation, http://kff.org/interactive/king-v-burwell/?utm_campaign=KFF%3A+Drew%27s+Columns&utm_source=hs_email&utm_medium=email&utm_content=14964169&_hsenc=p2ANqtz-_KtyDmOogfZF7c-bHazTuM0t4hvIVsQgN7eRgC_rqK3dYZjOZibCcr_T0lUVgbt2Q0rRnhlEAcRXpPnL9MhXll6QfVEA&_hsmi=14964169 (Accessed 3/18/2015).

263 "Premium Affordability, Competition, and Choice in the Health Insurance Marketplace, 2014" By Amy Burke et al., Office of the Assistant Secretary for Planning and Evaluation, U.S. Department of Health and Human Services, June 18, 2014, http://aspe.hhs.gov/health/reports/2014/premiums/2014mktplaceprembrf.pdf (Accessed 3/18/2015), p. 2.

264 "David King et al. v. Sylvia Mathews Burwell et al." Case No. 14-114 (SCOTUS 2015), Oral Argument, p. 15. Discussed in the Impact on Insurers section above.

265 "David King et al. v. Sylvia Mathews Burwell et al." Case No. 14-114 (SCOTUS 2015), Oral Argument, p. 15; "Will concern for states' rights win out in subsidies battle? Today's argument in Plain English" By Amy Howe, SCOTUSblog, March 4, 2015, http://www.scotusblog.com/2015/03/will-concern-for-states-rights-win-out-in-subsidies-battle-todays-argument-in-plain-english/ (Accessed 3/18/2015).

266 Ibid.

267 "King v. Burwell Obamacare Case Makes States Consider Creating Exchanges If Subsidies Are Struck Down" by Elizabeth Whitman, International Business Times, March 4, 2015, http://www.ibtimes.com/king-v-burwell-obamacare-case-makes-states-consider-creating-exchanges-if-subsidies-1834820 (Accessed 3/25/2015).

268 "King et al. v. Burwell, Secretary of Health and Human Services, et al" No. 14-114 (U.S. June 25, 2015), Slip Opinion, p. 4, 21.

269 "King et al. v. Burwell, Secretary of Health and Human Services, et al" No. 14-114 (U.S. June 25, 2015), Slip Opinion, p. 4, 21.

270 "King et al. v. Burwell, Secretary of Health and Human Services, et al" No. 14-114 (U.S. June 25, 2015), Slip Opinion, p. 15.

Section 36B can fairly be read consistent with what we see as Congress's plan, and that is the reading we adopt."[271]

Although the landmark decision in *King v. Burwell* preserved the ACA for a time, supporters of the law should not assume that the ACA is safe from further tests. As of June 2015, dozens of lawsuits have been filed challenging various aspects of the law, many of which target the ACA's rules regarding coverage of contraceptives.[272] Another lawsuit, filed by Republicans in the House of Representatives, claims that the ACA violates the House's constitutional power of appropriations.[273] These challenges illustrate the reality that the ACA will likely face opposition again in the future.

CONCLUSION

Some feel that the passage of HR 3590 and HR 4872 is one of the most important fundamental changes to federal healthcare policy and, on a similar scale, to the implementation of the Medicare and Medicaid programs.[274] Analyses and published opinion regarding the necessity of healthcare reform to institute effective cost-containment measures on healthcare expenditures have been growing in number, lending more weight to proponents of reform measures.[275] However, the successful implementation and potential impact of the new provisions detailed in this legislation depends largely on the outcomes of key judicial cases, as well as continued political, financial, and public support of federal, state, and individual stakeholders during the next few years. Additionally, without a permanent fix or reconciliation of growing Medicare expenditures and the SGR formula, problems regarding physician reimbursement and cost containment will continue to plague the U.S. healthcare industry, indirectly fueling problems, such as those related to access to care, the competitive healthcare environment, and the continued attack on niche providers. As evidenced by the debate and wide-ranging concerns and opinions regarding healthcare reform and, specifically, the provisions contained within the 2010 reform legislation, the public and political fight regarding the U.S. healthcare delivery system reform may be far from over.

Young physicians, who are plagued by medical school debt, are seeking a more comfortable lifestyle and are opting out of private, independent practices and pursuing salaried employment in hospitals and health systems. This trend has made it increasingly difficult for older independent practitioners to recruit junior partners, a struggle which, paired with the burden of rising costs and downshifting reimbursement, has led many physician-owners to sell their practices to hospitals and enter into salaried employment arrangements.

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271 "King et al. v. Burwell, Secretary of Health and Human Services, et al" No. 14-114 (U.S. June 25, 2015), Slip Opinion, p. 21.

272 "Legal Challenges Remain for Health Law" By Robert Pear, The New York Times, June 26, 2015, http://www.nytimes.com/2015/06/27/us/legal-challenges-remain-for-health-law.html?_r=0 (Accessed 7/7/2015).

273 "Legal Challenges Remain for Health Law" By Robert Pear, The New York Times, June 26, 2015, http://www.nytimes.com/2015/06/27/us/legal-challenges-remain-for-health-law.html?_r=0 (Accessed 7/7/2015).

274 "Historic Passage - Reform at Last" By John K. Iglehart, New England Journal of Medicine, March 24, 2010, http://healthcarereform.nejm.org/?p=3219&query=TOC (Accessed 3/24/2010).

275 Selected contrasting 2010 studies regarding healthcare reform and cost containment: "Health Reform Essential for Reducing Deficit and Slowing Health Care Costs" By Paul N. Van de Water, Center on Budget and Policy Priorities, February 3, 2010, p. 1; "Will Health Reform Slow Cost Growth" By John Sheils, The Lewin Group, March 26, 2010.

At the same time, the legislative and regulatory agenda at both federal and state levels to limit physician ownership of or investment in ASTC revenue stream enterprises has restricted physicians in private practice to receiving only professional fee component revenues. This has been viewed by some as a circumstance akin to relegating physicians to the status of *sharecroppers* or *hired help*, compelling many physicians to acquiesce to an untenable profitability squeeze and accept employee status under the substantial control of hospital systems or large corporate players.

Overall, this shift from small, physician- or provider-owned, independent private practices to captive practices within larger integrated health systems may also be viewed as the *corporatization* of healthcare professional practices, which may result in a weakening of the independent physician or provider-patient relationship, a characteristic of the *cottage industry* healthcare delivery system of old.[276] As discussed in this *Guide*, the current healthcare environment is one of the most dramatic and challenging in U.S. history, as indicated by recent efforts at regulatory and reimbursement reform, as well as the increasing change and complexity of the reimbursement, regulatory, competitive, and technological pillars of healthcare.[277] Given this trend in the delivery of care by professional practices, the days of the cottage industry of medicine may be coming to end, thus fulfilling the statement: "Marcus Welby[278] is dead!"

Healthcare reform is driven by complex, polar, and potentially conflicting market factors, including increased spending; a growing and graying demographic; workforce shortages and inefficiencies; problematic chronic and acute health indicators; and shortcomings in the delivery of efficient, quality care. The chapters in this *Guide* detail these issues, their implications, and the 2010 reform initiatives proposed to delicately counterbalance the U.S. healthcare delivery system on the nation's scale of justice. With increased regulatory scrutiny related to Stark and antitrust laws, the complete upheaval of the reimbursement landscape from new insurance industry rules and changing Medicare and Medicaid payments, the changing competitive environment of various sectors of the healthcare industry, and the rapid advance of technological developments, the 2010 healthcare reform has set the stage for a tumultuous and uncertain future for advisors in this era of reform. This book has addressed each of these very important aspects of reimbursement, regulatory, competition, and technology that are now part of an ever changing and increasingly unpredictable landscape of new provider configurations, tactics, and strategies, particularly in light of the 2010 healthcare reform legislation.

With the passage of healthcare reform, it is vital for providers to maintain an applied understanding of healthcare payment sources (for example, Medicare, Medicaid, State Children's Health Insurance Program, etc.), revenue and billing procedures (for example, the resource-based relative value scale payment system, relative value units and their components, Current Procedural Terminology codes, etc.), payment plans (for example, FFS plans, performance-based

276 "More Doctors Giving Up Private Practices" By Gardiner Harris, New York Times, March 25, 2010, http://www.nytimes.com/2010/03/26/health/policy/26docs.html (Accessed 4/12/2010); "The Social Transformation of American Medicine" By Paul Starr, New York, NY: Basic Books Inc., 1982, p. ix.

277 "Top 10 challenges facing physicians in 2014" by Jeffrey Bendix et al., Medical Economics, December 25, 2013, http://medicaleconomics.modernmedicine.com/medical-economics/content/tags/affordable-care-act/top-10-challenges-facing-physicians-2014 (Accessed 3/24/2015).

278 Marcus Welby was the main character in the television show, Marcus Welby, M.D, portrayed by Robert Young between 1969 and 1976, who portrayed Dr. Welby as an idealized version of the quintessentially altruistic, kindly, and unfailingly non-corporate family physician. "Marcus Welby, M.D." Internet Movie Database, http://www.imdb.com/title/tt0063927/?ref_=ttep_ep_tt (Accessed 7/9/2015).

payment plans, and consumer driven health plans), and the new rules related to overall insurance industry practices. Chapter 2, *Reimbursement Environment*, provides an overview of current and future trends in healthcare reimbursement.

The U.S. healthcare industry is governed by a network of ever-changing state and federal regulations relating to both physician and nonphysician professionals and is facing a completely new landscape of federal regulations in light of the 2010 healthcare reform, especially with increased scrutiny of fraud and abuse violations. Chapter 3, *Regulatory Environment*, contains a detailed overview of the general provisions that apply to the various practitioners and providers in the healthcare industry.

Changes in the healthcare competitive market may be attributed to 2010 healthcare reform, which attempts to address access and quality issues with individual insurance mandates and extensive quality requirements. These issues, and numerous others implicated by healthcare reform, shape the unique and dynamic healthcare competitive environment. Chapter 4, *Impact of Competitive Forces*, examines these issues in further detail within the context of Porter's five forces of competition.

Finally, advancements in medical technology have helped to revolutionize medicine as we know it, and they also have been significant factors in the passage of the 2010 healthcare reform legislation. The future of healthcare may well depend on a compromise between the advancement of medical technological capabilities and the cost of supporting those technologies that allows practitioners to provide the best quality care possible, a central issue in the 2010 healthcare reform legislation. Chapter 5, *Technology Development*, contains a discussion of the impact of technology on healthcare practices.

A multitude of unresolved issues remain related to the impact of these initial healthcare reform initiatives. In order to survive these dynamic changes, as during all times of significant upheaval and change, providers (both small and large) will need to seek the guidance of their professional advisors and informed managers, and consultants will need to stay knowledgeable of the changing aspects of the U.S. healthcare delivery system in an era of reform. This *Guide* was written to assist these professional advisors in meeting that objective.

Glossary

Accreditation: A process in which private organizations assess participating institutions and programs and issue accreditation certificates to those that meet their requirements. Ensuring the quality and safety of services is the focus of most accreditation standards; however, many also include documentation and other requirements.

Adverse Drug Effect (ADE): An injury caused by drugs, typically in the form of an allergic reaction or adverse physiological responses to a certain combination of medications. Preventable ADEs are injuries that are caused by human error.

Alert Fatigue: A CPOE error caused by a combination of critical medical alerts and a high volume of marginally medically consequential alerts.

Allopathic Medicine: "A method of healing founded on a scientific basis."

Ambulatory Surgery Center: A Medicare-certified healthcare facility that exclusively provides surgical services to patients not requiring an overnight stay.

Antitrust: A body of law charged with combating anticompetitive behavior that would impair the ability of free markets to function properly. Antitrust involves the regulation of mergers and acquisitions, as well as scrutiny of behavior between competitors which may restrain trade.

Biologics: Therapeutic products that are developed using living sources; examples of biologics include: vaccines, blood and blood products, and allergenic extracts and tissues.

Biopharmaceuticals: Drugs and biologics that treat an organism through the genetic manipulation of foreign DNA.

Biosimilar Production: Redevelopment of new generation biologics.

BlueCross/BlueShield: BlueCross provides beneficiaries with health insurance to cover hospital expenses, while BlueShield provides insurance to cover expenses associated with physician services. Together, they form BlueCross BlueShield, and the BlueCross Blue Shield Association (works to coordinate the nationwide plans by establishing standards for new plans and programs; assisting local plans with enrollment activities, national advertising, public education, professional relations, and statistical and research activities; and serving as the primary contractor for processing Medicare hospital, hospice, and home health claims.

Brachytherapy: Allows for treatment at higher doses of radiation to treat a smaller area in a shorter time by placing radiopharmaceuticals directly inside or next to the tumor. Brachytherapy can be temporary or permanent, with variable administration rates and doses.

Bundling: A form of reimbursement that combines institutional and professional charges into a single payment, including all staff for preoperative and postoperative care. Bundled payment schemes generally include outlier provisions for cases that become catastrophic.

Capitation: A pre-paid reimbursement method that pays a provider a set price for providing medical services to a defined population for a defined set of services, regardless of service utilization. Providers must manage the financial risk of providing adequate care by calculating the expected volume of referrals, the average cost, and their ability to control utilization.

Charge Capture: A process that entails the transfer of the provider's coding and documentation to the actual bill. Providers are tasked with recording the appropriate procedure and diagnosis codes on an encounter form, and the business staff is responsible for ensuring that the encounter form is accurate and then using it to bill patients and third-party insurers.

Cherry-pick or Cream-skim: To pick the best of a group and leaving the least desirable portion; for healthcare, choosing the most profitable patients and leaving the rest.

Children's Health Insurance Program: A state-federal partnership that provides assistance to children and pregnant women in families whose income is above the threshold for Medicaid. It was formerly known as the State Children's Health Insurance Program.

Chiropractic: A form of alternative medicine originating from the belief that vertebral aligning would serve to remedy diseases.

Civil Monetary Penalty: Financial penalties levied against parties found guilty of violating the antikickback statute or submitting false claims for government reimbursement.

Civilian Health and Medical Program of the Department of Veteran Affairs: The Department of Veterans Affairs' healthcare program for the spouses and children of veterans who meet certain eligibility requirements.

Civilian Health and Medical Program of the Uniformed Services: The former name for TRICARE.

Clinical Decision Support (CDS): A technology that provides clinicians with real-time feedback about a wide-range of diagnostic and treatment related information as they are entering electronic orders.

Commercial Reasonableness: The Department of Health and Human Services has interpreted "commercially reasonable" to mean that an arrangement appears to be "a sensible, prudent business agreement, from the perspective of the particular parties involved, even in the absence of any potential referrals." The Stark II Phase II commentary also suggests that "an arrangement will be considered 'commercially reasonable' in the absence of referrals if the arrangement would make commercial sense if entered into by a reasonable entity of similar type and size and a reasonable physician of similar scope and specialty, even if there were no potential DHS referrals."

Computerized Physician Order Entry (CPOE): A computer system that permits clinical providers to electronically order laboratory, pharmacy, and radiology services.

Corpus: A collection of works written by Hippocrates and his pupils. These works discuss specialties and pathologies, the practice of medicine, and medical ethics.

Cream Skimming: In healthcare, the purposeful targeting of patients that are considered the most profitable customers for a given provider, for example, specialty hospitals have been accused of cream-skimming more profitable services, such as cardiac and orthopedic care, from general hospitals, who serve a broader patient base.

Customary Prevailing and Reasonable: The historically implemented methodology that based Medicare-allowed amounts on past payments for the service.

Degrees of Freedom: The number of possible rotations that can be made by a robotic "hand."

Designated Health Service: One of eleven categories of healthcare entities subject to the Stark law:

1. Clinical lab services
2. Physical therapy, occupational therapy, and speech-language pathology services
3. Radiology and other imaging services (including nuclear medicine as of 01/01/07)
4. Radiation therapy services and supplies
5. Durable medical equipment and supplies
6. Prosthetics, orthotics and prosthetic devices and supplies
7. Home health services
8. Outpatient prescription drugs
9. Inpatient hospital services
10. Outpatient hospital services
11. Parental and enteral nutrients, associated equipment, and supplies

Diagnostic Related Groups: A classification system of patients by surgical procedure or diagnosis into major diagnostic categories for the purpose of Medicare reimbursement of hospitalization costs.

Disproportionate Share Hospital (DSH) Payments: A form of additional reimbursement under Medicaid for hospitals that care for a large number of Medicaid and uninsured patients. DSH payments are allotments from the federal government that augment basic Medicaid reimbursement, and under federal law, states are required to supplement disproportionate share hospitals in order to receive this additional Medicaid funding.

Eclectic Medicine: A school of medicine that uses herbal medicines and remedies to treat pathologic conditions; among less threatening therapies, eclectics were branded for their use of arsenic and mercury treatments.

Economic Demand: "Relationship between the price of a healthcare item or service and the quantity demanded."

Economic Supply: "Relationship between the price of a healthcare good, product, or service and the quantity provided my medical sellers."

Electronic Health Record (EHR): A longitudinal electronic record of patient health information generated and maintained within an institution containing information entered by a treating physician or clinician.

Electronic Health Record (EHR): Electronically maintained patient health information, such as patient demographics, notes, medications, medical history, laboratory date, or medical reports, that is generated by one or more encounters in any care delivery setting.

Enteral: Into the digestive system.

Epidural: Into the membranes surrounding the spinal cord.

External Beam Radiation Therapy (EBT): A procedure that involves the administration of high-energy x-ray beams to kill cancer cells and treat tumors. Often, some x-ray, ultrasound, or computerized tomography imaging is used prior to the delivery to insure that the path of the beam will align with the target area.

Fair Market Value (FMV): As defined by Stark II Phase I for the purpose of scrutinizing transactions between healthcare professionals, FMV is "the value in arm's-length transactions, consistent with general market value," without taking into account any ability between parties to refer business to each other.

Fee Schedule: A payment system under which the fees for procedures are explicitly laid out and the physician agrees to accept those fees as full payment unless the discounted charges are less than the fee schedule in which case the plan pays the lesser of the two.

Fee-for-Service: A payment policy under which providers receive a fee for each service provided (for example, an office visit, test, procedure, etc.).

Financial Relationship: The Stark law defines financial relationships as an ownership or investment interest in the DHS entity or a compensation arrangement between the DHS entity and the referring physician or a member of his immediate family. The law further describes "ownership/investment interest" to include debt, equity or other means. The term also includes an interest in an entity that holds an ownership or investment interest in any entity providing DHS services.

Follow-on Biologics: New generation biologics.

Gainsharing: An arrangement "under which a hospital gives physicians a share of the reduction in the hospital's costs (that is, the hospital's cost savings) attributable in part to the physician's efforts."

Gamma Knife: Employs computerized robotic technology to move patients at submillimeter increments during treatment.

Gene Therapy: A molecular means of cancer treatment.

Genomics: The evaluation of the hereditary information provided by an organism's DNA and the application of research findings to the fields of genetic engineering and enhancement, cloning, stem cell research, and eugenics.

Health Maintenance Organization (HMO): The entity responsible for providing, or arranging for the provision of, healthcare services (including preventative care) for plan enrollees by way of contractual arrangements with providers. HMO enrollees must receive all of their care from the plan's participating providers except for care provided in emergency situations or in instances in which the plan offers a point of service option.

Health Maintenance Organization: Any organization that, through an organized system of healthcare, provides or ensures the delivery of an agreed-upon set of comprehensive health maintenance and treatment services for an enrolled group of persons commonly under a capitation or prepaid fixed sum arrangement.

Health Savings Accounts: Special accounts into which employers and employees both contribute, and from which the employee can draw funds to pay for health services. If the employer contributes, the value of those contributions is not taxable to the employee. Similarly, if the employee makes contributions, they count as "above-the-line" deductions.

Homeopathic Medicine: A school of medicine that involves the assessment of overall health and environment, not just symptoms.

Independent Practice Association: An association of independent physicians who maintain their own private practices but have joined together to enter into an agreement to treat the plan's enrollees.

Industrial Hygiene: "The science of keeping people safe at work and in their communities. Industrial hygienists (IHs) are professionals dedicated to the health and well-being of workers. Originally industrial hygienists worked primarily in factories and other industrial settings but as our society has changed, so has the definition of industrial hygiene. Today, IHs can be found in almost every type of work setting. Industrial hygienists also use the term OEHS or occupational and environmental health and safety to refer to the work that they do."

Intensity Modulated Radiation Therapy (IMRT): An advanced form of radiation therapy using three-dimensional imaging and treatment delivery.

International Classification of Diseases, Ninth Revision (ICD-9): A system that has codes that supply the payor with information regarding both the patient diagnosis and the procedures performed in treating the diagnosis. The Health Insurance Portability and Accountability Act (HIPAA) requires all healthcare providers to use the ICD-9 codes when reporting diagnosis information to payors. In addition, HIPAA requires that hospitals use the ICD-9 procedural codes when reporting information to payors detailing the treatment of hospital inpatients.

International Classification of Diseases, Tenth Revision (ICD-10): In early 2009, the United States Department of Health and Human Services announced a final rule that called for the replacement of the current ICD-9 code set used to report healthcare diagnoses and procedures with the ICD-10 code set by October 1, 2013. The adoption of the new system offers several benefits, including the facilitation of quality data reporting, support for pay for performance payment methodologies, improved billing accuracy, and allowances for international comparison of the incidence and spread of disease.

Intravenous: Through the bloodstream.

Kickback: Remuneration received in return for referring an individual to a person for the furnishing of any item or service for which payment may be made under a federal health care program or remuneration received in return for purchasing, leasing, ordering, or arranging for or recommending purchasing, leasing, or ordering any good, facility, service, or item for which payment may be made under a federal health care program.

Laparoscopy: Minimally invasive surgery that involves the insertion of a slender, tubular endoscope through the abdomen wall. A laparoscopy involves the use of surgical instruments that the practitioner controls and fiber optic technology for visual navigation.

Legal Medicine: Referred to as "medical jurisprudence," involves the implementation of medical expertise for legal and judicial purposes.

Licensure: A set of minimum qualifications an individual must possess in order to practice a given profession. In healthcare, almost all practitioners are required to be licensed, and there exist state statutes in place to penalize those who practice without proper licensure.

Linear Accelerator (LINAC): Delivers uniform doses of high-energy x-rays to the localized area of the patient's tumor although sparing the surrounding normal tissue. It is the device most commonly used for EBT treatments for patients with cancer.

Lockboxes: Instead of handling the collection and processing of payments themselves, providers may decide to use a lockbox service. For a fee, lockbox services open a provider's mail, collect payments, and deposit the money into the provider's account.

Managed Care: Plans that integrate the financing (that is, insurance) and provision of health services under the administration of one organization in an effort to contain costs.

Medicaid: "The expanded assistance to the states for medical care."

Medicaid: A means-tested, state administered health insurance program for individuals below certain income thresholds predetermined by the state in which they reside. The federal government establishes coverage requirement guidelines for the categorically needy (for example, children, pregnant women), medically needy (for example, individuals with income above the threshold but who have a large amount of medical bills), and special groups. Although the federal government determines the medical services that will be covered and paid for by the federal portion of the program, Medicaid programs vary widely from state to state as state governments are free to add additional services or expand eligibility to additional groups.

Medical Imaging: A "non-invasive process used to obtain pictures of the internal anatomy or function of the anatomy using one of many different types of imaging equipment and media for creating the image."

Medicare Part A: "The Democratic plan for a compulsory hospital insurance program under Social Security."

Medicare Part B: "The revised Republican program of government-subsidized voluntary insurance to cover physicians' bills."

Medicare: An entitlement program available to individuals over the age of sixty-five and individuals with end-stage renal disease. Medicare is divided into four parts: (1) Part A, which covers inpatient hospital care; (2) Part B, which covers outpatient visits; (3) Part C, which people can choose as a managed care replacement of Part A and B; and (4) Part D, which covers prescription drug benefits.

Medicare: Passed by the United States Congress in 1964 and signed by President Lyndon B. Johnson on July 30, 1965; comprised of three layers: Part A, Part B, and Medicaid.

Monopsony: "A single purchaser in a healthcare market without rivals."

National Committee on Quality Assurance (NCQA): A nonprofit organization that works to improve the quality of healthcare through the accreditation of managed care plans. NCQA performs this duty, much like other accrediting bodies, through the setting of standards and collection of outcome and performance data.

Naturopathic Medicine: A school of medicine that utilizes natural elements (such as water, heat, and massage) in its therapies.

Niche Providers: Providers who focus on a section or group of buyers, a segment of a product line, or a specific area of a geographic market. What specific area niche providers focus on changes based on who is creating the definition.

NightHawk Radiology Services: The nation's first nighthawk company.

Nonparenteral Drug Delivery: A means of drug delivery in which the distribution is through a means other than a digestive one.

Nonparticipating Provider: Providers who have not agreed to accept the Medicare reimbursement amount for every claim. Yet, nonparticipating providers are allowed to accept Medicare assignment on a claim-by-claim basis, if they agree certain conditions. However, it should be noted that even though they have not accepted Medicare's fee as payment in full, nonparticipating providers are subject to a "limiting charge," that dictates what they may charge Medicare beneficiaries for covered services.

Nurse Licensure Compact: An interstate license for nurses created in 2000 by the National Council of State Boards of Nursing.

Osteopathic: A school of medicine that involves the assessment of overall health and environment, not just symptoms.

Participating Provider: A physician who has agreed to accept the reimbursement amount set by the Medicare Fee Schedule as payment in full for every claim. The physician's office may bill the patient for its share of the co-insurance and its deductible, but it cannot balance bill the patient, (that is, attempt to collect the difference between its usual fee and Medicare's lower allowed charge).

Pasteurization: Widely used in the preservation of perishable products, pasteurization involves the strategic application of heat to kill microbes without injuring the quality of its media (for example, wine, beer, etc.).

Personalized Medicine: The fusion of molecular diagnostics and therapeutic measures for specialized screening and treatment plans.

Physician-Owned Facilities: Healthcare entities in which their practicing physicians also have ownership investment in the facility, supplementing professional income with revenue from facility services. Many physician-owned facilities include limited-service facilities, such as surgical and specialty hospitals.

Physiotherapy: A term used to describe various kinds of medical therapy, including hydrotherapy, massage, mechanotherapy, electrotherapy, and heat therapy.

Picture Archives and Communications Systems (PACS): Used to connect digital x-rays and other imaging modalities. Has become a must for efficient imaging services, as it provides improved access to images with reduced delays.

Point-of-Care Technology: New technologies that help to manage patient treatment plans.

Point-of-Service Plans (POS): Plans that combine many of the elements of HMOs and PPOs. POS plans are usually an addition to an HMO product that allows members the benefit of seeking care from non-participating providers. As with an HMO, when members seek care from in-network providers they typically pay no deductible or coinsurance. However, similar to a PPO, members are free to seek services outside the network subject to higher cost sharing in the form of deductibles and coinsurance.

Preferred Provider Organization (PPO): "A health care delivery system where providers contract with the PPO at various reimbursement levels in return for patient steerage into their practices and/or timely payment."

Preferred Provider Organization (PPO): A hybrid of an HMO and traditional health insurance plan. It is a managed care plan that allows members to choose from an array of healthcare providers who have contracted with the plan to provide services on a discounted basis.

Prospective Payment System: The federal medical system that reimburses hospitals for Medicare Part A services based on diagnosis related groups.

Protected Health Information (PHI): Individually identifiable health information that is transmitted by, or maintained in, electronic media or any other form or medium. This information must relate to (1) the past, present, or future physical or mental health, or condition of an individual; (2) provision of healthcare to an individual; or (3) payment for the provision of healthcare to an individual.

Public Health: An area of healthcare centered around "community health point of view," that considers "the means of defen(s)e against disease a social problem."

Purple Pill: A treatment for bleeding ulcer patients, with a proton-pump inhibitor like Prilosec (omeprazole), that stops bleeding prior to endoscopy.

Qui Tam Action: Also known as a "whistleblower" suit, this action is filed by an individual who alleges that a particular entity has submitted false claims for reimbursement to the government in violation of the False Claims Act, including violations of the Stark law and the antikickback statute. Qui tam actions may be brought by employees, former employees, competitors, subcontractors, state and local governments, current and former federal employees, public interest groups, corporations, and other private organizations.

Radiation Therapies: Procedures that use high energy light beams or charged particles to stunt tumor cell proliferation thereby treating cancer.

Reciprocal (Limited) Licensure: Provides an interstate license for use with telemedicine practitioners applied for through a simple application process and reduced licensing fees. This license is solely used for telemedicine and may not be used to physically practice in another state.

Reparative Medicine: Therapies that heal the body's natural tissue.

Resource Based Relative Value System: A relative value scale that is based on the necessary resources used to perform a medical service.

Revenue Cycle: The process by which a provider practice schedules patients, diagnoses conditions, documents diagnoses, bills payors, and collects billable charges from the payor and the patient to recover revenue for the services provided.

Self-Insurance: Self-insuring employers make a conscious choice to undertake the risks associated with the cost of healthcare and set aside money to pay these costs as they arise. Often, a self-insurer will hire a commercial insurer or third-party administrator to run its medical benefits program and adjudicate claims.

Self-Referral: The practice of referring a patient for a designated health service (DHS) to an entity in which the referring physician (or a member of his immediate family) has an ownership or investment interest.

Stem Cells: Unspecialized cells capable of (1) renewing themselves through cell division, sometimes after long periods of inactivity and (2) specializing to a certain type of tissue or organ under the proper conditions.

Stereotactic Radiosurgery: A highly precise procedure involving the single, high-dose delivery of precisely-targeted gamma-ray or x-ray beams that is used in different parts of the body, but most frequently to treat brain tumors.

Store and Forward: The transfer of digital images between locations, most commonly seen in teleradiology and telepathology.

Studia Generalia: Universities in the Roman Empire at which law, theology, and philosophy were taught in addition to medicine.

Subcutaneous: Under the skin.

Telehealth: Closely related to telemedicine and is used to describe the broader definition of remote healthcare that does not always involve clinical services, although the two terms are often used interchangeably.

Telemedicine: The transfer of electronic medical data (high resolution images, sounds, live video, and patient records) from one location to another in order to enhance the quality and efficiency of patient comfort and care.

Teleradiology: Electronic transfer and storage of electronic imaging data.

The Joint Commission: An independent, nonprofit organization responsible for the certification and accreditation of health care organizations across the United States.

The National Center for Human Genome Research Institute (NCHGRI): Comprised of more than fifty researchers that are each dedicated to specific facets of genetic and genomic research and contribute accordingly to one of seven branches of the NCHGRI.

Treble Damages: Damages equal to three times the amount of the illegal remuneration in violation of the antikickback statute.

TRICARE: The Department of Defense's healthcare program for active duty military personnel; members of the National Guard and Reserves; retirees, their dependents, and survivors; and certain former spouses. The program uses military healthcare as the main provider of services, supplemented by civilian healthcare providers, facilities, pharmacies, and suppliers. TRICARE covers approximately 9.4 million beneficiaries worldwide through a variety of plans.

Two-Way Interactive Television: Used telemedicine for face-to-face consultations.

Upcoding: Inflating bills by using diagnosis billing codes that suggest a more expensive illness or treatment.

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