2011

Adviser's guide to health care: Volume 1, An Era of Reform

Robert James Cimasi

An Era of Reform 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 reform bill takeaways that affect your clients or your business.

In addition, *An Era of Reform* 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 at length, in terms of four pillars:

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

An Era of Reform is an essential tool to enable you to provide specialized advice to your clients or to your organization in the wake of recent 2010 legislation and in the years to come.

The Adviser's Guide to Healthcare is a comprehensive resource and reference guide for professionals seeking a working knowledge of the factors involved in consulting with and valuing healthcare practices. Developed by one of the foremost consultants in the healthcare industry, Robert James Cimasi, this *Guide* is founded on his seasoned knowledge and industry experience. This 18-chapter, three book 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 three books that comprise this set:

An Era of Reform: Provides in-depth discussions of the four pillars and the landmark legislation that has contributed to the current healthcare environment.

Professional Practices: Introduces different models of emerging healthcare practices and details industry subspecialties in terms of the four pillars framework.

Consulting with Professional Practices: Covers consulting related to healthcare practices and practice valuation strategies.

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

ISBN 978-0-87051-909-3

9 780870 519093

091081

AICPA® American Institute of CPAs

aicpa.org | cpa2biz.com

THE ADVISER'S GUIDE TO HEALTHCARE

An Era of Reform

AICPA®

The Adviser's Guide to HEALTH CARE

An Era of Reform

Robert James Cimasi
MHA, ASA, CBA, AVA, CM&AA

AICPA®

The Adviser's Guide to HEALTH CARE

An Era of Reform

10783-356

Robert James Cimasi
MHA, ASA, CBA, AVA, CM&AA

AICPA®

Notice to Readers

The Adviser's Guide to Healthcare: An Era of Reform does not represent an official position of the American Institute of Certified Public Accountants, and it is distributed with the understanding that the author and publisher are not rendering, legal, accounting, or other professional services in the publication. This work offers a detailed treatment of basic characteristics related to various statutes and regulations that address topics within the healthcare professional practices industry. This book is intended to be an overview of the topics discussed within, and the author has made every attempt to verify the completeness and accuracy of the information herein. However, neither the author nor publisher can guarantee the applicability of the information found herein. If legal advice or other expert assistance is required, the services of a competent professional should be sought.

1 2 3 4 5 6 7 8 9 0 PIP 0 9 8 7 6 5 4 3 2 1

ISBN: 978-0-87051-909-3 (Book 1) ISBN: 978-0-87051-908-6 (3 Book Set)

Publisher: Amy M. Stainken
Developmental Editor: Andrew Grow
Project Manager: Amy Sykes
Cover Design Direction: Clay Porter
Interior Designer: David McCradden

Dedication

Dedicated to my wife

Laura M. Baumstark, MBA, CAE

Acknowledgements

The assistance and support of a number of my HEALTH CAPITAL CONSULTANTS (HCC) colleagues were instrumental to the development and publication of this *Guide*. HCC's Vice President, Anne P. Sharamitaro, Esq., was central to the development of this project, both in conducting and directing the research for this book and in coordinating the efforts of all those who contributed to the project.

Todd A. Zigrang, MBA, MHA, FACHE, senior vice president, who has excelled for more than fifteen years in representing HCC throughout numerous healthcare professional practice and other client engagements, greatly assisted in contributing to this work.

HCC Senior Research Manager, Rachel L. Seiler, contributed significantly to this book and was tireless in her efforts and consistently innovative and enthusiastic throughout the research and writing phases of the project.

Kathryn A. Young, Esq.; Stephanie E. Gwillim, Esq.; Tim Alexander, MLS; and other members of HCC's library and research staff, as well as members of HCC's consulting and administrative support team, were of great help.

Also, many thanks to our professional colleagues who served as reviewers and commentators of the various drafts of this work along the way, including: David W. Ortbals, MD, FACP; William J. Hartel, DMD; and Timothy A. Wingert, OD, each of whom reviewed various chapters, as well as Richard D. Thorsen, CPA/ABV, CMEA, CVA, for his comments and contributing the *Foreword* to this *Guide*.

Finally, many thanks to Andrew J. Grow, Manager—Developmental Editing Services, at the AICPA, who served as my editor on this project. He deserves significant credit for his long suffering patience and persistent support.

Foreword

Whether we have been providing professional consulting services for many years, as I have, or we are relative newcomers to the field of consulting services, the current state of the healthcare environment certainly can tend to make us all feel a bit bewildered. The ongoing technological, economic, and political changes that are happening require all of us to arm ourselves with the knowledge and skills necessary to address these changes. Bob Cimasi's new, comprehensive, reference work is an essential tool if we are to be able to provide useful specialized advice to our clients.

This *Guide*, containing 18 chapters of up-to-date specialized information concerning every aspect of healthcare Professional Practices, is a monumental collection of detailed, useful information for CPAs, Business Valuators, Attorneys, Financial Planners, Health Care Executives, Administrators, and even for Physicians and Surgeons. It covers the waterfront of the types of entities providing healthcare services with specific attention to each medical and dental specialty.

In examining this vast range of entities and professionals, this *Guide* does not confine its presentations to highlights only. Rather, it delves deeply and precisely into the finer points of problems and opportunities confronting each of the specialized healthcare professional practice entities. A recurring theme throughout the book is to consider the delivery of healthcare professional services within the context of what Bob Cimasi terms "the four pillars of the healthcare industry, i.e., *regulatory, reimbursement, competition*, and *technology*."

As a CPA, business appraiser, and consultant who has practiced for 56 years, I believe that this monumental book should be in the library of every CPA firm, business valuation firm, legal firm, financial planner, and consultant who hopes to continue to serve clients in the healthcare field competently in these rapidly changing times. As I have learned as the father of a long-time practicing critical-care internist and hospitalist, I believe that the book also is a must for the libraries of professional physicians, surgeons, dentists, and administrators who are on the every-day firing lines trying to survive the sea of change in their respective professions. And before closing, I want to say some words about the author, Bob Cimasi. I have known Bob for many years, first as a participant in professional seminars and conferences in which he has been a presenter, and later on a more direct professional and personal basis. Throughout these years, I have been impressed with both his technical knowledge, and even more importantly, the unselfish and tireless sharing of his time, talent, and accumulated knowledge with his professional colleagues in the accounting, business valuation, and consulting professions. There are few people in the world that I have known who are of his caliber! This *Guide* confirms again what many of us know. Bob Cimasi is truly one-of-a-kind dedicated professional whose writings are worth reading.

Richard D. Thorsen, CPA/ABV, CMEA, CVA
May 2010
Past Member, Board of Directors and Vice President of the American Institute of CPAs (AICPA)

Preface

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

I was born in 1950, the fourth child in our family, and the first born in a hospital—my older brothers and sisters having been delivered in my grandmother's bed. In the small, upstate New York farming community where I was raised, doctor house calls were not unusual. 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. When our neighbors developed musculoskeletal conditions from working on the farms or in small manufacturing plants and machine shops, they would 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 prefluorination, widespread incidence of juvenile tooth decay. This was a time in U.S. history when *Marcus Welby* 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 sixty year period since 1950, the U.S. population has doubled from just more than 150 million to an estimated 300 million in 2010,[1] and the average life expectancy has increased from approximately 68 years to 78 years.[2] 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 estimated 13.2 percent in 2010.[3] This demographic shift is expected to continue, with the proportion of Americans over 65 expected to reach 20 percent of the total population by 2050—an estimated 360 percent increase over a single century.[4]

This increased life expectancy, and the subsequent "graying" of the U.S. 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.[5]

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 sixty years also may have influenced the increased incidence and prevalence of disease. Although the urbanization of the United

1 "Current Population Reports," Series P-25, Nos. 311, 917, 1095, National Population Estimates, U.S. Department of Commerce, Economics and Statistics Administration, Bureau of the Census, April 11, 2000, http://www.census.gov/population/estimates/nation/popclockest.txt (accessed 03/26/2010); "Current Population Reports: Population Projections of the United States by Age, Sex, Race, and Hispanic Origin: 1995 to 2050," Series P25-1130, U.S. Department of Commerce, Economics and Statistics Administration, Bureau of the Census, 1996, p. 1. "Table 1. Projections of the Population and Components of Change for the United States: 2010 to 2050 (NP2008-T1)," by U.S. Department of Commerce, Economics and Statistics Administration, Bureau of the Census, Population Division, August 14, 2008.

2 "United States Life Tables, 2003," by the U.S. Department of Health and Human Services, Centers for Disease Control and Prevention, National Center for Health Statistics, National Vital Statistics Report, Volume 54, Number 14, (April 19, 2006), p. 34; "International Data Base," United States Census Bureau, March 19, 2010, http://www.census.gov/ipc/www/idb/country.php (accessed 03/26/2010).

3 "Chapter 2—Age and Sex Composition," in "Demographic Trends in the 20th Century: Census 2000 Special Reports," by Frank Hobbs and Nicole Stoops, U.S. Department of Commerce, Economics and Statistics Administration, United States Census 2000, November 2002, CENSR-4, p. 56; "Table 3: Projections of the Population by Age, Race, and Hispanic Origin for the United States: 1995–2050—Principal Alternative Series," in "Current Population Reports: Population Projections of the United States by Age, Sex, Race, and Hispanic Origin: 1995 to 2050," Series P25-1130, U.S. Department of Commerce, Economics and Statistics Administration, Bureau of the Census, 1996, p. 90.

4 *Ibid.*

5 "The Impact of the Aging Population on the Health Workforce in the United States," by the National Center for Health Workforce Analysis, Bureau of Health Professions Health Resources and Services Administration, December 2005, p. 10; "Health, United States, 2008, With Special Feature on the Health of Young Adults," U.S. Department of Health and Human Services, National Center for Disease Statistics, March 2009, http://www.cdc.gov/nchs/data/hus/hus08.pdf#120 (accessed 09/11/2009), p. 4.

States was already under way in 1950, this shift continued to reshape the population distribution, with the urban population increasing from 64 percent of the U.S. population in 1950, to almost 80 percent in 2010.[6]

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.[7] 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). 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 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 more than 17 percent in 2010.[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 than half 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 workforce, growing as a significant trend in the 1950s.[13] In response to the past and present surge in demand, the physician population has increased from 219,997 in 1950 to 954,224 in 2009, and the number of physicians per 100,000 individuals has increased from 142.2 to 316.4.

Despite these growing workforce trends, it is expected that, with a disproportionate number of physicians retiring, an inadequate supply medical graduates, and the expected continuing growth in demand, the present shortage in supply of physician manpower will continue to worsen.[14] As a result, there has

6 "Table 1. Urban and Rural population: 1900–1990," by the U.S. Department of Commerce, Economics and Statistics Administration, Bureau of the Census, October 1995, http://www.census.gov/population/censusdata/urpop0090.txt (accessed 03/26/2010); U.S. Census Bureau 2010 Census Planning Data Base, U.S. Department of Commerce, Economics and Statistics Administration, Bureau of the Census, 2010, http://www.census.gov/procur/www/2010communications /tract%20level%20pdb%20with%20census%202000%20data%2001-19-07.pdf (accessed 03/26/2010).

7 "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; "The Role of Services in the Modern U.S. Economy," by Douglas B. Cleveland, Office of Service Industries, January 1999.

8 *Ibid.*

9 *Ibid.*

10 "Health Care Expenditures in the OECD," by the National Bureau of Economic Research, 2006, http://www.nber.org/aginghealth/winter06/w11833.html (accessed 03/26/2010); .

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

12 "Chapter 6—Health Care Personnel," and "Chapter 7—Financing Healthcare" in "Health Care USA: Understanding its Organization and Delivery," by Harry A. Sultz and Kristina M. Young, Jones and Bartlett Publishers, Sixth Edition (2009), p.196, 234–235.

13 "Chapter 7—Financing Healthcare" in "Health Care USA: Understanding its Organization and Delivery," by Harry A. Sultz and Kristina M. Young, Jones and Bartlett Publishers, Sixth Edition (2009), p. 231.

14 "Physician Characteristics and Distribution in the US 2010 Edition" American Medical Association, 2010, p. 458; "Table 201—Total and Active Physicians (MDs) and Physician-to Population Ratios, Selected Years: 1950-2000," in "Health Resources Statistics, 1965," by the U.S. Department of Health, Education, and Welfare, National Center for Health Statistics, PHS Pub. No. 1509, 1966.

been a further increase in diversification of the healthcare workforce, comprised of more than 13 million individuals, with fewer than one million being physicians.[15] 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 professional practice enterprises currently account for $447 billion of a $2.26 trillion healthcare market (19.8 percent), recent efforts at regulatory and reimbursement reform suggest that healthcare professional practices may be facing an unprecedented dramatic transition.[16] 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. 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 pursing salaried employment by hospitals and health systems.

These trends have made it increasingly difficult for older independent practitioners to recruit junior partners, 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. 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.[17] Given these trends in healthcare professional practices, it may not be far-fetched to believe that "Marcus Welby is dead!" (see chapter 2 of *Professional Practices*).

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

15 *Ibid.*
16 "Plunkett's Health Care Industry Trends and Statistics 2008 (Summary)," By Jack W. Plunkett, Plunkett Research Ltd., 2007, p. 44.
17 "More Doctors Giving Up Private Practices," by Gardiner Harris, New York Times, March 25, 2010; "The Social Transformation of American Medicine," by Paul Starr, Basic Books Inc. 1982, p. ix.

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 three 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 first publication of this *Guide*, we earnestly solicit reader comments, criticisms, and suggestions for improvements in future editions.

Sincerely,

Robert James Cimasi, MHA, ASA, CBA, AVA, CM&AA
Health Capital Consultants
Saint Louis, Missouri
November, 2010

Table of Contents

About the Author

Robert James Cimasi, MHA, ASA, CBA, AVA, CM&AA

Robert James Cimasi is President of Health Capital Consultants (HCC), a nationally recognized healthcare financial and economic consulting firm. With more than twenty-five years of experience in serving healthcare clients in forty-nine states. Mr. Cimasi's professional focus is on the financial and economic aspects of healthcare organizations including the valuation of enterprises, assets, and services; litigation support and expert testimony; business intermediary and capital formation services for healthcare industry transactions; certificate-of-need; and other regulatory and policy planning consulting.

Mr. Cimasi holds a Masters in Health Administration from the University of Maryland, the Accredited Senior Appraiser (ASA) designation in Business Valuation, as well as the Certified Business Appraiser (CBA), Accredited Valuation Analyst (AVA), and the Certified Merger & Acquisition Advisor (CM&AA). He is a nationally known speaker on healthcare industry topics and has served as conference faculty or presenter for such organizations as the American Society of Appraisers, the American Institute of Certified Public Accountants, the Institute of Business Appraisers, the National Association of Certified Valuation Analysts, the American College of Healthcare Executives, the National Society of Certified Healthcare Business Consultants, Academy Health, Healthcare Financial Management Association, the American Association of Ambulatory Surgery Centers, Physician Hospitals of America, the Health Industry Group Purchasing Association, and the National Litigation Support Services Association, as well as numerous other national and state healthcare industry associations, professional societies, trade groups, companies, and organizations. He has been certified and has served as an expert witness on cases in numerous federal and state venues, and he has provided testimony before federal and state legislative committees. In 2006, Mr. Cimasi was honored with the prestigious Shannon Pratt Award in Business Valuation conferred by the Institute of Business Appraisers.

Mr. Cimasi is the author of *A Guide to Consulting Services for Emerging Healthcare Organizations* (John Wiley & Sons, 1999), *The Valuation of Healthcare Entities in a Changing Regulatory and Reimbursement Environment* (IBA Course 1011 text—1999), and *An Exciting Insight Into the Health Care Industry and Medical Practice Valuation* (AICPA course text 1997, rev. 2006). He has authored chapters on healthcare valuation in *The Handbook of Business Valuation* (John Wiley & Sons), *Valuing Professional Practices and Licenses: A Guide for the Matrimonial Practitioner, 3rd ed., 1999* (Aspen Law & Business), and *Valuing Specific Assets in Divorce* (Aspen Law & Business) and has been a contributor to *The Guide to Business Valuations* (Practitioners Publishing Company), *Physician's Managed Care Success Manual: Strategic Options, Alliances, and Contracting Issues* (Mosby), and numerous other chapters. He has written published articles in peer review journals, frequently presented research papers and case studies before national conferences, and is often quoted by healthcare industry professional publications and the general media. Mr. Cimasi's latest book, *The U.S. Healthcare Certificate of Need Sourcebook*, was published in 2005 by Beard Books.

Introduction

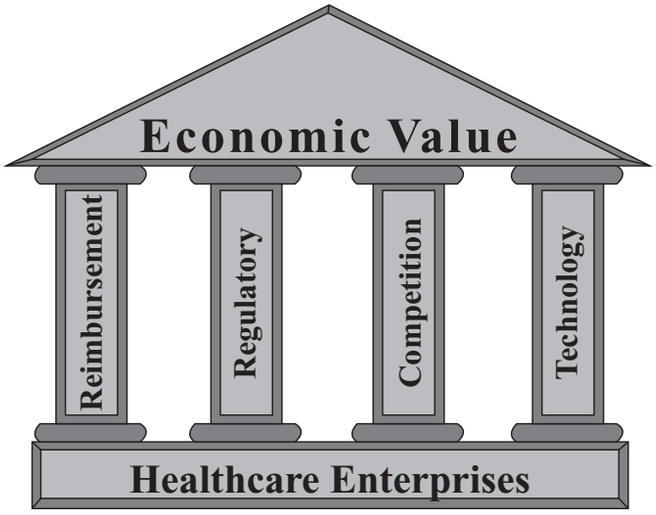
These papers, advocating a more active participation in public affairs by physicians than has been the custom in this country, are reprinted with the belief that such broader activity on the part of my colleagues will help to free the State from many present evils. A good doctor must be educated, honest, sensible and brave. Nothing more is needed in its citizens to make a state great.

John B. Roberts, 1908

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 Enterprises



Reimbursement

Chapter 2, *Reimbursement Environment* provides an overview of current and future trends in healthcare reimbursement. With healthcare reform on the horizon, 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.), and payment plans (for example, 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 industry variously has moved toward managed care, pay-for-performance programs, gainsharing arrangements, and patient-centered models of medical practice (for example, boutique medicine, the medical home model, etc.). 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.

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 and to the continuous development of new technologies, the latter which may enhance the quality and efficiency of the healthcare delivery system. In recent years, there has been a rapid growth in the number of limited-service providers, or "niche providers," such as specialty and surgical hospitals (for example, orthopedic and heart hospitals), which are sometimes referred to as "focused factories."[1] As a result of this trend toward specialization, concern has been raised that the medical care offered by niche providers may have a negative impact on the profitability of general acute care hospitals, which traditionally have provided specialty and primary care to patients. Similarly, there has been a movement toward increasing the scope and volume of mid-level provider-issued care, resulting in additional market competition for physicians.

The changing demographics of the patient population (that is, 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.

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 slowly becoming 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 three books:

1. *An Era of Reform*, consisting of six 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. The last chapter (chapter 6) provides an overview of the healthcare environment and related healthcare reform bills, at the time of the submission of this *Guide*.

2. *Professional Practices*, consisting of eight chapters, discusses the myriad of practice structures (chapter 1), 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 2–8, respectively), as well as information regarding the scope of subspecialties, types of providers, and practitioners of each service type.
3. *Consulting With Professional Practices*, consisting of four chapters, provides a descriptive overview for consultants advising professional practice clients on matters related to healthcare consulting (chapter 1); benchmarking strategies related to healthcare and valuation (chapter 2); compensation and income distribution (chapter 3); and financial valuation of healthcare enterprises, assets, and services (chapter 4). The information provided in these chapters should supply the reader with the tools necessary to translate healthcare consulting theory into practice.

It should be noted that the second and third books of this *Guide* focus on the professional practice component of the U.S. healthcare delivery system and do 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 second and third books 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.[2] The diverse healthcare workforce is instrumental to improving efficacy, quality of care, financial efficiency, patient satisfaction, workforce productivity, and professional satisfaction.[3] 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."[4] 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.[5]

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 American Medical Association, which classifies professionals based on the specialized area of medical practice under which they provide their services (table I-1B); and (3) the Centers for Medicare and Medicaid Services, 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.[6]

Alternately, multiple models can be synthesized to represent an industrywide, intrapersonal dynamic.[7] Elements from three models, the physician extender model, the triage model, and the 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."[8] 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.[9] 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.[10] These *physician extenders* (hereinafter "technicians and paraprofessionals") supplement physician care, either as highly technical or technological support or as manpower support.[11] 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*.[12] 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.[13] Historically, these providers could only practice under direct or indirect supervision of a physician.[14] As demand increased, namely for the provision primary care services, the autonomy of mid-level providers increased.[15] To date, these professionals are relied upon for the provision of specialized 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.[16] 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.[17]

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.[18] These allied health professionals are nonphysician practioners who practice independently and offer services that, despite some overlap with physician care, are largely outside the scope of physician practices.[19] 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: Bureau of Labor Statistics **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	
		Health Assessment and Treating Occupations	
		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 Sonographers	Magnetic Resonance Imaging Technologists
		Nuclear Medicine Technologists	

Table I-1A: Healthcare Professional Practices Provider Taxonomies *(continued)*
Organization: Bureau of Labor Statistics **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 (*continued*)		*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	
		Other Healthcare Practitioners/Technical Occupations	
		Occupational Health and Safety Specialists/Technicians	
		Occupational Health and Safety Specialists	Occupational Health and Safety Technicians
		Miscellaneous Health Practitioners/Technical Workers	
		Athletic Trainers	Other
Healthcare Support Occupations	Major Occupational Group K - Occupations concerned with other health care services for children and adults, mainly cater to the provision of support services.	**Nursing, Psychiatric, and Home Health Aides**	
		Home Health Aides	Nursing Assistants
		Psychiatric Aides	Orderlies
		Occupational Therapy/Physical Therapist Assistants/Aides	
		Occupational Therapy	
		Occupational Therapy Assistants	Occupational Therapy Aides
		Physical Therapy	
		Physical Therapy Assistants	Physical Therapy Aides
		Other Healthcare Support Occupations	
		Massage Therapists	
		Miscellaneous Healthcare Support Occupations	
		Dental Assistants	Medical Equipment Preparers
		Medical Assistants	

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" by the U.S. Department of Health and Human Services, Health Resources and Services Administration, 2009, http://bhpr.hrsa.gov/healthworkforce/reports/nursing/nurseaides/chap6.htm.
** "2010 Standard Occupational Classification," by the Bureau of Labor Statistics, January 2009, p. 16-19.
† "MOG—Level Definitions," in "Occupational Classification System Manual," by the U.S. Bureau of Labor Statistics, National Compensation Survey, http://www.bls.gov/ncs/ocs/ocsm/comMOGADEF.htm#mogaanchor (accessed 01/04/09).

Table I-1B: Healthcare Professional Practices Provider Taxonomies
Organization: Centers for Medicare and Medicaid **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/ Dental Medicine*	Interns and Residents*
		Doctor of Podiatric Medicine*	
Allied Health Providers	As stated in 42USC sec. 295p to include those professionals who: (A) who has received a certificate, an associate's degree, a bachelor's degree, a master's degree, a doctoral degree, or post baccalaureate 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 Technicians*,**,†,††,‡,‡‡,§	Dietetic Assistants††,‡,‡‡,§
		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," United States Code Title 42 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," United States Code Title 42 p.295.
‡‡ "Civil Remedies Decision CR1961," by the 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," by the 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 2009-2010

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		Optometrist*,**	
Complementary and Alternative Medicine		Chiropractic*,**	
Dentistry		Dentist*,**	
Pharmacy		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		*Clinical Psychologists*	
		Clinical Psychologists†,††,‡	
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†,††,‡	Dieticians/Dietetic Technicians†,††,‡
		Clinical Social Workers†,††,‡	
		Dietetics	
		Dietitian/Nutritionist*,**	Dietetic Technician*,**
		Dentistry and Related Fields	
		Dentist*,**	Dental Hygienist*,**
		Dental Assistant*,**	Dental Lab Technician*,**
		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*,**	

Table I-1C: Healthcare Professional Practices Provider Taxonomies *(continued)*

Organization: American Medical Association **Classification System:** As utilized in the Health Care Careers Directory 2009-2010

Category	Definition	Subcategories	
Allied Health Professional (*continued*)		**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 Technologist*,**	Cytotechnologist*,**
		Medical Imaging	
		Diagnostic Molecular Sonographer*,**	Magnetic Resonance Technologist*,**
		Histotechnician*,**	Medical Dosimetrist*,**
		Histotechnologist*,**	Nuclear Medicine Technologist*,**
		Pathologists' Assistant*,**	Radiation Therapist*,**
		Phlebotomist*,**	Radiographer*,**
		Diagnostic Medical Sonographer*,**	Registered Radiologist Assistant*,**
		Vision-Related Professions	
		Ophthalmic Assistant/Technician/ Technologist*,**	Orthoptist*,**
		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 2009-2010," by the American Medical Association, 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, Spring 2008, Volume 37, Number 1, p. 46-49

† "Physicians" in "The Public Health and Welfare," United States Code Title 42 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," 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	
		Physical	Audiologists/Speech
		Occupational	
		Physician Assistants	
		Physician Assistant	
		Registered Nurses	
		Registered Nurses	
		APRNS	
		Certified Registered Nurse Anesthetists	Dieticians & Nutritionists
		Nurse Practitioners	Nurse Midwives
		Technical Service Providers	
		Dental Hygientists	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, Attendants	Pharmacy Aides
		Therapists	
		Radiation Therapists	Respiratory Therapists

Table I-1D: Healthcare Professional Practices Provider Taxonomies *(continued)*
Organization: Health Capital Consultants **Classification System:** N/A

Category	Definition	Subcategories	
Technicians & Paraprofessionals *(continued)*		**Technologists**	
		Medical and Clinical Laboratory Technologists	Nuclear Medicine
		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 Sonographers	Medical Transcriptionists
		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
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

(continued)

Table I-2: Healthcare Professional Practices Provider Taxonomies Comparison Chart *(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]
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*	Mid-Level Provider*
Nurse Midwives	Mid-Level	Health Assessment and Treating Occupations	Mid-Level Provider*	Mid-Level Provider*
Nurse Practitioners	Mid-Level	Health Assessment and Treating Occupations	Mid-Level Provider*	Mid-Level Provider*
Physician Assistants	Mid-Level	Health Assessment and Treating Occupations	Mid-Level Provider*	Mid-Level Provider*
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
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

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

(continued)

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

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" by the "U.S. Department of Health and Human Services, Health Resources and Services Administration, 2009, http://bhpr.hrsa.gov/healthworkforce/reports/nursing/nurseaides/chapt6.htm."

2 "2010 Standard Occupational Classification," by the Bureau of Labor Statistics, January 2009, p. 16-19.

3 "MOG—Level Definitions," in "Occupational Classification System Manual," by the U.S. Bureau of Labor Statistics, National Compensation Survey, http://www.bls.gov/ncs/ocs/ocsm/comMOGADEF.htm#mogaanchor (accessed 01/04/09).

4 "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.

5 "Chapter 6A: Definitions, General Provisions, Health Professions Education, Public Health Service, The Public Health and Welfare," United States Code Title 42 295p.

6 "CR1961," by the 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," by the 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," by the 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," United States Code Title 42 1395x(r).

12 "Incident to' Services," MLN Matters, SE0441.

13 "Health Care Careers Directory 2009–2010," by the American Medical Association, 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, Spring 2008, Volume 37, Number 1, 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.

* 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.

Endnotes

1 "Specialty Hospitals, Ambulatory Surgery Centers, and General Hospitals: Charting a Wise Public Policy Course," by David Shactman, Health Affairs, Volume 24, Number 1, (May/June 2005), p. 869; "The Attack on Ancillary Service Providers at the Federal and State Level," by Robert Cimasi MHA, ASA, CBA, AVA, CM&AA, CMP, Orthopedic Clinics of America, Volume 39, Issue 1, (January 2008), p. 118.

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, Volume 37, Number 1, (Volume 37), 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, Volume 38, Number 3 (Fall 2009), p. e-92.

3 *Ibid.*

4 "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-92.

5 *Ibid.*

6 *Ibid.*

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, Volume 38, Number 3 (Fall 2009), p. e-92-e-93.

8 "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-92.

9 "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, Volume 66, Number 6, (December 2009), p. 36S.

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, Volume 38, Number 3 (Fall 2009), p. e-93.

11 *Ibid.*

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, Volume 38, Number 3 (Fall 2009), p. e-94.

13 *Ibid.*

14 *Ibid.*

15 *Ibid.*

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, Medical Group Management Association, 2006, p. 193-194.

17 "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, 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, Volume 38, Number 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, Volume 38, Number 3 (Fall 2009), p. e-94-e-95.

19 *Ibid.*

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
- Studia Generalia

Key Concept	Definition	Citation
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, HarperCollins Publishers Ltd., p. 46–47. "A History of Medicine," by Arturo Castiglioni, Alfred A. Knopf, Inc., 1947, p. 32.
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. (Pp. 260+ix; illustrated. 65s.) London: Elsevier, 1967.
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 Practices," by Sherwin B. Nuland, Random House Inc., 1988, p. 71; "The Western Medical Tradition 800 BC to AD 1800," by Lawrence I. Conrad, et. al., Cambridge University Press, 1995, p. 225.
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. (Pp. 260+ix; illustrated. 65s.) London: Elsevier, 1967.
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.
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.
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, HarperCollins Publishers Ltd., p. 98–9; "A History of Medicine," by Arturo Castiglioni, Alfred A. Knopf, Inc., 1947, p. 325–29.
The Rod and Serpent Today	Used as the modern symbol for medicine.	"The Rod and Serpent of Asklepios. Symbol of Medicine," by J. Schouten. (Pp. 260+ix; illustrated. 65s.) London: Elsevier, 1967.
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, John Wiley and Sons, Inc., p. 24–25.

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.

"A History of Medicine," by Arturo Castiglioni, 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 spiritualities 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.

"A History of Medicine," by Arturo Castiglioni, Alfred A. Knopf, Inc., 1947 p. 31–44.

The Greek god of healing, Asklepios, also was 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.[14]

Askleopios (left) and Caduceus (right). Source: 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).

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 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]

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

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

Deities and Religious Figures[*,**,†]

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
Buddah (Siddhattha Gotama)	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[*,§§,‡]

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. (Pp. 260+ix; illustrated. 65s.) London: Elsevier, 1967, in the British Medical Journal, Vol. 3, No. 5561, Aug. 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, HarperCollins Publishers Ltd.
§§ "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, Apr. 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 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.

"A History of Medicine," by Arturo Castiglioni, Alfred A. Knopf, Inc., 1947 p. 129–41.

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 7 of *Professional Practices*).[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.

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

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. "[I]t 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*.

"Chapter III: Antiquity," in "The Greatest Benefit to Mankind: A Medical History of Humanity," by Roy Porter, HarperCollins Publishers Ltd., p. 56;"A History of Medicine," by Arturo Castiglioni, Alfred A. Knopf, Inc., 1947, p. 148–49.

Box 1-2: Early Philosophers and Key Locations for Medicine

Eastern Philosophers*,**

Name	Birth/Death	Location	Claim to Fame
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
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

* "Zoroaster: The Prophet of Ancient Iran" by A.V. Williams Jackson, Columbia University Press, 1919, p. 15.
** "The Analects of Confucius" by Simon Leys, W.W. Norton & Company, Inc, 1997, p. xxi.
§ "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, HarperCollins Publishers Ltd.

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 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) is to demonstrate a commitment to uphold ethical standards as they practice medicine.[34] Although many attribute to Hippocrates the physician's commitment to "first do no harm" (translated from the Latin phrase "*primum non nocere*"), the true origins of the phrase are unknown and arguably not of Hippocratic origin.[35] Box 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).

Box 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.

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 assumed the title of "physician" without the training, further contributing

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 tests 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.

"A History of Medicine," by Arturo Castiglioni, Alfred A. Knopf, Inc., 1947 p. 233–35.

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 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.

"Chapter 3: The Reawakening," in "Doctors: The Illustrated History of Medical Practices," by Sherwin B. Nuland, Random House Inc., 1988, p. 71; "The Western Medical Tradition 800 BC to AD 1800," by Lawrence I. Conrad, et. al., Cambridge University Press, 1995, p. 225; "A History of Medicine," by Arturo Castiglioni, Alfred A. Knopf, Inc., 1947 p. 218–19.

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 **Studia Generalia**) 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 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]

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.[62] 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.[63] 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.[64] 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.[65] However, the University of Montpellier lost its prominence when the popes retreated from Avignon and religious warfare decimated the area.[66]

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.[67] Artist-anatomists such as Andrea Verrochio and Leonardo da Vinci were pioneers in the field.[68] Da Vinci performed dissections of human carcasses and made drawings of his observations.[69] 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.[70]

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.[71] His discoveries in anatomy, released in the mid-1500s, are medical landmarks.[72] 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.[73] 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."[74] Box 1-4 indicates the most influential figures and important locations in the history of healthcare during the Renaissance and Inquisition.

Box 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, HarperCollins Publishers Ltd.

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.[75] 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.[76] 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.[77]

Antoni van Leeuwenhoek's discovery of the microscope in the early 1670s triggered interest in the molecular implications of human anatomy.[78] Van Leeuwenhoek is credited with the discovery of red blood corpuscles, the advanced study of vessel walls, and the estimation of blood's velocity.[79] 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.[80]

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 infestations of The Black Death.[81] The Black Death decimated Europe from 1320–1420, with mortality counts of barely less than two-thirds the original population.[82] 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.[83] 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.[84]

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.

"Chapter IX: The New Science," in "The Greatest Benefit to Mankind: A Medical History of Humanity," by Roy Porter, HarperCollins Publishers Ltd., p. 236–40;"A History of Medicine," by Arturo Castiglioni, Alfred A. Knopf, Inc., 1947, p. 560–63.

Because disease was a significant problem in the military, sanitary measures and disease containment within the military became an area of significant focus.[85] The first substantial investigations into military hygiene were conducted by Florentine Orazio Monti and Antonio Porzio.[86] Porzio made notable advances on the subject of epidemic avoidance in armies, demonstrating the detrimental effects of intrabarrack contamination and, ultimately, civilian contamination.[87]

Bernardino Ramazzini of Capri became the father of **industrial hygiene** and authored the first treatise on occupational disease: *De morbis artificum*.[88] Ramazzini compiled research on the diseases of miners and issued a report of his findings that resembled a modern occupational risk assessment.[89] 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.[90] 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.[91]

Bernardo Ramazzini of Capri became known as the father of industrial hygiene; he authored the first treatise on occupational disease, *De morbis artificum*.

"Chapter X: Enlightenment," in "The Greatest Benefit to Mankind: A Medical History of Humanity," by Roy Porter, HarperCollins Publishers Ltd., p. 296; "A History of Medicine," by Arturo Castiglioni, Alfred A. Knopf, Inc., 1947, p. 564.

Legislators began passing sanitation laws toward the end of the seventeenth century.[92] When the plague broke out in Rome, the city took measures to contain the disease by means of regulatory sanitary controls.[93] For example, the College of Physicians was asked to report all patients who had been treated for certain diseases in the past six months.[94] 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.[95] The executions caused uproar among civilians, which brought an end to these measures for disease control.[96] Nonetheless, they prompted more efforts toward military hygiene.[97] From these advances in hygiene, preventative and sanitary control measures became areas of legislative reform that developed throughout the eighteenth and nineteenth centuries.[98]

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.

"Chapter XIII: Public Medicine," in "The Greatest Benefit to Mankind: A Medical History of Humanity," by Roy Porter, HarperCollins Publishers Ltd., p. 397–400, 405–7; "A History of Medicine," by Arturo Castiglioni, Alfred A. Knopf, Inc., 1947, p. 567.

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."[99] As the dark age of the ecclesiastic resistance to scientific advance culminated, advocates argued that medicine should be more philosophical and method-based.[100] Although the eighteenth century became known for Emmanuel Kant's suggestion "that philosophy is the queen of all the sciences," it is more renowned for landmark progress in the exact sciences.[101] Countless discoveries in chemistry, physics, biology, physiology, anatomy, and pathology yielded a single conclusion: without an applied understanding of each of these areas of science, the practice of medicine is arbitrary.[102] Box 1-5 outlines the most influential figures and a few key events in medical history during the seventeenth and eighteenth centuries.

According to Emmanual Kant and his followers: "philosophy is the queen of all sciences."

"A History of Medicine," by Arturo Castiglioni, Alfred A. Knopf, Inc., 1947, p. 580–82.

Box 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
Emmanuel 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, HarperCollins Publishers Ltd.
§ "Memorie storico-culturali delle Accademie orcianesi", by Franco Marini, Fondazione Cassa di Risparmio, www.fondazionecarifano.it/EventsDocs/2007/AccademieOrcianesi.htm (accessed 03/15/10).
§§ "The Black Death and the Transformation of the West," by David Herlihy, Harvard University Press, 1997.

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.[103] However, with Watson's work becoming perceived as outdated, in 1981, 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.[104] Osler's text, first published in 1982, established him as a leading authority on medicine and sold hundreds of thousands of copies; multiple editions were published throughout his life and posthumously.[105]

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.[106] Urban and industrial growth spurred demand for sanitary conditions.[107] "Together with the great increase in material and cultural growth, a deeper sense of human dignity was penetrating even to the lowest classes."[108] However, in many countries, a "realistic tendency and the pursuit of materialistic aims" shattered this idealism.[109] Finally, medicine was regarded as a necessary scientific field. Efforts to overcome "transcendental tendencies and further the progress of the natural sciences" resulted in experimental investigation and observation of all forms of life.[110] Scientists sought to understand complex biological issues that philosophical hypotheses previously disregarded.[111] As a result, various schools of thought emerged and advances in science fostered medical specialization.[112]

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[113] medical knowledge, and technological capabilities, **allopathic** (traditional) Western physicians adopted "a method of healing founded on a scientific basis"[114] At the time of its establishment in 1847, the American Medical Association (AMA) was largely comprised of allopathic physicians.[115] The AMA recognized the potency of Western medicine and understood that danger may result from inadequately regulated growth and expansion of biologically based methodologies.[116]

> *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.*[117]

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.[118]

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**.[119] 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."[120] Though not as prominent as allopathic medicine, practioners 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.[121]

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.[122] Eclectics use herbal medicines and remedies to treat pathologic conditions.[123] Among less threatening therapies, eclectics are known primarily for their use of arsenic and mercury treatments.[124] Naturopathic physicians utilize natural elements like water, heat, and massage in their therapies.[125] Chapter 7 of *Professional Practices* contains more information about alternative medicine in the modern healthcare industry.

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.[126] 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.[127] See chapter 6 of *Professional Practices* for further discussion of chiropractic medicine as an allied health professional practice.

One of the two most reputed schools of medicine in the United States is osteopathic medicine.[128] Andrew Taylor Still founded osteopathic medicine, treating patients by assessing not only their symptoms but also their overall health and environment.[129] He opened the American School of Osteopathy in 1892 in Kirksville, Missouri.[130] By the 1960s, there were six schools for osteopathy, and, as of 1985, Doctors of Osteopathic Medicine were certified in all specialties.[131] Because osteopathic medicine contributes a great deal to the modern practice of medicine, chapter 1 of *Professional Practices* addresses in detail the similarities and differences between Doctors of Medicine and Doctors of Osteopathic Medicine.

As of April 1985, Doctors of Osteopathy (D.O.) were certified in all specialties.

"History of Osteopathy" In "An Osteopathic Approach to Diagnosis and Treatment," by Eileen L. DiGiovanna and Stanley Schiowitz, 1997, p. 1–3.

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.[132] In the later portion of the century, the scientific and medical communities began to grapple with the social and economic implications of healthcare.[133] As such, medicine "assume[d] its role as a social science," transforming itself from an elite and sophisticated trade[134] The national prevalence of infectious disease resulted in an emphasis on community and hygienic medicine.[135]

Public health is an area of science and medicine characterized by a "community health point of view."[136] 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.[137] Unfortunately, progress in prevention is difficult to quantify, and its value within the healthcare industry is not concrete.[138] As a result, preventative care is dismissed as inferior, and public health has faced significant resistance and alienation from the medical community.[139]

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 and Surgery* entering print in 1812.[140] 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.[141] 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.[142]

Through his investigations of fermentation and pathogenic bacteria, Louis Pasteur pioneered a branch of microbiology now known as bacteriology.[143] 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.[144] **Pasteurization** involves the strategic application of heat to kill microbes without injuring the quality of its media (for example, wine, beer, etc.).[145] 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."[146] Pasteur improved healthcare and enhanced its economic benefits through his contributions to the fields of clinical, hygienic, and social medicine.[147]

Specialization of Medicine

Specialized forms of internal medicine emerged contemporaneously with developments in pathology and microbiology.[148] The nineteenth century marked the discovery of anesthesia and asepsis which resulted in unmatched advances in the study of surgery.[149] Surgical specialization fostered the inception of plastic surgery, neurosurgery, pathological (namely, cancer related) surgery, surgical procedures in gynecology and obstetrics, and countless other areas.[150] Similar scientific milestones enhanced both diagnostic and therapeutic capabilities in various medical fields including obstetrics and gynecology, pediatrics, otology, laryngology, rhinology, urology, dermatology, syphilology, orthopedics, dentistry, neurology, and psychiatry.[151]

Specialty Diagnostics

Physicians in the nineteenth century were among the first to engage in the identification, classification, and reporting of various pathologies and diseases.[152] In order to conduct the necessary laboratory procedures, physicians had to possess a substantial amount of knowledge in a condensed area of medicine.[153] As a result, the range of available specialties grew, became more focused, and ultimately led to more specialized medical research.[154] At the turn of the twentieth century, diagnostic medicine endured a transformation, with Wilhelm Conrad Roentgen's discovery of x-rays in 1895 that promulgated the rapid advancement of quantum physics and Antoine Beclere's implementation of the first x-ray machine in 1906.[155] Soon after, these nuances in radiation diagnostics would leak into therapeutics, with discoveries in radiation therapy (see chapter 5, *Technology Development* for an in depth discussion of radiation as a diagnostic and therapeutic technology).[156]

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.[157] The treatment of diseases, however, always has been at the apex of the medical practice.[158] Physician inquiry in specialized areas of medicine allowed for the expansion of diagnostic capabilities in the nineteenth century.[159] Additionally, the nineteenth century brought with it the unparalleled evolution of therapeutic technology.[160] It was not until the 1800s that pharmacology gained scientific credibility through animal and clinical trial investigations.[161] Ancient forms of **physiotherapy** slowly transformed over time, only to emerge in various specialized forms including hydrotherapy, massage, mechanotherapy, electrotherapy, and heat therapy.[162] Box 1-6 summarizes the key people, places, and events of the nineteenth century in medical history.

Box 1-6: 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; it was the prominent general medical treatise for forty years
Sir William Osler	1849–1919	Montreal, Canada	Authored *The Principles and Practice of Medicine*, a premier medical text published in 1892, which solidified him as the leading authority on medicine at the time for both students and practitioners
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 Beclere	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; usually produces a gas
Pathogenic Bacteria	Bacteria that causes disease
Pasteurization	A process which preserves perishable products involving strategic application of heat to kill microbes without injuring the media
Antirabic Treatment	A treatment for rabies developed at the Pasteur Institute
Anthrax	A fatal bacterial infection of warm-blooded animals
Chicken Cholera	A disease affecting poultry, Pasteur's work with the disease led him to discover vaccinations
Staphylococci	A set of spherical bacteria
Streptococci	A set of spherical bacteria, which grow in chains and can cause serious diseases; 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, HarperCollins Publishers Ltd.
† "The Life of Sir William Osler," by Harvey Cushing, Oxford, 1925.
†† "Our History, Illustrated Highlights," the American Medical Association, 2009, www.ama-assn.org/ama/pub/about-ama/our-history/illustrated-highlights.shtml, (accessed 09/10/09).
‡ "Dr. Holmes at 200—The Spirit of Skepticism" by Charles S. Bryan, M.D., and Scott H. Podolsky, M.D., 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.

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.[163] 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.[164]

Technological Advances

With physicians developing expertise in exceedingly specialized areas of medicine, the expectation was that they would administer care with the same level of expertise.[165] As such, the demand for innovative technologies increased to allow for the provision of services that advanced diagnoses required. Over time, demand took a completely different form to account for more than just advances in diagnostics and therapeutics, and, moreover, it grew at astronomical rates.[166] To match a growing and shifting demand, increased spending, demographic trends, and a pathologic shift (discussed further herein), existing technologies evolved to improve the quality and efficiency of services delivered.[167]

Accompanying the increase in spending, healthcare practitioners became viewed not only as healers but also as businessmen. As the demand for increasingly expensive medical technology grew, the old adage, "no Buck Rogers," defined the cyclical relationship between technological demand and business investment. Within that context, demand for more sophisticated management technologies to enhance practice efficiency and reliability increased significantly.[168] Chapter 5, *Technology Development* extensively addresses both management and clinical technology.

The Inception of Medicare and Medicaid Services

The economic devastation that plagued a war-torn 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.[169] Despite resistance from conservative stakeholders, that is, the AMA, the Progressive movement emerged in hopes of relinquishing "inequities and poverty in America."[170] 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.[171] Both attempts were in vain, and FDR's sudden, tragic death in 1945 left health reform in the hands of his successor, Harry S. Truman.[172]

Truman was a zealous proponent of "universal, comprehensive coverage," and actively sought enactment of a program for the entirety of his presidency.[173] However, he faced opposition from the AMA, perceived to be "the country's richest and most influential post-World War II lobby."[174] His stance on healthcare was viewed by the AMA and other conservative stakeholders as "socialistic" and "un-American."[175] 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.[176]

In the 1960s, John F. Kennedy's presidential campaign once again targeted the recession, unemployment, and stagnant economy introduced by World War II.[177] 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."[178] Starr also recognized that the need for an increase in "health manpower" would result in an expansion of education programs and initiatives.[179]

President Lyndon B. Johnson, like President Kennedy, recognized the connection between bad healthcare and poverty and lobbied for social programs to ensure the poor received healthcare coverage.[180] Although Medicare had been a political issue since the late 1950s, it was not until the "Democratic sweep in 1964" that a Congressional majority passed the **Medicare** program and President Johnson signed the bill into law.[181] The Medicare program of the 1960s was comprised of three layers: (1) **Medicare Part A**, "the Democratic plan for a compulsory hospital insurance program under Social Security;" (2) **Medicare Part B**, "the revised Republican program of government-subsidized voluntary insurance to cover physicians' bills;" and (3) **Medicaid**, "the expanded assistance to the states for medical care."[182] The introduction of the Medicare and Medicaid programs dramatically increased access to care for indigent individuals and proved to be the first of many steps toward healthcare reform.[183]

Shift to Managed Care

Following the movement toward a **prospective payment system (PPS)** in the late 1980s, the U.S. healthcare delivery system underwent fundamental changes that proved, in some ways, as significant as the introduction of Medicare in the mid 1960s. The sea change in the U.S. healthcare delivery system during those decades continues to present both challenges and opportunities for healthcare professional providers and investors alike.[184] As one of the largest payors of healthcare benefits, the government continues to attempt to control healthcare costs by developing reimbursement policies that serve as significant drivers of current trends in healthcare delivery.[185]

Although most professions saw an increase in compensation since the 1990s, physician compensation has been fairly stagnant.[186] 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.[187] The realignment of the Inpatient Prospective Payment System (IPPS) with the introduction of severity adjusted **diagnostic related groups (DRGs)**, as well as heightened initiatives aimed at restricting physician ownership of ancillary services and technical component revenue streams (most recently through the Children's Health and Medicare Protection provision removing the whole hospital exception to the Stark law) have raised some investor concerns.[188]

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, M.D., 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, ". . . most physicians would be salaried employees of not-for-profit, prepaid group practices," may have redefined his stance on physician "independence."[189]

> *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.*[190]

Historically, Medicare and Medicaid paid for hospital services using a *cost plus* method of reimbursement, in which hospitals received reimbursement in excess of all of their costs.[191] In 1983, the federal government introduced a PPS in an effort to remedy the rising healthcare costs.[192] Under this PPS, hospitals are reimbursed an average, qualified, and predetermined fee for every recognized DRG.[193] The government has also developed a PPS for ambulatory surgery centers, home healthcare, hospital outpatient services, rehabilitation facilities, and skilled nursing facilities.[194]

In 1983, the federal government introduced a prospective payment system (PPS) in an effort to remedy the rising healthcare costs.

"Assessing payment adequacy and updating payment in fee-for-service Medicare" in Report to the Congress: Medicare Payment Policy, March 2005, p. 29–32.

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.[195] This new payment system, based on estimates of resource costs incurred in an efficient medical practice, replaced the previous **customary prevailing and reasonable** charge system.[196] The five-year implementation and subsequent updates to this system affected the reimbursement levels of various specialties unevenly with primary care physicians generally faring well under the new system.[197] The RBRVS was intended to bring medical practice more in line with a PPS in which payments are made based on set fees for types of procedures or diagnosis For more information about trends in reimbursement, see chapter 2, *Reimbursement Environment*.[198]

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.

"A Guide to Consulting Services for Emerging Healthcare Organizations" by Robert James Cimasi, CBI, CBC, John Wiley and Sons, Inc., p. 24–25.

Managed competition between larger, consolidated provider entities was an inevitable goal of the shift to managed care and capitation from a fee-for-service medical system.[199] The expeditious consolidation of healthcare entities, in both public and private sectors, into emerging healthcare organizations within both private and public sectors is a result of the gradual transition into managed care through regulatory action at both state and federal levels.[200]

Health maintenance organizations and **preferred provider organizations** have sought to combine the roles of insurance companies, utilization review organizations, and medical services providers in order to offer prepaid medical plans to subscribers, forcing cost containment by integrating operational and financial functions.[201] The transition into managed care has reinforced the primary care physician's role as "gatekeeper."[202] As such, the value attributed to primary care physicians has increased, though the trend toward specialization prevails.[203]

The inception of managed care, as well as the industry hype instigated by Starr's romanticized call for "corporatization," promulgated the increased integration of healthcare organizations.[204] However, the industry did not see the desired improvements in quality and efficiency promised by managed care.[205] Most organizations only consolidated in order to survive the backlash of managed care; in light of this misalignment, increased integration has only furthered the fragmentation of healthcare delivery.[206] Consolidation to date has, in some respects, deterred from managed care's intended goal: the fluid and comprehensive continuum of quality care. In all respects, however, organizational integration has merely created a façade of increased consolidation in a healthcare system that remains, inherently, a "cottage industry."[207] 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.[208]

Inpatient and Outpatient Market Trends

The Bureau of Health Professions predicted that between 2000 and 2020, the U.S. population would increase by 18 percent.[209] Also, the number of people aged sixty-five and older is anticipated to account for 13 percent of the total world population in 2030.[210] The market for outpatient services more than doubled from 1987 to 2007 in order to offset trends in population demand.[211] Continuing increases in healthcare costs containment pressures should preserve growth in outpatient demand.

The Bureau of Health Professions predicted that, between 2000 and 2020, the U.S. population would increase by 18 percent. Also, the number of people aged sixty-five and older is anticipated to account for 13 percent of the total world population by 2030.

"Trend Watch" American Hospital Association, 2002, p. 62.

It would be incorrect to assume that the expansion of outpatient care is the sole factor influencing the healthcare market and competitive arena. Demand is bifurcated due to increased incidence of several chronic diseases paired with emerging infectious diseases that are resistant to existing therapies.[212] Though not as drastic, inpatient demand has increased from 96 million visits in 1995 to 119 million visits in 2006, with the percentage of inpatients older than sixty-five years of age nearly doubling from 1970 to 2006.[213] An expected population increase by 2030 of 30 million people suggests that both outpatient *and* inpatient markets can expect positive trends in demand.[214]

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 enrollment was put in place to control supply of physicians to the market.[215] 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.[216] 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.[217]

The healthcare industry faces present and projected healthcare professional manpower shortages due to the repercussions of previously capped medical school enrollment, the economic recession, and the demographic shift.[218] Based on the number of additional physicians needed to meet current market demands, the projected 10 percent physician shortage is expected to double in the next decade.[219] In November of 2008, the AAMC projected a physician shortage of 159,000 physicians by the year 2025.[220] In 2000, thirty states experienced nursing shortages greater than 3 percent.[221] In recent years, the average age of registered nurses has increased steadily due to a six-fold decrease in nursing school enrollment since 2002, higher average ages of recent graduating classes, and aging of the nursing population as a whole.[222] The U.S. Department of Health and Human Services anticipates 1 million unfilled nursing positions by 2020.[223]

In November of 2008, the Association of American Medical Colleges (AAMC) projected a physician shortage of 159,000 physicians by the year 2025.

"The Complexities of Physician Supply and Demand: Projections Through 2025," by Michael J. Dill and Edward S. Salsberg, Center for Workforce Studies, Association of American Medical Colleges, November 2008, p. 6.

The U.S. Department of Health and Human Services anticipates 1 million unfilled nursing positions by 2020.

"Nursing, doctor numbers worsen," By Gregory Lopes, The Washington Times, July 27, 2007, www.newser.com/archive-science-health-news/1G1-166859372/nursing-doctor-numbers-worsenbusiness.html (accessed April 10, 2009).

In addition to the shortage of physicians across all specialties, there is a growing shortage of physicians seeking to practice in primary care medicine.[224]

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.[225] Given that medical students graduate with a significant amount of debt (often more than $100,000), the reason for choosing a more lucrative specialization is obvious.[226]

Old Medical Adage

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

Because medical schools rely on funds from advanced specialties for their student training programs, the programs tend to have a highly specialized emphasis.[227] Additionally, training in primary care has been hindered by cuts to training grants (Section 747, Title VII Public Health Service Act) that provide medical students with exposure to primary care settings outside the academic medical center, often in rural and medically underserved areas.[228] Potential solutions to the shortage of primary care physicians include providing more financial incentives to attract new graduates to the primary care practice, as well as expanding exposure to primary care practices during medical school.[229]

Old Medical Adage

"Specialists and surgeons relegate the complaints of primary care physicians as 'the revenge of the C student.'"

Further, analysts project that allied health professionals will see a 1.6 to 2.5 million practitioner shortage in coming years.[230] Factors driving the allied health practioner shortage are similar to that of the nursing shortage: allied health professionals earn more money working than they do teaching, resulting in a lack of academic faculty.[231] Additionally, underfunded educational institutions and community colleges do not inform waitlisted students about the availability of seats at other teaching institutions.[232]

Box 1-7 outlines several of the most important twentieth century figures and events as they relate to the healthcare profession.

There is a projected shortage of 1.6 to 2.5 million allied health professionals.

"Workforce Shortage Crisis," By George Lauer, Allied Health Professionals Week Highlights, January 27, 2007, www.californiahealthline.org/Features/2009/Shortage-of-Allied-Health-Workers (accessed April 10, 2009).

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."[233] However, business objectives built around these ethical values may conflict with the entrepreneurial objectives that take priority in most industries.[234] 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.[235] As such, the healthcare professional's ethical duties are rooted deeply in community benefit.[236] 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.[237]

Box 1-7: Influential Figures and Key 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 the U.S. Department of Health and Human Services, 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 02/17/2010)
† "The Social Transformation of American medicine," by Paul Star, Basic Books Inc. 1982.
†† "Paul Starr: Biographical Sketch", Princeton University, October 19, 2008, www.princeton.edu/~starr/starrbio.html (accessed 02/24/10)
‡ "Projected supply, demand, and shortages of registered nurses: 2000–2020," By the 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 04/10/09).

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.*[238]

Unfortunately, the public's perception of healthcare providers gradually has 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.[239] In the face of rapidly accelerating changes in the healthcare industry, it is an increasing 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.

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 detail in subsequent books of this *Guide: Professional Practices and Consulting with Professional Practices*.

Key Sources

Key Source	Description	Citation	Hyperlink
The Social Transformation of American Medicine	Paul Starr's work discussing the evolution of American Medicine.	"The Social Transformation of American medicine," by Paul Star, 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: Johns Hopkins Press, 1943. **Modern:** "The Hippocratic Oath and the Ethics of Medicine," by Steven H. Miles, Oxford University Press, 2004.	**Original:** http://guides.library.jhu.edu/content.php?pid=23699&sid=190555 **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."	"Mission, Vision & Goals," Centers for Medicare and Medicaid, July 17, 2009, www.cms.hhs.gov/MissionVisionGoals/, (accessed 09/09/09).	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," by Roberts, J. B. (1908), Chicago, IL: American Medical Association.	n/a

Associations

Type of Association	Professional Association	Description	Citation	Hyperlink	Contact Information
National	American Medical Association	"The American Medical Association helps doctors help patients by uniting physicians nationwide to work on the most important professional and public health issues."	"Our Mission," American Medical Association, 2009, www.ama-assn.org/ama/pub/about-ama/our-mission.shtml, (accessed 09/09/09).	www.ama-assn.org	American Medical Association 515 N. State Street Chicago, IL 60654 Phone: 800-621-8335 Fax: n/a E-mail: n/a
National	Association of American Medical Colleges (AAMC)	The AAMC represents all 131 accredited U.S. and 17 accredited Canadian medical schools; approximately 400 major teaching hospitals and health systems, including 68 Department of Veterans Affairs medical centers; and nearly 90 academic and scientific societies. Through these institutions and organizations, the AAMC represents 125,000 faculty members, 75,000 medical students, and 106,000 resident physicians.	"About the AAMC," the Association of American Medical Colleges, 2009, www.aamc.org/about/start.htm, (accessed 09/09/09).	www.aamc.org	Association of American Medical Colleges 2450 N Street, NW Washington, DC 20037-1126 Phone: 202-828-0400 Fax: 202-828-1125 E-mail: n/a

Endnotes

1 Paul Starr is a reputed scholar of Sociology and Public Affairs known for his writings on the development of American medicine.

2 "The Social Transformation of American Medicine" By Paul Starr, Basic Books Inc. 1982, p. ix.

3 "A History of Medicine" By Arturo Castiglioni, New York, NY: Alfred A. Knopf, Inc., 1947, p. 3, 12.

4 "A History of Medicine" By Arturo Castiglioni, New York, NY: Alfred A. Knopf, Inc., 1947, p. 31-32; "The Greatest Benefit to Mankind: A Medical History of Humanity" By Roy Porter, HarperCollins Publishers Ltd., 1997, p. 44-45.

5 "A History of Medicine" By Arturo Castiglioni, 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, HarperCollins Publishers Ltd., 1997, p. 46-47.

7 "A History of Medicine" By Arturo Castiglioni, New York, NY: Alfred A. Knopf, Inc., 1947, p. 32; "The Greatest Benefit to Mankind: A Medical History of Humanity" By Roy Porter, HarperCollins Publishers Ltd., 1997, p. 46-47.

8 "A History of Medicine" By Arturo Castiglioni, New York, NY: Alfred A. Knopf, Inc., 1947, p. 31-44.

9 "A History of Medicine" By Arturo Castiglioni, New York, NY: Alfred A. Knopf, Inc., 1947, p. 33.

10 "A History of Medicine" By Arturo Castiglioni, New York, NY: Alfred A. Knopf, Inc., 1947, p. 33-41.

11 "A History of Medicine" By Arturo Castiglioni, New York, NY: Alfred A. Knopf, Inc., 1947, p. 38.

12 *Ibid.*

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.

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

16 "A History of Medicine" By Arturo Castiglioni, New York, NY: Alfred A. Knopf, Inc., 1947, p. 73-77; "The Greatest Benefit to Mankind: A Medical History of Humanity" By Roy Porter, HarperCollins Publishers Ltd., 1997, p. 85-87.

17 "The Greatest Benefit to Mankind: A Medical History of Humanity" By Roy Porter, 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, New York, NY: Alfred A. Knopf, Inc., 1947, p. 245-246.

19 "A History of Medicine" By Arturo Castiglioni, New York, NY: Alfred A. Knopf, Inc., 1947, p. 246.

20 "A History of Medicine" By Arturo Castiglioni, New York, NY: Alfred A. Knopf, Inc., 1947, p. 244-247.

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

22 "A History of Medicine" By Arturo Castiglioni, New York, NY: Alfred A. Knopf, Inc., 1947, p. 55; "A History of Medicine" By Arturo Castiglioni, New York, NY: Alfred A. Knopf, Inc., 1947, p. 130; "The Greatest Benefit to Mankind: A Medical History of Humanity" By Roy Porter, HarperCollins Publishers Ltd., 1997, p. 44-45.

23 "A History of Medicine" By Arturo Castiglioni, New York, NY: Alfred A. Knopf, Inc., 1947, p. 129-33, 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.*

28 "A History of Medicine" By Arturo Castiglioni, New York, NY: Alfred A. Knopf, Inc., 1947, p. 148.

29 *Ibid.*

30 "A History of Medicine" By Arturo Castiglioni, New York, NY: Alfred A. Knopf, Inc., 1947, p. 55; "A History of Medicine" By Arturo Castiglioni, New York, NY: Alfred A. Knopf, Inc., 1947, p. 148-149, 153; "The Greatest Benefit to Mankind: A Medical History of Humanity" By Roy Porter, HarperCollins Publishers Ltd., 1997, p. 55-56.

31 "A History of Medicine" By Arturo Castiglioni, New York, NY: Alfred A. Knopf, Inc., 1947, p. 150-153.

32 "A History of Medicine" By Arturo Castiglioni, New York, NY: Alfred A. Knopf, Inc., 1947, p. 150-51, 153; "The Greatest Benefit to Mankind: A Medical History of Humanity" By Roy Porter, HarperCollins Publishers Ltd., 1997, p. 62-63, 71.

33 "A History of Medicine" By Arturo Castiglioni, 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.

36 "A History of Medicine" By Arturo Castiglioni, New York, NY: Alfred A. Knopf, Inc., 1947, p. 232-233; "The Greatest Benefit to Mankind: A Medical History of Humanity" By Roy Porter, HarperCollins Publishers Ltd., 1997, p. 69.

37 "The Greatest Benefit to Mankind: A Medical History of Humanity" By Roy Porter, HarperCollins Publishers Ltd., 1997, p. 69-70.

38 "A History of Medicine" By Arturo Castiglioni, New York, NY: Alfred A. Knopf, Inc., 1947, p. 232-233.

39 "A History of Medicine" By Arturo Castiglioni, New York, NY: Alfred A. Knopf, Inc., 1947, p. 233.

40 *Ibid.*

41 *Ibid.*

42 "A History of Medicine" By Arturo Castiglioni, New York, NY: Alfred A. Knopf, Inc., 1947, p. 233-234.

43 "A History of Medicine" By Arturo Castiglioni, New York, NY: Alfred A. Knopf, Inc., 1947, p. 233-235.

44 *Ibid.*

45 "A History of Medicine" By Arturo Castiglioni, New York, NY: Alfred A. Knopf, Inc., 1947, p. 232-241.

46 "A History of Medicine" By Arturo Castiglioni, New York, NY: Alfred A. Knopf, Inc., 1947, p. 217-218.

47 "A History of Medicine" By Arturo Castiglioni, 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.

48 "A History of Medicine" By Arturo Castiglioni, 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, 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, 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, HarperCollins Publishers Ltd., 1997, p. 74-75, 76-77.

51 "A History of Medicine" By Arturo Castiglioni, New York, NY: Alfred A. Knopf, Inc., 1947, p. 220-222; "The Greatest Benefit to Mankind: A Medical History of Humanity" By Roy Porter, HarperCollins Publishers Ltd., 1997, p. 74-75, 76-77.

52 "Doctors: The Illustrated History of Medical Practices" 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.

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

54 "A History of Medicine" By Arturo Castiglioni, New York, NY: Alfred A. Knopf, Inc., 1947, p. 326.

55 "A History of Medicine" By Arturo Castiglioni, New York, NY: Alfred A. Knopf, Inc., 1947, p. 325-327.

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

57 "A History of Medicine" By Arturo Castiglioni, New York, NY: Alfred A. Knopf, Inc., 1947, p. 325; "The Greatest Benefit to Mankind: A Medical History of Humanity" By Roy Porter, HarperCollins Publishers Ltd., 1997, p. 110.

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

59 "The Greatest Benefit to Mankind: A Medical History of Humanity" By Roy Porter, 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, HarperCollins Publishers Ltd., 1997, p. 98-99.

61 "A History of Medicine" By Arturo Castiglioni, New York, NY: Alfred A. Knopf, Inc., 1947, p. 220-222; "The Greatest Benefit to Mankind: A Medical History of Humanity" By Roy Porter, HarperCollins Publishers Ltd., 1997, p. 74-75, 76-77.

62 "A History of Medicine" By Arturo Castiglioni, New York, NY: Alfred A. Knopf, Inc., 1947, p. 329-333.

63 "A History of Medicine" By Arturo Castiglioni, New York, NY: Alfred A. Knopf, Inc., 1947, p. 326, 330, 332-333; "Doctors: The Illustrated History of Medical Practices" By Sherwin B. Nuland, New York, NY: Black Dog & Leventhal Publishers, Inc., 2008, p. 70-73.

64 "A History of Medicine" By Arturo Castiglioni, New York, NY: Alfred A. Knopf, Inc., 1947, p. 333-335.

65 "A History of Medicine" By Arturo Castiglioni, New York, NY: Alfred A. Knopf, Inc., 1947, p. 338-339; "The Greatest Benefit to Mankind: A Medical History of Humanity" By Roy Porter, HarperCollins Publishers Ltd., 1997, p. 110.

66 "A History of Medicine" By Arturo Castiglioni, New York, NY: Alfred A. Knopf, Inc., 1947, p. 338-339.

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

68 "A History of Medicine" By Arturo Castiglioni, New York, NY: Alfred A. Knopf, Inc., 1947, p. 410-413; "Doctors: The Illustrated History of Medical Practices" 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, HarperCollins Publishers Ltd., 1997, p. 176-177.

69 "A History of Medicine" By Arturo Castiglioni, New York, NY: Alfred A. Knopf, Inc., 1947, p. 413; "The Greatest Benefit to Mankind: A Medical History of Humanity" By Roy Porter, HarperCollins Publishers Ltd., 1997, p. 176-177.

70 "A History of Medicine" By Arturo Castiglioni, New York, NY: Alfred A. Knopf, Inc., 1947, p. 413-417.

71 "A History of Medicine" By Arturo Castiglioni, 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, HarperCollins Publishers Ltd., 1997, p. 179-181.

72 "A History of Medicine" By Arturo Castiglioni, New York, NY: Alfred A. Knopf, Inc., 1947, p. 420-423.

73 "A History of Medicine" By Arturo Castiglioni, New York, NY: Alfred A. Knopf, Inc., 1947, p. 422-423.

74 "The Growth of Medicine" By Frederick Stenn, Springfield, IL: Charles C. Thomas Publisher, 1967, p. 78-79.

75 "A History of Medicine" By Arturo Castiglioni, New York, NY: Alfred A. Knopf, Inc., 1947, p. 410-425; "Doctors: The Illustrated History of Medical Practices" 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, HarperCollins Publishers Ltd., 1997, p. 176-177, 179-181.

76 "A History of Medicine" By Arturo Castiglioni, 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, HarperCollins Publishers Ltd., 1997, p. 183-184.

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

78 "The Greatest Benefit to Mankind: A Medical History of Humanity" By Roy Porter, HarperCollins Publishers Ltd., 1997, p. 224.

79 "A History of Medicine" By Arturo Castiglioni, New York, NY: Alfred A. Knopf, Inc., 1947, p. 529.

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

81 "A History of Medicine" By Arturo Castiglioni, 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.

82 "The Black Death and the Transformation of the West" By David Herlihy, Cambridge, MA: Harvard University Press, 1997, p. 17-18.

83 "A History of Medicine" By Arturo Castiglioni, New York, NY: Alfred A. Knopf, Inc., 1947, p. 560-563; "The Greatest Benefit to Mankind: A Medical History of Humanity" By Roy Porter, HarperCollins Publishers Ltd., 1997, p. 236-240.

84 "A History of Medicine" By Arturo Castiglioni, New York, NY: Alfred A. Knopf, Inc., 1947, p. 562-563.

85 "A History of Medicine" By Arturo Castiglioni, New York, NY: Alfred A. Knopf, Inc., 1947, p. 563.

86 *Ibid.*

87 *Ibid.*

88 "A History of Medicine" By Arturo Castiglioni, New York, NY: Alfred A. Knopf, Inc., 1947, p. 564; "The Greatest Benefit to Mankind: A Medical History of Humanity" By Roy Porter, HarperCollins Publishers Ltd., 1997, p. 296.

89 "The Greatest Benefit to Mankind: A Medical History of Humanity" By Roy Porter, HarperCollins Publishers Ltd., 1997, p. 296.

90 *Ibid.*

91 "A History of Medicine" By Arturo Castiglioni, New York, NY: Alfred A. Knopf, Inc., 1947, p. 565.

92 "A History of Medicine" By Arturo Castiglioni, New York, NY: Alfred A. Knopf, Inc., 1947, p. 566-567.

93 "A History of Medicine" By Arturo Castiglioni, New York, NY: Alfred A. Knopf, Inc., 1947, p. 566-567; "The Greatest Benefit to Mankind: A Medical History of Humanity" By Roy Porter, HarperCollins Publishers Ltd., 1997, p. 125-126.

94 "A History of Medicine" By Arturo Castiglioni, New York, NY: Alfred A. Knopf, Inc., 1947, p. 567.

95 *Ibid.*

96 *Ibid.*

97 *Ibid.*

98 "A History of Medicine" By Arturo Castiglioni, New York, NY: Alfred A. Knopf, Inc., 1947, p. 567; "The Greatest Benefit to Mankind: A Medical History of Humanity" By Roy Porter, HarperCollins Publishers Ltd., 1997, p. 397-400, 405-407.

99 "The Western Medical Tradition 800 BC to AD 1800" By Lawrence I. Conrad et. al., Cambridge University Press, 1995, p. 374.

100 *Ibid.*

101 "A History of Medicine" By Arturo Castiglioni, New York, NY: Alfred A. Knopf, Inc., 1947, p. 580.

102 "A History of Medicine" By Arturo Castiglioni, New York, NY: Alfred A. Knopf, Inc., 1947, p. 580-582.

103 "The Life of Sir William Osler" By Harvey Cushing, Third Impression, Vol. 1, Oxford: The Clarendon Press, 1925, p. 339.

104 *Ibid.*

105 "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.

106 "A History of Medicine" By Arturo Castiglioni, New York, NY: Alfred A. Knopf, Inc., 1947, p. 667.

107 "A History of Medicine" By Arturo Castiglioni, New York, NY: Alfred A. Knopf, Inc., 1947, p. 668; "The Greatest Benefit to Mankind: A Medical History of Humanity" By Roy Porter, HarperCollins Publishers Ltd., 1997, p. 405.

108 "A History of Medicine" By Arturo Castiglioni, New York, NY: Alfred A. Knopf, Inc., 1947, p. 668.

109 *Ibid.*

110 *Ibid.*

111 *Ibid.*

112 "A History of Medicine" By Arturo Castiglioni, New York, NY: Alfred A. Knopf, Inc., 1947, p. 668; "The Greatest Benefit to Mankind: A Medical History of Humanity" By Roy Porter, HarperCollins Publishers Ltd., 1997, p. 386-389.

113 "Theory of Valuation" By John Dewey, The University of Chicago Press, 1996.

114 "The AMA and U.S. Health Policy Since 1940" By Frank D. Campion, Chicago, IL: Chicago Review Press, 1984, p. 468.

115 "Our History, Illustrated Highlights" American Medical Association, 2009, http://www.ama-assn.org/ama/pub/about-ama/our-history/illustrated-highlights.shtml (Accessed 09/10/09).; "The AMA and U.S. Health Policy Since 1940" By Frank D. Campion, Chicago, IL: Chicago Review Press, 1984, p. 468.

116 "The AMA and U.S. Health Policy Since 1940" By Frank D. Campion, Chicago, IL: Chicago Review Press, 1984, p. 467-468.

117 "AMA: Voice of American Medicine" By James G. Burrow, Balitmore, MD: The Johns Hopkins Press, 1963, p. 252-253.

118 "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.

119 "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.

120 "Medical Essays: 1842-1882" By Oliver Wendell Holmes, New York, NY: Houghton Mifflin Company, 1911, p. 101.

121 "The AMA and U.S. Health Policy Since 1940" By Frank D. Campion, Chicago, IL: Chicago Review Press, 1984, p. 468-469.

122 "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, HarperCollins Publishers Ltd., 1997, p. 390-391.

123 "The AMA and U.S. Health Policy Since 1940" By Frank D. Campion, Chicago, IL: Chicago Review Press, 1984, p. 468.

124 *Ibid.*

125 *Ibid.*

126 "The AMA and U.S. Health Policy Since 1940" By Frank D. Campion, Chicago, IL: Chicago Review Press, 1984, p. 469.

127 "Principles and Practice of Chiropractic" By Scott Haldeman, Third Edition, McGraw-Hill, 2004, p. 112.

128 "An Osteopathic Approach to Diagnosis and Treatment" Eileen L. DiGiovanna and Stanley Schiowitz, Second Edition, New York, NY: Lippincott–Raven, 1997, p. 1.

129 "An Osteopathic Approach to Diagnosis and Treatment" Eileen L. DiGiovanna and Stanley Schiowitz, Second Edition, New York, NY: Lippincott–Raven, 1997, p. 1, -3.

130 "An Osteopathic Approach to Diagnosis and Treatment" Eileen L. DiGiovanna and Stanley Schiowitz, Second Edition, New York, NY: Lippincott–Raven, 1997, p. 3.

131 "An Osteopathic Approach to Diagnosis and Treatment" Eileen L. DiGiovanna and Stanley Schiowitz, Second Edition, New York, NY: Lippincott–Raven, 1997, p. 1, -3.

132 "A History of Medicine" By Arturo Castiglioni, New York, NY: Alfred A. Knopf, Inc., 1947, p. 742-743.

133 *Ibid.*

134 "A History of Medicine" By Arturo Castiglioni, New York, NY: Alfred A. Knopf, Inc., 1947, p. 764.

135 "Two Centuries of American Medicine: 1776-1976" By James Bordley III and A. McGehee Harvey, Philadelphia, PA: W.B. Saunders Company, 1976, p. 47.

136 "A History of Medicine" By Arturo Castiglioni, New York, NY: Alfred A. Knopf, Inc., 1947, p. 901.

137 "A History of Medicine" By Arturo Castiglioni, New York, NY: Alfred A. Knopf, Inc., 1947, p. 901.

138 "The Greatest Benefit to Mankind: A Medical History of Humanity" By Roy Porter, HarperCollins Publishers Ltd., 1997, p. 405.

139 "A History of Medicine" By Arturo Castiglioni, New York, NY: Alfred A. Knopf, Inc., 1947, p. 901; "The Greatest Benefit to Mankind: A Medical History of Humanity" By Roy Porter, HarperCollins Publishers Ltd., 1997, p. 405.

140 "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.

141 "A History of Medicine" By Arturo Castiglioni, New York, NY: Alfred A. Knopf, Inc., 1947, p. 668; "The Greatest Benefit to Mankind: A Medical History of Humanity" By Roy Porter, HarperCollins Publishers Ltd., 1997, p. 305.

142 "A History of Medicine" By Arturo Castiglioni, New York, NY: Alfred A. Knopf, Inc., 1947, p. 668-672; "The Greatest Benefit to Mankind: A Medical History of Humanity" By Roy Porter, HarperCollins Publishers Ltd., 1997, p. 305.

143 "A History of Medicine" By Arturo Castiglioni, New York, NY: Alfred A. Knopf, Inc., 1947, p. 809; "The Greatest Benefit to Mankind: A Medical History of Humanity" By Roy Porter, HarperCollins Publishers Ltd., 1997, p. 428-431.

144 "A History of Medicine" By Arturo Castiglioni, New York, NY: Alfred A. Knopf, Inc., 1947, p. 810-811.

145 "A History of Medicine" By Arturo Castiglioni, New York, NY: Alfred A. Knopf, Inc., 1947, p. 811.

146 "A History of Medicine" By Arturo Castiglioni, New York, NY: Alfred A. Knopf, Inc., 1947, p. 813; "The Greatest Benefit to Mankind: A Medical History of Humanity" By Roy Porter, HarperCollins Publishers Ltd., 1997, p. 431-435.

147 "A History of Medicine" By Arturo Castiglioni, New York, NY: Alfred A. Knopf, Inc., 1947, p. 812.

148 "A History of Medicine" By Arturo Castiglioni, New York, NY: Alfred A. Knopf, Inc., 1947, p. 829.

149 "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, New York, NY: Alfred A. Knopf, Inc., 1947, p. 843-845; "The Greatest Benefit to Mankind: A Medical History of Humanity" By Roy Porter, HarperCollins Publishers Ltd., 1997, p. 360, 374.

150 "A History of Medicine" By Arturo Castiglioni, New York, NY: Alfred A. Knopf, Inc., 1947, p. 829, 843-845, 847, 852, 853, 861-881.

151 "A History of Medicine" By Arturo Castiglioni, New York, NY: Alfred A. Knopf, Inc., 1947, p. 861-881; "The Greatest Benefit to Mankind: A Medical History of Humanity" By Roy Porter, HarperCollins Publishers Ltd., 1997, p. 381-392.

152 "A History of Medicine" By Arturo Castiglioni, New York, NY: Alfred A. Knopf, Inc., 1947, p. 698-699; "The Greatest Benefit to Mankind: A Medical History of Humanity" By Roy Porter, HarperCollins Publishers Ltd., 1997, p. 304-316.

153 "A History of Medicine" By Arturo Castiglioni, New York, NY: Alfred A. Knopf, Inc., 1947, p. 701-711; "The Greatest Benefit to Mankind: A Medical History of Humanity" By Roy Porter, HarperCollins Publishers Ltd., 1997, p. 304-316.

154 "A History of Medicine" By Arturo Castiglioni, New York, NY: Alfred A. Knopf, Inc., 1947, p. 701-711.

155 "Early History of X Rays" By Alexi Assmus, Beamline Publication, Summer 1995, p. 10.

156 "Early History of X Rays" By Alexi Assmus, Beamline Publication, Summer 1995, p. 10, 11,-18, 24.

157 "A History of Medicine" By Arturo Castiglioni, New York, NY: Alfred A. Knopf, Inc., 1947, p. 891.

158 *Ibid.*

159 "A History of Medicine" By Arturo Castiglioni, 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, HarperCollins Publishers Ltd., 1997, p. 304-316.

160 "A History of Medicine" By Arturo Castiglioni, New York, NY: Alfred A. Knopf, Inc., 1947, p. 891-899.

161 "A History of Medicine" By Arturo Castiglioni, New York, NY: Alfred A. Knopf, Inc., 1947, p. 891-892; "The Greatest Benefit to Mankind: A Medical History of Humanity" By Roy Porter, HarperCollins Publishers Ltd., 1997, p. 333-334.

162 "A History of Medicine" By Arturo Castiglioni, New York, NY: Alfred A. Knopf, Inc., 1947, p. 895-899.

163 "The Social Transformation of American Medicine" By Paul Starr, Basic Books Inc. 1982, p. 17.

164 *Ibid.*

165 "A History of Medicine" By Arturo Castiglioni, New York, NY: Alfred A. Knopf, Inc., 1947, p. 701-711.

166 "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 07/06/09).

167 "Biomarket Trends: Pharmaceutical Industry Undergoing Transformation" By Steve Arlington and Anthony Farino, Genetic Engineering and Biotechnology News, Vol. 27, No. 15, (September 1, 2007), http://genengnews.com/gen-articles/biomarket-trends-b-pharmaceutical-industry-undergoing-b-b-b/2197/ (Accessed 05/18/10).

168 "Studies Show Electronic Medical Records Make Financial Sense" By Stacy Lawrence, Sept. 14, 2005, CIO Insight, (August 2008), http://www.cioinsight.com/c/a/Health-Care/Studies-Show-Electronic-Medical-Records-Make-Financial-Sense (Accessed 5/20/10).

169 "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.

170 "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.

171 "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 02/17/10).

172 "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.

173 "Harry S. Truman Versus the Medical Lobby: The Genesis of Medicine" By Monte M. Poen, Columbia, MO: University of Missouri Press, 1979, p. ix.

174 *Ibid.*

175 *Ibid.*

176 *Ibid.*

177 "The Social Transformation of American Medicine" By Paul Starr, Basic Books Inc. 1982, p. 363.

178 *Ibid.*

179 "The Social Transformation of American Medicine" By Paul Starr, Basic Books Inc. 1982, p. 364.

180 "The Social Transformation of American Medicine" By Paul Starr, Basic Books Inc. 1982, p. 363-364.

181 "The Social Transformation of American Medicine" By Paul Starr, Basic Books Inc. 1982, p. 369.

182 *Ibid.*

183 "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. 239, 252, 256-257; "The Corporate Transformation of Health Care: Can the Public Interest Still Be Served?" By John P. Geyman, New York, NY: Springer Publishing Company, 2004, p. 1, -3.

184 "A Guide to Consulting Services for Emerging Healthcare Organizations" By Robert J. Cimasi, New York, NY: John Wiley & Sons, Inc., 1999, p. 4; "The Corporate Transformation of Health Care: Can the Public Interest Still Be Served?" By John P. Geyman, New York, NY: Springer Publishing Company, 2004, p. 1, -3.

185 "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. 239, 252, 256-257.

186 "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.

187 "A Guide to Consulting Services for Emerging Healthcare Organizations" By Robert J. 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), Accessed at http://www.mgma.com/article.aspx?id=1142 (Accessed 2/3/10).

188 "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 Michael D. Maves, American Medical Association, The Council on Health Care Economics and Policy: Sept. 10, 2004, p. 24.

189 "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.

190 "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).

191 "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. [?].

192 "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. [?].

193 "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. [?].

194 "Report to the Congress: Medicare Payment Policy" Medicare Payment Advisory Commission (MedPAC), March 2005, p. 29-32.

195 "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.

196 *Ibid.*

197 *Ibid.*

198 *Ibid.*

199 "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. 242.

200 "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.

201 *Ibid.*

202 "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.

203 "A Guide to Consulting Services for Emerging Healthcare Organizations" By Robert J. Cimasi, New York, NY: John Wiley & Sons, Inc., 1999, p. 31.

204 "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.

205 *Ibid.*

206 "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.

207 *Ibid.*

208 "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).

209 "Projected supply, demand, and shortages of registered nurses: 2000-2020" United States Department of Health and Human Services et al., July 2002, Accessed at www.ahcancal.org/research_data/staffing/Documents/Registered_Nurse_Supply_Demand.pdf (Accessed 4/10/09).

210 "Why Population Aging Matters: A Global Perspective" National Institute on Aging, et al.,http://www.nia.nih.gov/NR/rdonlyres/9E91407E-CFE8-4903-9875-D5AA75BD1D50/0/WPAM.pdf (Accessed 5/26/10).

211 "Trendwatch Chartbook 2009: Supplementary Data Tables, Utilization, and Volume" American Hospital Association, 2009, p. A.29.

212 "Health, United States, 2008 With Special Feature on the Health of Young Adults" National Center for Disease Statistics, U.S. Department of Health and Human Services, March 2009, Accessed at http://www.cdc.gov/nchs/data/hus/hus08.pdf#120 (Accessed 09/11/09).

213 "2006 National Hospital Discharge Survey" By Carol J. DeFrances et al., U.S. Department of Health and Human Services, National Health Statistics Reports, No. 5 (June 30, 2008), p. [?].

214 "Population Projections of the United States by Age, Sex, Race, and Hispanic Origin: 1995 to 2050" U.S. Department of Commerce, et. al., February 1996, http://www.census.gov/prod/1/pop/p25-1130/p251130.pdf (Accessed 12/14/05).

215 "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.

216 "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.

217 "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.

218 "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. 6.

219 "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.

220 "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. 6.

221 "Projected supply, demand, and shortages of registered nurses: 2000-2020" United States Department of Health and Human Services et al., July 2002, Accessed at www.ahcancal.org/research_data/staffing/Documents/Registered_Nurse_Supply_Demand.pdf (Accessed 4/10/09).

222 *Ibid.*

223 "Nursing, Doctor Numbers Worsen" By Gregory Lopes, The Washington Times (July 27, 2007), http://www.newser.com/archive-science-health-news/1G1-166859372/nursing-doctor-numbers-worsenbusiness.html (Accessed 04/10/09).; "Projected supply, demand, and shortages of registered nurses: 2000-2020" United States Department of Health and Human Services et al., July 2002, Accessed at www.ahcancal.org/research_data/staffing/Documents/Registered_Nurse_Supply_Demand.pdf (Accessed 4/10/09).

224 "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).; "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.

225 "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).

226 *Ibid.*

227 "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).

228 *Ibid.*

229 "What Doctor Shortages Mean for Healthcare" By Rebecca Ruiz, Forbes (December 2, 2008), http://www.forbes.com/2008/12/02/health-doctor-shortage-forbeslife-cx_rr_1202health.html (Accessed 03/27/09).

230 "Allied Health Professionals Week Highlights Workforce Shortage Crisis" Medical News Today, November 12, 2006, http://www.medicalnewstoday.com/articles/56473.php (Accessed 04/10/09).

231 "Closing the Health Workforce Gap in California: The Education Imperative" By Rebecca Hargreaves et al., The Campaign for College Opportunity, November 2007, http://www.collegecampaign.org/assets/docs/hcwfs/cco_alliedhealth_report_10-30-07_final.pdf (Accessed 04/21/09).

232 *Ibid.*

233 "'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. 36-39.

234 "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.

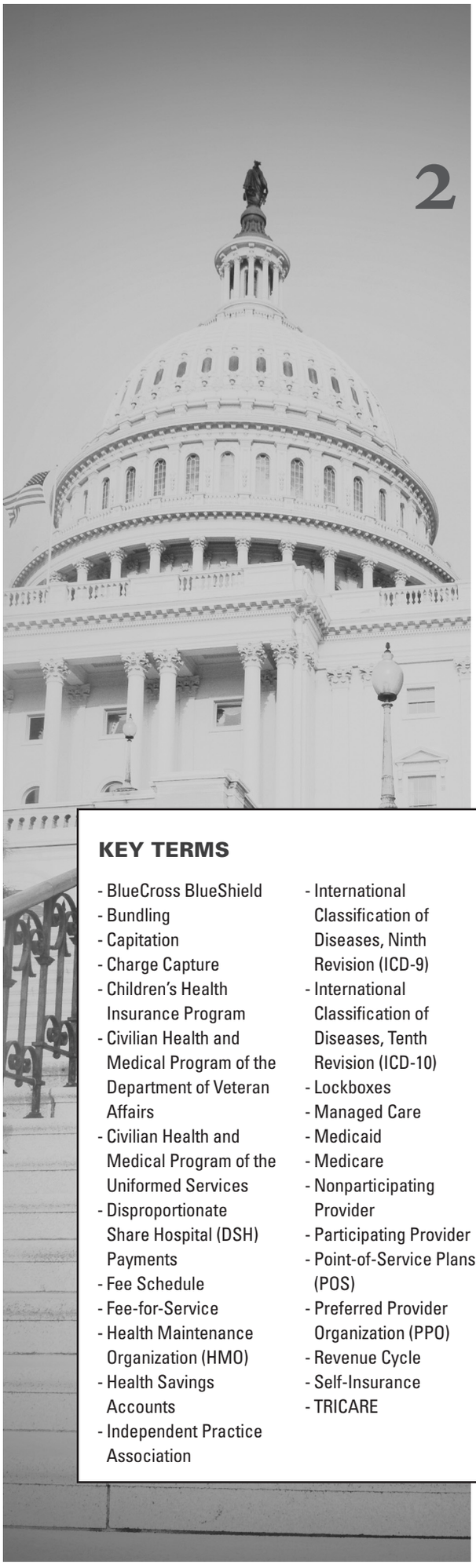
235 “No Margin, No Mission: Health-Care Organizations and the Quest for Ethical Excellence” By S.D. Pearson, J.E. Sabin and E.J. Emanuel, New York, NY: Oxford University Press, 2003, p. vii- viii.

236 “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.

237 “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.

238 “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.

239 “Futurescan: A Forecast of healthcare trends, 2003-2007” By R. Coile, Chicago, Il: Health Administration Press, 2003, p. 33.



2 Reimbursement Environment

Trust not to the omnipotency of gold, or say not unto it, thou art my confidence.

Thomas Browne, 1643

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
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.	Source: "Reimbursements" in "Medical Practice Management System" by Linda Nadeau, Thomson Delmar Learning, 2007, pg. 198; "Financial Environment of Health Care Organizations" in Essentials of Health Care Finance, Sixth Edition" by William O. Cleverley and Andrew E. Cameron, Jones and Bartlett Publishers, Inc., 2007, pg. 36–37.
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, Congressional Research Service, The Library of Congress, November 2, 2006, p. CRS-2-4.
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, White Paper Analysis of HIN Monthly E-Survey Results on Trends Shaping the Healthcare Industry" by Laura M. Greene, Healthcare Intelligence Network, May 2009.
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, 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 October 5, 2009).
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. 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 (PLI). The estimated value of malpractice cost for the service—approximately 3 percent of RVU value.	"Gauging Emergency Physician Productivity: Are RVUs the Answer," by John Proctor, MD, MBA, American College of Emergency Physicians, ACEP Reimbursement Committee, www.acep. org/practres.aspx?id=30306 (accessed April 1, 2009).
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, Sixth Edition, by William O. Cleverley and Andrew E. Cameron, Jones and Bartlett Publishers, Inc., 2007, pg. 18.
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.	"CPT Coding" in "Understanding Health Insurance: A Guide to Billing and Reimbursement, Ninth Edition" by Michelle A. Green and JoAnn C. Rowell, Delmar Cengage Learning, 2008, p. 191.
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.	"Health Law: Cases Materials and Problems," by Barry R. Furrow, et al., Third ed., West Publishing (1997), p. 845–46.
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.	"Workers' Compensation" in "Understanding Health Insurance: A Guide to Billing and Reimbursement, Ninth Edition" by Michelle A. Green and JoAnn C. Rowell, Delmar Cengage Learning, 2008, p. 532.

Key Concept	Definition	Citation
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, IHS.gov, June 2009, www.ihs.gov/PublicInfo/PublicAffairs/Welcome_Info/IHSintro.asp, (accessed August 10, 2009); "IHS Fact Sheets" by Indian Health Service, IHS.gov, June 2009, http://info.ihs.gov/QuickLook09.asp, (accessed August 10, 2009).
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, Third Edition" by Louis C. Gapenski, Health Administration Press/Association of University Programs in Health Administration, 2005, p. 35.
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.
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.
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.
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.
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.
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.
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.
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.

Overview

Healthcare reimbursement is the payment received by providers for the services they render to patients. 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.[1] 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.[2] 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.[3]

In 2007, U.S. healthcare expenditures totaled $2.2 trillion, or 16.2 percent of the gross domestic product (GDP).[4] U.S. healthcare costs have exceeded general inflation for twenty years.[5] 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 these efforts have had little success in slowing this continued growth.[6] 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, 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.

In 2007, the average healthcare expenditure per person was $7,421. Nearly a third of the money spent in 2007, 31 percent, was used to pay for hospital care. Another 25 percent was spent on dental services, home health, and other professional services; durable medical equipment, over-the-counter drugs, and other personal healthcare; and public health research, structure, and equipment. Rounding out the expenditures, physician and clinical services comprised 21 percent of the spending, prescription drugs 10 percent, program administration and net cost 7 percent, and nursing home care 6 percent. In terms of payment sources, state and federal government payors were responsible for 46 percent of these expenditures, private insurance paid for 35 percent, patients covered 12 percent out-of-pocket, and other private payors funded the remaining 7 percent of healthcare expenditures.

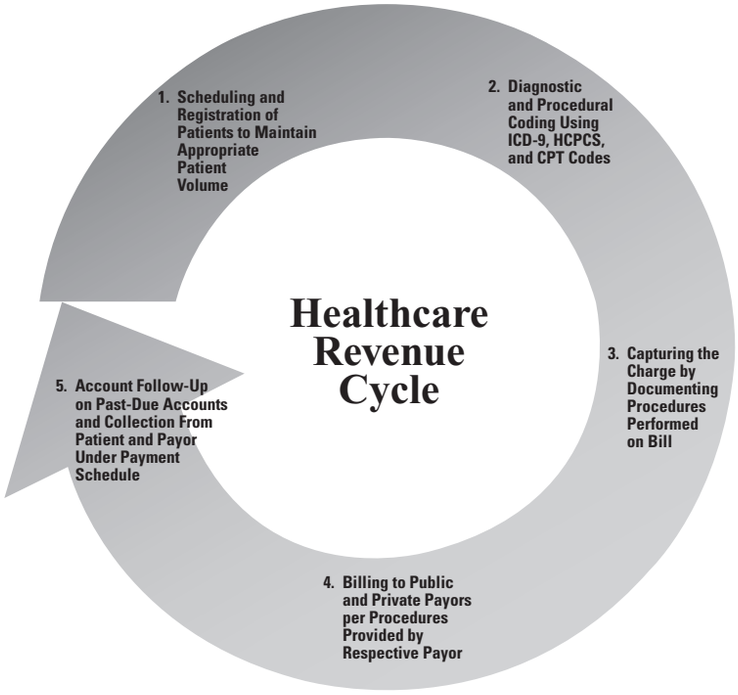
www.cms.hhs.gov/NationalHealthExpendData/downloads/PieChartSourcesExpenditures2007.pdf.

Healthcare Revenue Cycle

The **revenue cycle** describes 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.[7] See figure 2-1 for a pictorial description of the revenue cycle in healthcare.

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.[8] The importance of a practice's scheduling system should not be underestimated, as patient-physician relationships and a healthy revenue cycle depend on it.[9] 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.[10] Therefore, to maximize 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.[11]

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.[12] To ensure revenue maximization, a patient's demographic information should be verified every time the patient sees a provider.[13] 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.[14]

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.[15] 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.[16] 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.[17] An appointment system based on these criteria will ensure a workable schedule that maximizes patient satisfaction and physician efficiency.[18]

Step 2: 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.[19] 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.[20]

In the case of diagnostic services, providers typically bill for both a professional fee component and a technical component (see the following section, *Professional Component versus Ancillary Services and Technical Component*), or they may report a global diagnostic code, which is a combination of both the professional fee and technical components.[21] 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.[22]

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

www.cms.hhs.gov/NationalHealthExpendData/downloads/PieChartSourcesExpenditures2007.pdf.

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 (HIPPA)*).[23]

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, the Current Procedural Terminology (CPT-4) for physician procedures in both inpatient and outpatient settings, the Current Dental Terminology for dental procedures (to be implemented on October 1, 2013), and the National Drug Code system.[24] 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 (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.[25] Table 2-1 illustrates the coding systems used for services provided by each provider type within each setting.[26]

The most commonly implemented coding systems include: ICD-9, HCPCS, ICD-10, CPT-4, Current Dental Technology, and the National Drug Codes.

"Overview: Transaction Code Sets Standards," by Centers for Medicare and Medicaid, 04/26/2009, www.cms.hhs.gov/TransactionCodeSetsStands/ (accessed September 15, 2009).

Table 2-1: HIPAA-Designated Coding*

	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)

* "Billing and Coding for Health Services" In Essentials of Health Care Finance, Sixth Edition, By William O. Cleverley and Andrew E. Cameron, Jones and Bartlett Publishers, Inc., 2007, p. 17.

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.[27] HIPAA requires all healthcare providers to use the ICD-9 codes when reporting diagnosis information to payors.[28] In addition, HIPAA requires that hospitals use the ICD-9 procedural codes when reporting information to payors detailing the treatment of hospital inpatients.[29]

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.[30] 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.[31]

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:

- **Size.** The ICD-9 code set contains 17,000 codes and parts of the code set are running out of space, whereas the ICD-10 code set contains more than 155,000 codes and has ample room for the addition of new diagnoses and procedures.
- **Specificity.** The new ICD-10 code set provides for greater specificity when diagnosing conditions. For example, under the new system, 1,170 codes describe angioplasty, whereas the ICD-9 code set has only one.
- **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.[32]

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: employee education and training, business processes, billing documents, information technology systems, documentation, and disruptions in cash flow.[33] Although the extent of these expenditures will vary by practice, the study estimates that they will range from a little 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 100 providers, ten full time coders, and fifty-four medical records employees.[34]

> Expenditures for the shift from ICD-9 to ICD-10 is estimated to cost anywhere from $83,000 to $2.7 million, depending on the size of the practice.

"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 October 7, 2009) p. 3–4, 6.

Healthcare Common Procedure Coding System (HCPCS)

The *Healthcare Common Procedure Coding System* (*HCPCS*) provides a payor information in regard to the procedures performed in the treatment of patients.[35] The system does not relay diagnosis information.[36] Hospitals use HCPCS codes to report information on procedures performed for outpatient services; physicians use them to report information in connection with the performance of procedures in both the inpatient and outpatient settings.[37] 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 which CPT codes do not yet exist.[38]

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.[39] 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.[40]

Many times, multiple combinations of HCPCS and CPT codes apply to a particular procedure.[41] Despite the many ways in which to code for a procedure, however, providers are not allowed to separate, or "unbundle," codes for different components of a comprehensive procedure if a code exists for the entire procedure.[42] 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.[43] 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.[44] 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.[45] 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.[46] For more information on the liability associated with improper coding see chapter 3, *False Claims Act* (*FCA*).

Modifiers

Modifiers are two-digit codes added to five-digit CPT codes to clarify the services and procedures performed.[47] 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.[48] Both the AMA and CMS update the list of modifiers on a continuous basis.[49] The expansion of modifiers presents the potential for some of the same operational and financial challenges as does the expansion of CPT codes.[50] A provider's costs may increase if billing time increases and the need for staff training arises.[51] 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.[52]

Step 3: 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."[53] Capturing the charge entails the transfer of a provider's coding and documentation to the actual bill.[54] Providers are tasked with recording the appropriate procedure and diagnosis codes on an encounter form, and their business staff is responsible for ensuring that the encounter form is accurate before using it to bill patients and third-party insurers.[55]

Electronic Charge Capture

To improve **charge capture** and revenue generation, the more technologically advanced practices have begun using personal digital assistants to capture charges.[56] 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.[57] These systems help reduce errors that may occur in the capture process, and they reduce the time between service and charge entry.[58]

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.[59] Other practices hire staff to review hospital charts onsite for all patients seen by the practice's physicians.[60] 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, in order to record the relevant patient information, and from which the staff performs the relevant billing actions when the office reopens.[61]

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.[62]

Step 4: 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.[63] Many providers implement practice management systems, process 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.[64] 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.[65] Details on billing to particular payors are included in *Current Reimbursement Environment*.

Step 5: Account Follow-Up 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.[66] Thus, the revenue cycle is complete with the successful performance of the account follow-up and collection process.[67] A practice's past due accounts should be continually monitored, and when attempting to collect payment, it should use frequent phone calls, e-mails, and collection letters and other forms of communication as needed.[68]

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.[69] 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.[70]

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."[71] 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.[72]

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.[73] 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.[74] 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.[75] 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 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.[76]

Current Reimbursement Environment

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, surmounting 50 percent of total national health expenditures by 2016.[77] This prevalence of public payors in the healthcare marketplace typically tends to set the benchmark for private reimbursement rates.[78] 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).

Medicare

Overview

Medicare was created in 1965 as Title XVIII of the Social Security Act.[79] 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.[80] During the 1970s, benefits were extended to include the disabled and individuals with end-stage renal disease (ESRD).[81] 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, created under the MMA and implemented in 2006, which covers prescription drug benefits.[82] Individuals may enroll in coverage for Parts A and B, in which they pay a premium only for Part B, or they may elect to enroll in Medicare Advantage (MA), also known as Medicare Part C, managed care plan that will cover both inpatient and outpatient services. Individuals may or may not decide to enroll in Part D.[83]

Medicare reimburses providers using a combination of **fee-for-service (FFS)**, managed care arrangements, and payments from health savings accounts (HSA).[84] Medicare does not process or pay claims directly, rather it contracts with insurance companies to perform these services for them.[85] *Fiscal intermediaries* are insurance companies that handle claims for hospitals, skilled nursing facilities, intermediate care facilities, long-term care facilities, and home health agencies.[86] By contrast, *carriers* process claims for physicians, providers, and suppliers.[87] In addition, private companies provide medical and hospital coverage to enrollees of MA (Part C).[88]

Medicare reimburses for services provided to enrollees of Medicare Part A and Medicare Part B. Medicare Part A provides insurance coverage for inpatient care in acute care hospitals, critical access hospitals, and skilled nursing facilities, and Medicare Part B covers a portion of the costs associated with the beneficiary's physician services, outpatient hospital care, and other services not covered by Part A.[89] 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[90] (see chapter 3, *False Claims Act (FCA)*).

Medicare should be billed as the primary payor when:

- An employee has chose not to enroll in, or has recently dropped, his or her coverage in a group health plan;
- An employee is not yet eligible for group health plan coverage or has depleted his or her benefits under the plan;
- The insurance plan only covers the self-employed;
- The insurance plan is an individual plan and was not obtained through a group;
- The patient has coverage through TRICARE;
- 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;
- 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;
- 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); or
- The patient has both Medicare and Medicaid.[91]

Medicare administrative contractors are required to pay clean claims, that is, 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.[92] 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.[93] 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.[94] Typically, if an electronic claim is submitted, providers can receive Medicare reimbursement in fourteen days.[95]

As mentioned previously, Medicare pays for services provided by physicians, allied health professionals, nurse practitioners, and other paraprofessionals, with few exceptions.[96] In particular, Medicare makes certain distinctions for reimbursement based on the site of service of particular allied health practices. For more information on reimbursement of nonphysician providers, refer generally to topics covered in *Professional Practices*, chapters 4 and 5, and specifically to the following sections in those chapters: *Dental Reimbursement, Optometric Reimbursement, Chiropractic Reimbursement, Psychology Reimbursement,* and *Podiatry Reimbursement*.

A unique aspect of the Medicare reimbursement system is the participating physician program, which originated with the 1984 Deficit Reduction Act.[97] 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.[98] 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.[99]

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.[100]

Reimbursement and Billing

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. For reimbursement under Part A, hospitals are reimbursed under the Inpatient Prospective Payment System (IPPS) using diagnosis-related groups (DRGs) that classify patients based on the average per discharge cost of caring for their diagnosis.[101] Each DRG is assigned a relative rate based on its average cost, which is then multiplied by the input-price level of each market to determine the payment rate for the DRG.[102] In certain cases, these payments are increased for hospitals with academic medical centers or for hospitals that serve a disproportionate amount of low-income patients, although payments are reduced for some transfer cases. Finally, additional reimbursement may be paid in cases of patients who represent particularly expensive outliers.[103]

For reimbursement under Part B, hospital outpatient departments (HOPD), ambulatory surgery centers (ASCs), and physician offices are all reimbursed under distinct payment systems.[104] When physicians provide services and perform procedures in their offices, they are reimbursed under the MPFS for their professional services. When procedures are provided in hospitals or ASCs, however, they are reimbursed under both the MPFS (for the physician services) and the hospital Outpatient Prospective Payment System (OPPS), which reimburses for the cost of facilities, equipment, supplies, and hospital staff for services provided in a HOPD or ASC.[105] 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.[106] Each APC has a relative weight that reflects the median cost of services in that group.[107]

For most services performed in an ASC, payment is made under a revised ASC payment system that began implementation in 2008. The revised system bases ASC payment rates on the APC relative weights for similar services and extends payment to more surgical services in ASCs.[108] The new payment system aligns ASC reimbursement rates at a percentage of the OPPS rates.[109] Due to the need to ensure budget neutrality between the old ASC payment system and the revised system, the reimbursement rate for ASC procedures was set at 65 percent of the HOPD rate in 2008.[110] CMS cut this rate to 59 percent of the HOPD rate in 2009 and only increased the conversion factor for payments to ASCs by 1.2 percent for 2010, despite an increase of 2.1 percent for HOPDs for the same year.[111] However, CMS significantly expanded Medicare reimbursement for procedures performed in ASCs to any procedure that does not pose a significant safety risk and that would not require longer than a twenty-four-hour stay.[112]

Few procedures performed in ASCs exist that are not reimbursed at the OPPS percentage. Of these, services performed in ASCs that are generally performed in physician offices at least 50 percent of the time constitute "new, office-based procedures," which CMS began paying for in ASCs in 2008.[113] 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.[114] 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, instead applying the same reimbursement policy as for office-based procedures.[115] CMS also decided to reimburse for drugs provided in ASCs at the OPPS rate, rather than the ASC revised rate, under the same theory.[116]

Appendix A, found at the end of this chapter, shows historic changes in Medicare payments charged in the industry segments discussed in this section.

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.[117]

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 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.[118] 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.[119] The RBRVS system was implemented in 1992, and it is updated annually by the CMS.[120]

> 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.

"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. 172–73.

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.[121] 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.[122] 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.[123]

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.[124] The MPFS became effective January 1, 1992, and replaced the previous customary prevailing and reasonable (CPR) charge system with the RBRVS, which is based on estimates of resource costs incurred in an efficient medical practice.[125] 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.[126] 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 physicians who traditionally had seen higher payments to specialists and lower payments to family practitioners.[127]

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.[128] The MPFS bases its payments on a single cross-specialty RBRVS with payment determined by a procedure's relative value units (RVUs).[129]

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.[130]

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.[131]

The formula for calculating the Medicare physician reimbursement amount for a specific procedure and location is as follows: [132]

Payment = [(wRVU * GPCI work) + (RVU PE * GPCI PE) + (RVU malpractice * GPCI malpractice)] * CF

RVUs are updated annually by committees from the AMA. Committees listen to testimony from practitioners and update the RVU modifiers as necessary.[133] 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.[134] The higher the value of the code, the more skill, time, and work it takes to complete.

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 nonadministrative staff.[135] The practice expense RVU component is calculated using a bottom-up methodology in which direct costs (for example, costs than 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.[136]

The practice expense RVU component may be a different type of RVU depending on whether services were provided in a facility setting (for example, a hospital), or in a nonfacility setting (for

example, a freestanding center) because of differences in the cost of operation.[137] The formula discussed previously can therefore be rewritten as:

2009 Facility Payment Amount =

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

2009 Nonfacility Payment Amount =

Payment = [(Work RVU * Work GPCI) + (Nonfacility PE RVU * PE GPCI) + (MP RVU * MP GPCI)] * [Conversion Factor adjusted for budget neutrality][138]

Services that are billed by a nonfacility 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.[139] When a service is billed by a nonfacility, the practice expense RVU component compensates the physician's practice for the costs of owning and operating a practice, but when a service is billed by the facility, costs associated with clinical personnel, equipment, and supplies are incurred by the facility, not the practice.[140] This makes the practice expense RVU component lower.[141] The 2009 practice expense RVU components are often described as "transitioned" or "transitional," because 2009 is the third year of transition to a new methodology for calculating practice expense. The new methodology will be implemented fully in 2010.[142]

A sample set of RVU data can be found in appendix B at the end of this chapter to illustrate how to calculate the various components involved in determining compensation using this approach.

Malpractice Expense Component

Section 1848(c) of the Social Security Act, "Payment for Physician Services," requires CMS to develop resource-based malpractice RVU components as part of the method for physician reimbursement.[143] These RVUs correspond to the relative malpractice practice expense for medical procedures.[144] These values are updated at least every five years and typically comprise the smallest component of the RVU.[145] Due to the variation in malpractice costs among states and specialties, the malpractice component must be weighted geographically and across specialties.[146]

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.[147] 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.[148] There were eighty-nine GPCI payment localities as of 2009.[149]

Conversion Factor

The CF is a monetary amount that is multiplied by the RVU from a locality to determine the payment amount for a given service.[150] 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.[151] All physician services, except anesthesia services, use a single conversion factor.[152]

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 includes application of the sustainable growth rate (SGR) when determining MPFS rates.[153] Based on inflation, Medicare enrollment, growth of GDP, and regulatory developments, the SGR represents a spending target set for total annual expenditures under Medicare on Part B services, and annual adjustments are made to the MPFS based on whether actual spending came in above or below the target.[154] If actual spending is above the target, payment update rates are adjusted down; likewise, if actual spending is below the target, payment update rates are adjusted up. [155]

Table 2-2: Medicare Updates: Changes in Physician Payment*

Year	Physician Update (%)
1998	2.3%
1999	2.3%
2000	5.5%
2001	5.0%
2002	-4.8%
2003	1.7%
2004	1.5%
2005	1.5%
2006	0.2%
2007	0.0%
2008	0.5%
2009	1.1%
Average: 1998-2009	1.07%

* "Estimated Sustainable Growth Rate and Conversion Factor, for Medicare Payments to Physicians in 2010," Centers for Medicaid and Medicare Services, November 2007, p. 8, http://www.cms.hhs.gov/SustainableGRatesConFact/Downloads/sgr2010p.pdf (accessed October 10, 2009).

The SGR formula has indicated downward adjustments to the MPFS every year since 2002; however, CMS averted the adjustment in 2003, and the United States Congress has intervened and overridden the MPFS decreases to the CF for the past several years, typically replacing scheduled cuts with increases in payment.[156] The annual changes in physician reimbursement from 1998 through 2009, after Congressional intervention, are shown in table 2-2.

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).[157] 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.[158] Providers then perform the professional component when they interpret the results of those tests or write reports.[159] 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.[160]

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.[161] However, that provider may not "mark-up" the bill he or she submits for Medicare reimbursement above the amount he or she paid for the test to reflect additional professional component costs associated with reading and interpreting the test.[162] 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.[163] For example, with a group practice, both the professional component and the technical component must be performed in the same building, rather than the technical component being performed at a separate diagnostic testing facility.[164] However, the 2009 MPFS lessened the rigidity of

the 2008 MPFS rule by incorporating the following two exceptions for times when the billing physician is exempted from the "anti-markup rule:"

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.
2. The technical component is conducted and supervised in the "same building" as the medical office of the ordering physician or authorized nonphysician provider is located.[165]

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.[166] 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.[167] 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.[168] 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.[169] In cases in which physicians receive only the professional fee component, many physician owners are finding it very difficult to recover both the operating and capital expenses associated with running a practice.

Participating Providers (PARs)—Medicare Allowable Charge

In 2008, approximately 95 percent of all physicians billing Medicare were **participating providers (PARs)**.[170] To encourage physicians to enter into PAR agreements, Congress has developed special incentives including:

- direct payment of all claims;
- a 5 percent higher fee schedule than for non-participating providers (non-PARs);
- bonuses provided to Medicare administrative contractors for recruitment and enrollment of PARs;
- publication of an annual, regional PAR directory made available to all Medicare patients;
- a special message printed on all unassigned Medicare Summary Notice forms mailed to patients, reminding them of the reduction in out-of-pocket expenses if they use PARs and stating how much they would have saved by choosing PARs;
- hospital referrals for outpatient care that provide the patient with the name and full address of at least one PAR provider each time the hospital provides a referral for care; and
- faster processing of assigned claims.[171]

In 2008, 94.9 percent of all physicians billing Medicare were participating providers.

"Providers and Suppliers: Table VI.6—Medicare Participating Physician Program" in "Centers for Medicare and Medicaid Services Data Compendium" CMS/OFM, December 2008, http://www.cms.hhs.gov/DataCompendium/16_2008_Data_Compendium.asp#TopOfPage, (accessed August 18, 2009).

When a PAR bills Medicare for reimbursement 10 percent of cost (the difference between the cost of the service and the allowable fee) is written off by the PAR.[172]

Nonparticipating Providers (non-PARs)

Nonparticipating providers (non-PARs) are providers that have not agreed to accept the Medicare reimbursement amount for every claim. Yet, non-PARs are allowed to accept Medicare assignment on a claim-by-claim basis (see *Nonparticipating Providers Accepting Medicare Assignment on a Claim-by-Claim Basis*), if they agree to:

- file all Medicare claims,
- restrict their fees for non-assigned claims in accordance with the aforementioned "limiting charge,"
- forgo balance billing patients,
- collect only the patient deductible and co-insurance amounts at the time of service when accepting assignment on a claim,
- require patients to sign a "surgical disclosure notice" when charges for nonassigned surgical fees exceed $500, and
- accept assignment on clinical laboratory charges.[173]

However, it should be noted that even though they have not accepted Medicare's fee as payment in full, non-PARs are subject to a "limiting charge," which dictates what they may charge Medicare beneficiaries for covered services.[174]

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.[175] 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. The patient would be responsible for paying the PAR the remaining 20 percent, or $20. 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. Then, Medicare would pay the non-PAR 80 percent of the non-PAR fee schedule of $95, or a payment of $76. The patient would be responsible for paying the non-PAR the remaining 20 percent, or $19.

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 (see chapter 4, *Boutique and Concierge Medicine*).[176]

Nonparticipating Providers Rejecting Medicare Assignment—115 Percent of 95 Percent of Medicare Allowable Charge (100 pPercent 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.[177] 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 an amount equal to 115 percent of the allowable fee for non-PARs.[178] Thus, the provider could charge a fee equal to 115 percent of $95, or $109.25. In this instance, the provider must file the unassigned claim with Medicare, which will then write the beneficiary a check for $76, or 80 percent of the allowable fee of $95. The provider must then collect the $76 from the patient, plus the patient's 20 percent co-insurance rate, or $19, and the additional $15 that the non-PAR was allowed to bill because he or she chose not to accept assignment on the claim. 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 (see chapter 4, *Boutique and Concierge Medicine*).

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.[179] 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.[180]

These parameters determine mandatory eligibility groups and mandatory services, that is, the groups and services the state must cover to receive federal Medicaid money.[181] In addition to individuals below a certain income threshold, the federal government mandates that states offer Medicaid coverage to children six and older whose families earn below 100 percent of the federal poverty level, children under age six below whose families earn 133 percent of the federal poverty level, parents who earn below their state's welfare eligibility cutoff for 1996 (roughly 50 percent of the federal poverty level), pregnant women earning at or below 133 percent of the federal poverty level, elderly and disabled individuals earning at or below 74 percent of the federal poverty level who are receiving Supplemental Security Income, certain working disabled individuals, and Medicare buy-in groups.[182]

In addition to mandatory groups and services, states may also receive federal funds for covering other "optional" groups and services.[183] 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.[184] Additionally, many states extend Medicaid benefits to individuals with significant recurring healthcare expenses and long-term healthcare needs.[185]

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.[186] Mandatory services include physician services; inpatient and outpatient hospital care; skilled nursing facility care; laboratory and x-ray services; early and periodic screening, diagnostic, and treatment services for individuals under the age of twenty-one; family planning and supplies; federally qualified health center services; rural health clinic services; nurse midwife services; certified pediatric and family nurse practitioner services; nursing facility services for individuals age twenty-one and older; and home health services for individuals entitled to skilled nursing facility care.[187] Optional services, by contrast, may include prescription drugs, dental services, and medical care provided by allied health professionals and

other nonphysician providers.[188] It is important to look at a particular state's Medicaid coverage manual to determine which optional groups and services that state covers.

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.[189] Enacted under the Balanced Budget Act of 1997, and formerly known as SCHIP, CHIP covered approximately 4.8 million children in 2008, which is in addition to the number of children already covered under Medicaid (22.6 million in 2008).[190]

CHIP covered approximately 4.8 million children in 2008 which is in addition to the number of children already covered under Medicaid (22.6 million in 2008).

"Monthly CHIP Enrollment," by Kaiser State Health Facts, http://www.statehealthfacts.org/comparemaptable.jsp?ind=236&cat=4&st=3 (accessed October 6, 2009); "Monthly Medicaid Enrollment for Children," Kaiser State Health Facts, www.statehealthfacts.org/comparemaptable.jsp?ind=612&cat=4 (accessed October 6, 2009).

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.[191] 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.[192]

After a temporary reauthorization of the program in 2007, the Children's Health Insurance Program Reauthorization Act of 2009 (CHIPRA) most recently reauthorized SCHIP through September 2013.[193] It is estimated that CHIPRA could extend CHIP and Medicaid coverage to 6.5 million children by 2013.[194] CHIPRA extends previous SCHIP coverage by now including dental services under the CHIP program, and it requires states offering coverage for mental health and substance abuse to have mental health parity.[195]

Billing and Reimbursement

Reimbursement for services provided to Medicaid patients are paid by states on either a FFS basis or under a pre-paid managed care arrangement.[196] The Medicaid program requires the use of the CMS-1500 claim form when seeking FFS reimbursement.[197] Providers should consult their state's Medicaid managed care organization (MCO) billing manual in order to determine how to bill for noncapitated managed care services, as these procedures may vary by state.[198] Deadlines for filing a Medicaid claim range from two months to one year from the date of treatment.[199] 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.[200] 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.[201]

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 disproportionate share hospitals (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.[202]

Thus, states may impose deductibles, co-insurance, or co-payments on certain recipients for particular services.[203] 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.[204] Medicaid reimburses on a lump-sum basis, meaning providers will receive one payment for several submitted claims.[205]

Medicaid is considered the "payor of last resort."[206] Thus, 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.[207] Claims should only be submitted to Medicaid if one of the other payors denies responsibility for payment or 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.[208]

Disproportionate Share Hospital (DSH) Payments

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.[209] DSH payments are allotments from the federal government which augment basic Medicaid reimbursement, and under federal law, states are required to supplement DSHs in order to receive this additional Medicaid funding.[210] DSH payments are intended to supplement hospitals when costs are not adequately covered by traditional Medicaid and Medicare payments, by SCHIP payments, or by other health insurance.[211]

DSH payments are calculated differently for each state according to a statutory formula, but no state receives more than 12 percent of its annual total Medicaid benefits in DSH allotments.[212] The states with the highest DSH allotments are California, New York, Texas, Louisiana, and New Jersey.[213] 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.[214] The only limit on this discretion is that a state may not distribute DSH payments to any hospital with a Medicaid utilization rate less than 1 percent, and 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.[215] If a state wants to distribute DSH payments to additional hospitals, it is free to do so; however, the state must distribute payments at a rate in line with the Medicaid DSH payment methodology or based on the hospital's low-income utilization rate.[216]

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.[217] The program uses military healthcare as the main provider of services, and supplements it with civilian healthcare providers, facilities, pharmacies, and suppliers.[218] TRICARE covers approximately 9.4 million beneficiaries worldwide through a variety of plans, including FFS and managed care plans.[219]

Billing and Reimbursement

TRICARE reimburses providers for services rendered to beneficiaries using both FFS and managed care arrangements.[220] 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.[221] 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.[222] Providers seeking reimbursement must submit claims using the CMS-1500 claim form within one year from the date the services were rendered.[223]

TRICARE offers a variety of programs with different beneficiary cost-sharing requirements, including co-insurance, annual enrollment fees, co-pays, catastrophic caps, and deductibles.[224] 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.[225] 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.[226] 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.[227] A potential downside to not accepting TRICARE's allowable fee schedule is that the beneficiary files the claim using DD Form 2642 and is reimbursed by TRICARE.[228] Thus, the provider must attempt to collect the entire bill from the beneficiary, which is not always an easy task. TRICARE takes pride in the timeliness of its claims processing, paying more than 99 percent of claims in thirty days and all claims within sixty days.[229]

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.[230] In addition, TRICARE will not pay for occupational injuries or diseases covered by workers' compensation laws unless these benefits have been exhausted.[231] Thus, 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.[232] 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.[233]

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.[234] All claims for reimbursement must be submitted to the CHAMPVA Health Administration Center within one year from the date of service.[235] Claims submitted by providers should use the CMS 1500 or the UB-04 (institutional providers) forms, and an itemized list of charges for each service must accompany every claim.[236]

CHAMPVA typically does not sign contracts with providers.[237] Instead, providers elect to participate in the program by either submitting a claim or agreeing to treat a beneficiary.[238] 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.[239] 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.[240] In these instances, the patient is responsible for paying the entire bill and submitting a claim to CHAMPVA for reimbursement up to the allowable amount.[241] CHAMPVA reimburses more than 95 percent of their claims within thirty days.[242]

It is important for providers to understand the relationship among payors, because CHAMPVA assumes the role of both primary and secondary payor. 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 payor and all claims should be filed with CHAMPVA first.[243] 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.[244]

Other Public Payors

Workers' Compensation

Federal and state laws mandate that employers provide workers' compensation coverage for their employees.[245] *Workers' compensation laws* provide 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.[246] In addition, the laws limit the financial liability of employers, and they nearly eliminate the financial liability of co-workers for most accidents.[247]

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.[248]

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.[249] Depending on the state, employers can comply with workers' compensation laws by obtaining coverage through:[250]

- *State insurance (or compensation) funds*—Agencies that provide workers' compensation insurance coverage to both public and private employers.
- *Self-insurance plans*—Plans under which employers set aside a percentage of capital funds to cover expenses that may arise.
- *Commercial workers' compensation insurance*—Policies purchased from commercial insurance companies.
- *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 Program Act.[251] A modified version of the fee schedule is used to reimburse providers treating patients covered under the Federal Black Lung Benefits Act.[252] The OWCP's schedule is based in part on the fee schedule developed by CMS with some program specific adjustments.[253] 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.[254] In addition, various forms, progress reports, and supplemental reports may be required as well.[255] 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.[256]

> Medicare claims for physician services must be submitted using the CMS-1500 claim form, whereas ambulance companies, ambulatory surgery centers, home health agencies, hospice organizations, hospitals, psychiatric drug or alcohol treatment facilities, skilled nursing facilities, sub-acute facilities, stand alone clinical or laboratory facilities, and walk-in clinics must submit the UB-04 claim form. Medicare claims must be filed before December 31 of the year in which the services were provided, except in instances in which the service was provided between October 1 and December 31. These claims receive an extension, and must be filed before December 31 of the following year.

"Understanding Health Insurance: A Guide to Billing and Reimbursement, Ninth Edition" by Michelle A. Green and JoAnn C. Rowell, Delmar Cengage Learning, 2008, p. 305, 449.

Most state workers' compensation programs reimburse providers using a fee schedule based on RUVs established by the state compensation board or commission, but some states have developed managed care plans, as well.[257] The claims forms, progress reports, and supplemental reports used, as well as the filing deadlines for them, vary from state to state.[258]

Providers treating patients eligible for coverage under workers' compensation programs must accept assignment, meaning they must accept the compensation as payment in full.[259] Patients covered by workers' compensation programs are charged no fees at the time of treatment; they pay no deductible and no co-payment.[260] In addition, the patient's employer pays all premiums.[261]

Indian Health Services (IHS)

The *Indian Health Services* (*IHS*) *Agency* is located within HHS.[262] The agency 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.[263] Most of the agency's resources fund the care of American Indians or Native Alaskans living on or near reservations or Alaskan villages.[264] However, Congress has provided some funding for programs for eligible individuals in urban areas as well.[265]

Billing and Reimbursement

On occasion, IHS needs to purchase healthcare services from private providers.[266] 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.[267]

Typically, IHS pays providers for these services in accordance with the terms of the negotiated contract.[268] 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.[269] Providers should submit their claims to the IHS fiscal intermediary, Blue Cross Blue Shield (BCBS) of New Mexico, using the appropriate claim form.[270]

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."[271] The contract standards between IHS and BCBS of New Mexico call for 95 percent of clean claims submitted to the IHS fiscal intermediary to be completed within twenty-one days.[272]

Private Payors

Private health insurance consists of commercial insurers, BCBS plans, MCOs, and self-funded plans. In 2007, private health insurance financed 35 percent of the amount spent on personal healthcare.[273]

Commercial Insurers

Overview

Commercial health insurers entered the health insurance market in the 1940s.[274] *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.[275] *Commercial insurers* are taxable entities organized as either mutual or stock insurers.[276] Mutual insurance companies are owned by their policyholders, whereas stock insurance companies are owned by their stockholders.[277]

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.

Billing and Reimbursement

To compete in today's health insurance market, many commercial insurers offer a variety of plan options. Thus, 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.[278] Thus, 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.

Blue Cross Blue Shield

Overview

Blue Cross began providing private health insurance in 1929 by offering coverage for hospital expenses.[279] Blue Shield began providing insurance to cover expenses associated with physicians' services in 1939.[280] 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).[281] Today, the BCBSA consists of thirty-nine independent BCBS companies.[282] 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.[283]

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.[284] 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.[285]

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.[286]

Billing and Reimbursement

BCBS reimburses providers using a variety of FFS payments and managed care arrangements.[287] The allowable fee varies based on the plan—some plans use the physician fee schedule and others use a "usual, customary, and reasonable" system to determine the amount commonly charged by providers in the region.[288] BCBS requires PARs to accept the allowable fee as payment in full.[289] Non-PARs may collect their full fee from the patient, who will in turn receive payment directly from BCBS.[290]

Depending on the enrollee's coverage and the services sought, patients usually are subject to deductible and co-pay requirements, with co-pay amounts commonly ranging from 20 percent to 25 percent.[291] 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.[292] Although reimbursement

for claims processed by BCBS varies by plan, some plans pay electronically submitted claims within fifteen days.[293]

Managed Care

Overview

Managed care plans integrate the financing (that is, insurance) and provision of health services under the administration of one MCO in an effort to contain costs.[294] 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.[295]

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.[296] 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 responsible for providing, or arranging for the provision of, healthcare services (including preventative care) for plan enrollees by way of contractual arrangements with providers.[297] The HMO structure benefits health plans, enrollees, and providers.[298] 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. Enrollees receive the benefit of little or no deductibles 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.[299]

> 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.

"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.

HMO enrollees must receive all of their care from the plan's PARs except for care provided in emergency situations or in instances in which the plan offers a POS option.[300] 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.[301] In addition, because enrollees are typically limited to seeking care from the plan's PARs, HMOs do assume responsibility for quality assurance and are able to transfer some of the financial risk to their preferred providers.[302]

The following are common forms of HMOs:[303]

1. *Staff model HMOs* directly employ all the physicians who provide healthcare services to plan enrollees.
2. *Group model HMOs* contract with one physician practice to provide care to plan enrollees.
3. *Network model HMOs* contract with many independent physician practices that may also treat other patients who are not enrolled in the plan.
4. **Independent Practice Association** *HMOs* contract with 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.

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.[304] 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.[305] 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.[306]

> 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."
>
> *"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).*

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.[307] 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.[308] Also different from HMOs, PPOs do not transfer financial risk to their preferred providers.[309]

Point-of-Service (POS) Plans

Point-of-service (POS) plans combine many of the elements of HMOs and PPOs.[310] POS plans are usually an addition to an HMO product that allows members the benefit of seeking care from non-PARs.[311] As with an HMO, when members seek care from in-network providers they typically pay no deductible or coinsurance.[312] 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.[313] Although the cost is higher, this freedom of choice is why many consider POS plans to be the least restrictive form of managed care.[314]

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.[315] This primary care physician is also responsible for referrals to specialists and hospitals.[316] 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.[317]

Reimbursement

Types of Managed Care Reimbursement

MCOs 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 FFS.[318]

Capitation

In order to reduce healthcare service utilization, MCOs have passed some of their risk to providers in the form of **capitation**.[319] 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. 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.[320] These decisions need to be based on actuarial or historical data to determine an appropriate capitation amount and acceptable amount of risk to the organization.[321]

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.[322]

Full Risk Capitation

Full risk capitation occurs when a healthcare plan, facility, or provider accepts the entire financial risk for a plan's members.[323] However, due to the significant risk involved, any medical group undertaking full risk capitation must have strong financial management skills and management information systems.[324] In absence of such safeguards, many MCOs will refuse such arrangements in order to avoid the risk of failure.[325] Usually, large groups or an organized system of providers are best suited to support full risk capitation.[326]

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.[327] 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.[328] Similarly, capitation rewards provider activities that strive for high clinical quality and customer service.[329] 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.[330] As a result, organizations have moved toward reimbursing their providers using a per-member-per-month capitation system in combination with FFS payments for specified procedures in an attempt to better balance the multiple objectives of encouraging individual productivity and clinical cooperation.[331]

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.).[332] Critics condemn FFS systems, stating that physicians tend to over-treat patients upcode andunbundle services in order to receive higher reimbursement.[333] Nonetheless, FFS systems are often used as an incentive for healthcare providers to join an MCO in markets where managed care penetration is low.[334]

MCOs 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.[335]

Specialty Care Reimbursement

The most commonly utilized reimbursement methods for specialty care physicians (SCPs) are risk-based models: FFS and capitation.[336] 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.[337]

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.[338] 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 payment*, a fixed percentage of the bill the patient is required to pay after meeting their deductible, is required instead.[339] It should be noted that all providers are typically 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.[340] In turn, HMOs use these claims to adjust rates and track the quality of care.[341]

PPO Billing

PPOs contract with providers to render services to the plan's enrollees on a reduced fee basis.[342] 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.[343] 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.[344]

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.[345] 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.[346] 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.[347]

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 begun to implement "defined contribution" health insurance plans instead of the traditional "defined benefit" plans.[348] The goal is to model health insurance programs after "defined contribution" pension programs, such as 401(k)s.[349] 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.[350]

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.[351] 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 from whom to purchase them.[352] 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.[353]

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.[354] 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.[355]

Individuals excluded from HSA eligibility are those covered by insurance other than a HDHP, those who can be claimed as a dependent on someone else's tax return, veterans who have received medical care or prescription drugs from a VA facility within the last three months, active duty military personnel, and Medicare recipients who did not have an HSA prior to enrolling in Medicare.[356] However, an individual is not precluded from enrolling in an HSA if he or she has automobile, dental, vision, disability, or long-term care insurance or is covered by an employer wellness plan, as long as the wellness plan does not pay for a significant portion of one's medical care.[357] In addition, enrollees are allowed to have insurance coverage for a specific disease or illness, as long as the coverage, when invoked, pays only a set monetary amount.[358] 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.[359]

Legislative Support

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.[360]

However, legislative support for HSAs has waned a bit under President Barack Obama's administration, as lawmakers struggle to develop a comprehensive plan for national healthcare reform. A common theme in the new administration is the setting of tighter limits on contributions to HSAs and the increasing oversight of how the money is spent.[361]

Prevalence and Growth of HSAs

According to a 2009 census conducted by America's Health Insurance Plans (AHIP), the number of individuals covered by HSAs and HDHPs has increased steadily every year since their inception, with just more than eight million individuals covered as of January 2009.[362]

According to a 2009 census conducted by America's Health Insurance Plans (AHIP), the number of individuals covered by HSAs or HDHPs has increased steadily every year since the plans were established, with just more than eight million individuals covered as of January 2009.

"January 2009 Census Shows 8 Million People Covered By HSA/High-Deductible Health Plans" by Anna Yoo, America's Health Insurance Plans, ahipresearch.org, May 2009, www.ahipresearch.org/pdfs/2009hsacensus.pdf, (accessed August 27, 2009).

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."[363] 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.[364] 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.[365] 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.[366]

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.[367] 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.[368] Often, a self-insurer will hire a commercial insurer or third-party administrator to run its medical benefits program and adjudicate claims.[369]

Self-insurance plans vary by the amount of risk an employer is willing to assume.[370] In a fully self-funded plan, the employer undertakes the responsibility for 100 percent of the healthcare expenses submitted for reimbursement.[371] 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.[372] However, employers with fewer than 5,000 employees often are unwilling to assume the risk of funding their entire health insurance program.[373] Thus, these employers may opt for a partially self-funded plan.[374] The most common type of partially self-funded plans is the "minimum premium plan."[375] Under a *minimum premium plan*, the employer covers claims up to a predetermined amount, and an insurance policy assumes liability for claims thereafter.[376] Another popular form of partially self-funded plans involves combining self-funding with stop-loss insurance.[377] 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.[378]

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.[379] In addition, because self-insurance technically is not insurance, state taxes assessed on premium revenue can be avoided.[380] 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.[381] 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.[382]

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 POS.[383] However, some states may prohibit a self-insured employer from signing capitated contracts with physicians.[384] 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.

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.[385] In addition, most private insurers have the bargaining power to negotiate discounts.[386] However, most self-pay patients will lack the ability to set their payment amount or negotiate lower charges, and as a result, at times, they have been presented with bills up to two and a half times higher than what public or private insurers would pay for the same procedure.[387] 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.[388] 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 the provider will have to write off the visit as bad debt.[389] 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.[390]

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 by an array of payment sources using a variety of payment methods, FFS, capitation, and self-pay, all of which can affect financial performance.[391]

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.[392] 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.[393] 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 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 a FFS basis, practice revenues increase as patient visits and the intensity of the services provided increase.[394] 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.[395] 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.[396]

Emerging Reimbursement Trends

Move Toward Capitation

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 without the requisite economic and actuarial skills.[397] A recent 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.[398] 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.[399]

However, beginning in 2008, it appears that capitation as a replacement for FFS may be making a comeback. The resurgence was led, at least in part, by BCBS of Massachusetts and its "Alternative Quality Contract" (AQC).[400] 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 offers providers the opportunity to earn substantial rewards for quality.[401] The new contract reimburses 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.[402]

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."[403] 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.[404] The commission recommended that the payment model include, in addition to other features, accountable care organizations (ACO), consisting of hospitals, physicians or other clinicians, and nonclinicians, 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.[405]

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 and the subsequent leadership under the Obama administration. Twenty-first century reform efforts share many common themes, all aimed at combating the problems of uninsured individuals and the rising cost of services.[406]

A significant amount of reform rhetoric has been 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.[407] However, there has been resistance to that idea, and at least one proposal includes the possibility of creating a nonprofit consumer owned and operated health insurance plan instead of a public option.[408] Further, many reform proposals include provisions to penalize individuals who fail to obtain health insurance coverage, though at least one proposal includes subsidies for the purchase of health insurance with tax credits.[409]

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 either provide health insurance for their employees or contribute to a fund on their behalf.[410]

To control costs, one proposal would implement the use of ACOs and medical homes, as well as bundle provider payments for acute and post-acute care and simplify paperwork.[411] In addition, the plan would require the restructuring of physician payments under Medicare by eliminating the SGR and through rewarding primary care services, care coordination, and efficiency.[412]

Increased Emphasis on Quality: Pay-for-Performance (P4P) and Gainsharing

Pay-For-Performance

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 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.[413]

> A 1999 study from the Institute of Medicine (IOM) reported that as many as 44,000–98,000 deaths may be linked directly to medical errors.
>
> *"Errors in Health Care: A Leading Cause of Death and Injury" in "To Err is Human: Building a Safer Health System" edited by Linda T. Kohn, Janet M. Corrigan and Molla S. Donaldson, Committee on Quality Health Care in America, Institute of Medicine, 2000, p. 26.*

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.[414] 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.[415] 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.[416]

P4P's Impact on Practice Revenue

The impact of P4P on quality outcomes has been demonstrated by two distinct studies. A 2003 study conducted by CMS and Premier, Inc., measured cost and quality improvements among P4P providers for five different patient populations.[417] 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."[418]

A second study, conducted by researchers from University of California, Los Angeles, and supported by the Hawaii Medical Service Association in Honolulu, showed improved quality of care among P4P providers in PPO settings, as well as an increased number of patients going to P4P physicians.[419] The study analyzed eleven quality indicators for patients enrolled in PPOs over six years and found that the patients who visited only physicians who were participating in the study had significantly higher odds of receiving recommended care as measured by the indicators.[420]

However, some providers are worried that the transition from a FFS payment system to a P4P model could have a profound impact on practice revenue. Providers may have to undertake the time consuming process of hand collecting and reviewing the data needed to satisfy reporting requirements or make a significant capital investment in an electronic health records system.[421] 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.[422] 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.[423]

Healthcare Professional Practice Gainsharing Arrangements

The term "gainsharing" refers to a shared savings program "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."[424]

History and Background

In 2008, CMS proposed a new exception to the Stark law for certain incentive payment (that is, P4P) and shared savings programs, including gainsharing arrangements.[425] An exception to the Stark law is necessary, despite the fact that successful gainsharing programs can foster high quality, cost-effective care, because the arrangements involve making payments to physicians whose efforts contribute to these successes. The concern is that "improperly designed or implemented programs pose [a high risk of program or patient abuse]," and that "additional risk is posed by [gainsharing arrangements] that reward physicians based on overall cost savings without accountability for specific cost reduction measures."[426] Recognizing the potential for abuse, but also the potential to improve quality and cost effectiveness, the proposed exception to the Stark law for properly structured gainsharing arrangements focuses on three crucial aspects: transparency, quality controls, and safeguards against payments for referrals.[427]

Office of the Inspector General's (OIG's) Denial and Subsequent Approval

Historically, gainsharing arrangements were found to violate the civil monetary penalty statute and the antikickback statute, despite the potential cost-saving benefits of well-structured arrangements.[428] In 2005, however, the Office of Inspector General (OIG) began to approve gainsharing arrangements in light of their cost-saving and quality improving potential, despite the fact that the basic arrangements themselves were still *technical* violations of the statutes, reasoning that the potential for fraud was reduced when certain safeguards were present.

In those arrangements that it approved, the OIG looked for three types of safeguards: (1) measures that promote accountability and transparency, (2) adequate quality controls, and (3) controls on payments related to referrals.[429] To this end, in 2008, OIG approved an existing arrangement between a hospital and four cardiology groups and one other radiology group that sought to pay the physicians a portion of cost savings resulting from physician efficiency.[430] The cost savings paid to physicians were derived from the use of supplies and equipment during certain procedures.[431] Savings were created through the standardization of procedures and reduction in the inappropriate use of supplies and medical devices.[432] Although the agreement could have led to illegal payments to physicians, the transparency of the calculated payments, a cap on the amount of payments, and the fact that there was found to be no encouragement for physicians to reduce services, resulted in the OIG declining to issue sanctions against the group thereby permitted their gainsharing arrangement.[433]

Legislative Parameters and Safeguards

To be protected under the exception to the Stark law proposed by CMS, a gainsharing arrangement must abide by the following requirements. These also represent common elements considered by the OIG when reviewing a gainsharing arrangement.

1. The arrangement must include patient care quality or cost savings measures (or both) which are in CMS's Specifications Manual for National Hospital Quality Measures and supported by objective, independent medical evidence indicating that the measures would not adversely affect patient care.
2. The arrangement must employ cost savings measures that use an objective methodology, are verifiable, supported by credible medical evidence indicating that the measures would not adversely affect patient care, can be traced individually, and reasonably relate to the services provided.
3. The arrangement must be able to be reviewed prior to implementation and at least annually thereafter to ascertain the program's impact on patient quality of care. Such reviews must be independent medical reviews conducted by a person or organization with relevant clinical expertise.
4. The arrangement must provide for immediate and corrective action (up to and including termination of the program) in the event a review reveals an adverse impact on quality.
5. The arrangement must limit participation in the program to those physicians who are members of the hospital's medical staff at the commencement of the program. Participating physicians participate in "pools" of five or more (formed at the commencement of the program) among whom the aggregate cost savings that result from the efforts of the physicians in the "pool" be shared on a per capita basis.
6. The arrangement must support the distribution of shared savings program payments with written documentation.
7. The arrangement may not determine eligibility for physician participation in the program based on the volume or value of referrals or other business generated between the physician the hospital.
8. The arrangement may not limit the discretion of physicians to make medically appropriate decisions for their patients, nor may it limit the availability of, or access of physicians to, any specific item, supply, or device that is linked through objective evidence to improved outcomes, is clinically appropriate, and was available at the commencement of the program.[434]

Payments made under shared savings programs

1. must be distributed on a per capita basis,
2. may not include any amount that takes into account the provision a greater volume of federal healthcare patient procedures or services than the volume provided by the participating physician or qualified physician organization during the period of the same length immediately preceding the commencement of the program as that covered by the payment, and
3. must be limited in duration (no shorter than one year and no longer than three years) and amount.[435]

Two potential ways to limit amount of payments exist, one or both of which may be adopted:

1. limits based on set percentages of cost savings available to hospital through program, and
2. limits to address the risk that physicians will continue to receive financial rewards for already implemented changes.[436]

Also, arrangements in which physicians receive payments for actions taken that result in a reduction below a predetermined target based on objective historical and clinical measures will not be protected.

Additionally, CMS is considering whether to extend the exception for qualified physician organizations to multispecialty physician practices composed of both PARs and non-PARsparticipating and nonparticipating physicians. To promote transparency, hospitals and participating physicians will be required to disclose the nature of the program to patients affected by it.

Requirements related to transparency include:

1. tracking of the ages and payors of the patient population treated by participating physicians (to prevent cherry picking, etc);
2. limiting physician payment to only that which is related to the physician's own efforts, combined with the efforts of the other physicians in their pool, on a per capita basis;
3. applying all measures uniformly to all patients, including Medicare beneficiaries (and not applying them disproportionately to federal healthcare program beneficiaries), with the possibility of having the program audited; and
4. prohibiting the counseling or promotion of a business arrangement or other activity that violates any federal or state law.[437]

Increased Reimbursement to Encourage Implementation of Electronic Health Records (EHR)

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).[438] 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.[439] As part of this process, the HITECH Act officially established the Office of the National Coordinator for Health Information Technology (ONCHIT) and HIT Policy and Standards Committees to recommend, develop, and promote a national HIT infrastructure.[440]

In particular, the HITECH Act permits the secretary of HHS to appropriate funds each year, beginning 2009 through 2013, to promote the implementation of EHR.[441] Under the act, nonhospital-based physicians will receive financial incentives or penalties through Medicare for use or nonuse of EHRs. Beginning in 2011, eligible professionals can receive incentive payments of 75 percent of allowed Medicare charges to a total maximum of $44,000 over a five-year period if meaningful use of an EHR system begins by 2012.[442] Adoption by 2013 reduces the total maximum charges to $39,000, and adoption by 2014 reduces the total maximum charges to $24,000.[443] Beginning in 2015, practitioners not adopting meaningful EHR use will receive a 1 percent reduction in their MPFS payment.[444] This will increase to a 2 percent penalty in 2016 and 3 percent penalty in 2017. The secretary of HHS will have the discretion, if less than 75 percent of practitioners have not adopted meaningful use of EHRs before 2018, to raise the penalty to as high as 5 percent. Medicaid providers will also receive incentives.[445]

Similarly, hospitals will receive millions of dollars in increased reimbursement under Medicare and Medicaid for successfully implementing HIT and certified EHR systems.[446] Additionally, rural health clinics, federally qualified health centers, and other providers other than physicians and hospitals will be

eligible for incentive funding under Medicaid or through grants offered for the implementation of EHR systems.[447]

Although the term "meaningful use" has yet to be defined, it would include electronic prescribing, information exchange between systems, qualitative reporting methods, additional coding of the use of and EHR system, and the ability to complete survey responses in the system.[448] ONCHIT would set standards for EHS systems for the hospital setting and the Certification Commission for Health Information Technology would certify software meeting this definition. In 2011, funding will become available for Medicare ($23.1 billion) and Medicaid ($21.6 billion) incentives.[449]

A total of $1.5 billion will go toward federal grants for the implementation of EHR systems and capital improvements of EHR systems.[450] In 2011, for every $10 the federal government provides toward state planning and implementation grants to promote HIT, the state must provide $1. In 2012, this ratio drops to seven to one. Starting in 2013, for every $3 of federal grant money the state must provide $1.[451]

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 2008, there were 17 million plastic surgery procedures performed in the United States, a number up 3 percent from the previous year.[452] Of these, 12.1 million were cosmetic procedures, divided between surgical (1.7 million) and minimally-invasive (10.4 million), while 4.9 million were reconstructive procedures.[453]

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.[454] Because aesthetic procedures are elective surgeries, they generally are not covered by health insurance plans.[455]

By contrast, *reconstructive* procedures are necessary for the correction of physical disfigurement or function or to restore a normal appearance following trauma or disease.[456] Examples include skin grafts and the rebuilding of bones for burn and accident victims.[457] 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.[458]

When procedures that typically are classified as cosmetic are medically necessary to correct a problem or relieve symptoms (for example, a patient needs rhinoplasty to correct a breathing problem), insurance carriers may treat that procedure as reconstructive and cover part or all of the cost of the surgery.[459] 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.[460]

Like most private payors, Medicare and Medicaid do not cover cosmetic procedures that are not medically necessary.[461]

Concierge Medicine

Recent years have seen the emergence of the practice of concierge, or boutique, medicine. Although this trend is further explored in chapter 4, *Boutique and Concierge Medicine*, and in chapters 1 and 2 of *Professional Practices*, 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.[462]

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."[463] 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.[464]

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.[465]

In addition to being endorsed by various medical associations, the medical home model has gained the attention of the federal government. The Tax Relief and Health Care Act of 2006 mandated a Medicare medical home demonstration project to measure the effectiveness of the model.[466] The two-year project will examine the efficacy of "targeted, accessible, continuous, and coordinated care to Medicare beneficiaries with chronic or prolonged illnesses requiring regular medical monitoring, advising, or treatment" and is slated to run from 2010 through 2012.[467] This reform initiative is also discussed in chapters 2 and 3 of *Professional Practices*—as well as various sections in chapter 2 of *Professional Practices*.

Payment Bundling

Bundling is a method of reimbursement that combines institutional and professional charges into a single payment (see chapter 4, *Physician or Provider Suppliers*, and chapter 2 in *Professional Practices*).[468] Recently, several proposals have been 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. This trend is demonstrated 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.[469] Further, CMS has also created a pilot program to examine the benefits of bundling Part A and Part B Medicare payments.[470]

The intent of the Senate Finance Committee's proposal is 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 would include 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."[471]

In addition to the Senate Finance Committee's proposals, the Acute Care Episode Demonstration (ACE) project is a pilot program developed by CMS to provide for greater efficiencies and continuity of care amongst Part A and Part B providers (also discussed in chapter 2 of *Professional Practices*). The three-year program effectively eliminates the MPFS and provides one, global payment under the IPPS. The new, bundled payment will cover both hospital and physician fees for one "episode of care" for cardiovascular or orthopedic procedures. Participating sites (referred to as "Value-Based Care Centers") have met certain volume thresholds, have quality care initiatives in place, and have competitively bid for their bundled DRG payments. The program also provides for gainsharing arrangements with physicians who meet or exceed quality standards.[472] Further, patients who choose to receive care from participating demonstration providers based on quality and cost are eligible to receive up to 50 percent of the savings to Medicare, as long as such payments do not exceed the patient's Part B premium of $1,157 per year.[473]

Proponents of bundled payments assert that the move toward bundled payments could provide higher coordination between providers and more efficient levels of care.[474] 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.[475] 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.[476] 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 healthcare delivery and payment system.[477] Finally, the American Association of 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.[478]

Although no actual bundling policy has been implemented, recent actions by both the Senate and CMS have demonstrated that such initiatives on the healthcare horizon and may soon become a part of the healthcare reimbursement environment.

Accountable Care Organizations (ACOs)

Also being proposed for inclusion in the healthcare reimbursement environment is a concept called the "accountable care organization" (ACO) or accountable care system.[479] These entities would bring a patient's healthcare providers voluntarily together in order to better coordinate patient care.[480] This could be 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.[481] Because of this, ACOs could more effectively implement initiatives to improve the quality and control the cost of care and be held accountable for the resulting outcomes and spending.[482] This method can be distinguished from the medical home model discussed previously because a separate entity focuses on coordinating all of a patient's healthcare providers instead of placing the responsibility on physicians and their staff.[483] A combination of additional physician payment updates, capitation, P4P, and gainsharing bonuses could be used to incentivize healthcare providers to join ACOs and reduced co-insurance or lower deductibles could be used to incentivize private-pay patients.[484] For more information see chapter 2 in *Professional Practices*.

Conclusion

Major shifts are taking place in the healthcare reimbursement environment. As healthcare reform efforts that focus on reducing costs begin to gain traction, providers may feel even more squeezed between the cost of services and the value of reimbursement. As more emphasis is placed on quality improvement efforts like P4P and gainsharing, however, providers are likely to see increased efficiency, which should reduce the cost of service and give providers some degree of reprieve. These trends will most likely be dictated by federal and state government payors, which, as the benchmarks for all healthcare reimbursement, will lead any future developments of the reimbursement environment.

Key Sources

Key Source	Description	Citation	Hyperlink
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 October 6, 2009).	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.	"Mission, Vision & Goals: Overview" Centers for Medicare and Medicaid Services, U.S. Department of Health and Human Services, www.cms.hhs.gov/MissionVisionGoals/ (accessed September 22, 2009).	www.cms.hhs.gov

(continued)

Key Source	Description	Citation	Hyperlink
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 September 22, 2009).	http://oig.hhs.gov
TRICARE	The TRICARE website provides useful information to program beneficiaries.	"TRICARE," www.tricare.mil (accessed October 6, 2009).	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, www.va.gov/hac/forbeneficiaries/champva/champva.asp (accessed October 6, 2009).	www.va.gov/hac/forbeneficiaries/champva/champva.asp
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 October 6, 2009).	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 October 6, 2009).	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 October 6, 2009).	www.dol.gov

Appendix A

Changes in Medicare Payments in Select Industry Sectors From 2005–Present

			2004–05	2005–06	2006–07	2007–08	2008–09	2009–10 (Jan.-Feb.)
Specialties	Primary Care	General Practice	2%	0.20%	3%	0%	0%	6%
		Internal Medicine	2%	-0.10%	5%	0%	0%	5%
	Surgical Specialties	General Surgery	2%	0.20%	0%	-1%	0%	4%
		Orthopedic Surgery	1%	-0.40%	-1%	-1%	0%	2%
	Medical Specialties	Anesthesiology	2%	-0.70%	-7%	14%	-1%	3%
		Radiology	2%	0.40%	-5%	0%	0%	-16%
Practitioners	Allied Health Practitioners	Chiropractor	1%	-1.30%	-8%	-2%	-1%	4%
		Podiatrist	2%	1.30%	-1%	2%	2%	6%
	Mid-Level Providers	Nurse Anesthetist	2%	-0.40%	-8%	22%	0%	4%
		Physical or Occupational Therapist	-1%	1.50%	-5%	1%	1%	8%
Suppliers		Diagnostic Testing Facility	3%	-2.40%	-2%	0%	-1%	-34%
Source			(1)	(2)	(3)	(4)	(5)	(6)

Sources:

1 "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 (change in total allowed charges).

2 "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.

3 "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 and Medicaid Services, Federal Register, Vol. 71, No. 231, December 1, 2006, p. 69766.

4 "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.

5 "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.

6 "Medicare Program, Payment Policies Under the Physician Fee Schedule, and Other Part B Payment Policies for CY 2010, Proposed Rule", Federal Register, Vol. 74, No. 132 (July 13, 2009), p. 33661.

Appendix B

Sample Analysis of Compensation—General Surgery

Table 1: Range of Annual Total Compensation (Excluding Trauma Call Coverage) per Level of Work RVU Productivity

A	B	C	D	E	F
Work RVUs (1)	WRVU per Physician (2)	Base Cash Compensation (3)	Incentive Comp wRVU>8,500 (4)	Productivity Incentive Payment (5)	Total Productivity Cash Compensation (6)
7,000	$45.00	$ 315,000	$ 0.00	$ 0	$ 335,000
7,500	$45.00	$ 340,000	$ 0.00	$ 0	$ 360,000
8,500	$45.00	$ 380,000	$10.00	$ 0	$ 400,000
1,100	$45.00	$ 480,000	$10.00	$ 22,000	$ 500,000
30,500	$45.00	$1,400,000	$10.00	$220,000	$1,420,000

Table 2: Industry Annual Work RVU Production (wRVU)

	Notes	N=
MGMA WRVU—ALL	(13)	671
AMGA WRVU—ALL	(15)	756
Sullivan Cotter WRVU—ALL	(16)	181
Weighted Average Industry Annual WRVU Production	(17)	

Table 3: Industry Annual Compensation per Work RVU

	Notes	N=
MGMA Comp/WRVU—ALL	(13)	671
AMGA Comp/WRVU—ALL	(15)	756
Sullivan Cotter Comp/WRVU—ALL	(16)	181
Weighted Average Industry Compensation per Work RVU	(19)	

Notes:

1. Hypothetical total annual work RVUs to be performed by employed physicians.
2. According to hypothetical agreements, employed physicians will be compensated $45.00 for each work RVU generated.
3. Calculated base cash compensation given per work RVU production in Column A ($45/work RVU).
4. Per hypothetical agreements, employed physicians will be compensated an incentive amount of $10.00 for each work RVU generated above 8,500.
5. Calculated compensation given per work RVU production in Column A ($55/work RVU for over 8,500 work RVU).
6. Calculated cash compensation given per work RVU production in Column A, that is, $45/work RVU under 8,501 and $55/work RVU over 8,500 (Column C + Column E).
7. Per hypothetical agreements, employed physicians will be compensated for meeting established quality of care and patient satisfaction performance measures of up to $20,000 per each year of the Employment Term.
8. Calculated cash compensation given per work RVU production in Column A, that is, $45/work RVU under 8,501 and $55/work RVU over 8,500 + Quality Incentive Payment (Column C + Column E + Column G).
9. Total nose coverage cost to subject enterprise per employed physician.
10. One-fifth of nose coverage cost (Column J5) (assuming amortization of nose coverage cost over five-year employment agreement).

G	H	I	J	K	L
Quality Incentive Payment (7)	Total Cash Compensation (8)	Total Nose Coverage Cost (9)	Annual Nose Coverage Cost (10)	Total Annual Compensation (11)	Total Compensation per WRVU—Excluding Trauma Call (12)
$20,000	$ 335,000	$82,000.00	$16,400	$ 351,400	$ 50.20
$20,000	$ 360,000	$82,000.00	$16,400	$ 376,400	$ 50.19
$20,000	$ 400,000	$82,000.00	$16,400	$ 416,400	$ 48.99
$20,000	$ 522,000	$82,000.00	$16,400	$ 538,400	$489.45
$20,000	$1,640,000	$82,000.00	$16,400	$1,656,400	$ 54.31

Survey Weight of Consideration (18)	25th Percentile	Median	Mean	75th Percentile	90th Percentile
33%	5,565	6,893	7,308	8,703	10,681
33%	5,410	7,163	7,585	9,537	11,002
33%	5,250	6,335	6,858	8,004	10,114
100%	5,577	6,936	7,383	8,803	10,703

SurveyWeight of Consideration (18)	25th Percentile	Median	Mean	75th Percentile	90th Percentile
33%	$41.13	$49.25	$54.09	$59.94	$77.51
33%	$37.68	$48.07	$50.95	$62.00	$74.25
33%	$36.69	$45.26	$47.45	$54.59	n/a
100%	$42.26	$50.11	$53.41	$61.46	$76.83

11. Calculated cash compensation given per work RVU production in Column A, that is, $45/work RVU under 8,501 and $55/work RVU over 8,500 + Quality Incentive Payment + amortization of nose coverage (Column H + Column J).
12. Calculated proposed total annual compensation (Column L5) divided by Work RVUs generated (Column B5).
13. Industry Annual Work RVU Productivity for all general surgeons. Source: Medical Group Management Association (MGMA) "Physician Compensation and Production Survey 2009 Interactive Report Based on 2008 Data."
14. Industry Annual Work RVU Productivity for midwest general surgeons. Source: Medical Group Management Association (MGMA) ""Physician Compensation and Production Survey 2009 Interactive Report Based on 2008 Data."
15. Industry Annual Work RVU Productivity for all general surgeons. Source: American Medical Group Association (AMGA) "2009 Medical Group Compensation and Financial Survey: 2009 Report Based on 2008 Data."
16. Industry Annual Work RVU Productivity for all general surgeons. Source: Sullivan Cotter and Associates, Inc. "2008 16th Annual Physician Compensation and Productivity Survey Report."
17. Weighted average industry annual work RVU production based upon survey weight of consideration (Column D).
18. Survey weight of consideration based upon geographical location and number of survey responses.
19. Weighted average industry compensation per work RVU based upon survey weight of consideration (Column D).

Endnotes

1 "Medical Practice Management System" By Linda Nadeau, Clifton Park, NY: Thomson Delmar Learning, 2007, p. 198.

2 "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.

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. 36-45.

4 "NHE Fact Sheet" Centers for Medicare and Medicaid Services, August 07, 2009, http://www.cms.hhs.gov/NationalHealthExpendData/25_NHE_Fact_Sheet.asp (Accessed 08/25/09).

5 "IT Investments for Naught Unless They Cut Healthcare Costs, Says Greenspan" By Neil Versel, Healthcareitnews.com, April 9, 2009, http://www.healthcareitnews.com/news/it-investments-naught-unless-they-cut-healthcare-costs-says-greenspan (Accessed 08/25/09).

6 "Introduction to Health Services" By Stephen J. Williams and Paul R. Torrens, Seventh Edition, Clifton Park, NY: Thomson Delmar Learning, 2008, p. 106.

7 "Financial Management of the Medical Practice" By Max Reiboldt, Second Edition, The Coker Group, American Medical Association, 2002, p. 12-14.

8 "Financial Management of the Medical Practice" By Max Reiboldt, Second Edition, The Coker Group, American Medical Association, 2002, p. 11.

9 "Financial Management of the Medical Practice" By Max Reiboldt, Second Edition, The Coker Group, American Medical Association, 2002, p. 12; "Medical Practice Management System" By Linda Nadeau, Clifton Park, NY: Thomson Delmar Learning, 2007, p. 96.

10 *Ibid.*

11 *Ibid.*

12 "Financial Management of the Medical Practice" By Max Reiboldt, Second Edition, The Coker Group, American Medical Association, 2002, p. 12.

13 *Ibid.*

14 "Financial Management of the Medical Practice" By Max Reiboldt, Second Edition, The Coker Group, American Medical Association, 2002, p. 14; "Medical Practice Management System" By Linda Nadeau, Clifton Park, NY: Thomson Delmar Learning, 2007, p. 96.

15 "Medical Practice Management System" By Linda Nadeau, Clifton Park, NY: Thomson Delmar Learning, 2007, p. 96.

16 *Ibid.*

17 "Medical Practice Management System" By Linda Nadeau, Clifton Park, NY: Thomson Delmar Learning, 2007, p. 96-98.

18 "Medical Practice Management System" By Linda Nadeau, Clifton Park, NY: Thomson Delmar Learning, 2007, p. 96.

19 "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.

20 "Financial Management of the Medical Practice" By Max Reiboldt, Second Edition, The Coker Group, American Medical Association, 2002, p. 12.

21 "Medicare Program; Payment Policies Under the Physician Fee Schedule and Other Revisions to Part B for CY 2010; Proposed Rule" 74 Fed. Reg. 33526 (July 13, 2009).33526.

22 *Ibid.*

23 "Transaction Code Sets Standards: Overview" Centers for Medicare and Medicaid Services, April 26, 2009, http://www.cms.hhs.gov/TransactionCodeSetsStands/ (Accessed 09/15/09).

24 *Ibid.*

25 "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.

26 *Ibid.*

27 *Ibid.*

28 *Ibid.*

29 *Ibid.*

30 "Health Insurance Reform: Modifications to the Health Insurance Portability and Accountability Act (HIPAA); Final Rule" 74 Fed. Reg. 3328, January 16, 2009. 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).

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

32 *Ibid.*

33 "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).

34 *Ibid.*

35 "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.

36 *Ibid.*

37 *Ibid.*

38 *Ibid.*

39 "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. 191.

40 *Ibid.*

41 "National Correct Coding Initiative Policy Manual for Medicare Services" Correct Coding Solutions, LLC, Version 15.3, August 31, 2009, p. I-1.

42 "National Correct Coding Initiative Policy Manual for Medicare Services" Correct Coding Solutions, LLC, Version 15.3, August 31, 2009, p. xii.

43 "National Correct Coding Initiatives Edits: Overview" Centers for Medicare and Medicaid Services, 2009, http://www.cms.hhs.gov/NationalCorrectCodInitEd/ (Accessed 10/07/09).

44 "National Correct Coding Initiative Policy Manual for Medicare Services" Correct Coding Solutions, LLC, Version 15.3, August 31, 2009, p. I-2.

45 *Ibid.*

46 "National Correct Coding Initiative Policy Manual for Medicare Services" Correct Coding Solutions, LLC, Version 15.3, August 31, 2009, p. I-3.

47 "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. 202.

48 "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. 203, 206.

49 "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. 202.

50 "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).

51 *Ibid.*

52 *Ibid.*

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

54 *Ibid.*

55 "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.

56 "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.

57 "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; "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. 170; "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.

58 "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.

59 "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. 48.

60 "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.

61 *Ibid.*

62 "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 08/26/09).

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

64 *Ibid.*

65 "Financial Management of the Medical Practice" By Max Reiboldt, Second Edition, The Coker Group, American Medical Association, 2002, p. 14.

66 *Ibid.*

67 *Ibid.*

68 *Ibid.*

69 "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.

70 *Ibid.*

71 "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. 137.

72 *Ibid.*

73 "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).

74 "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).

75 "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).

76 *Ibid.*

77 "National Health Expenditure Projections 2008-2018: Forecast Summary and Selected Tables" The Centers for Medicare and Medicaid Services, 2009, http://www.cms.gov/NationalHealthExpendData/downloads/proj2008.pdf (Accessed 05/26/10).

78 "Intensity Modulated Radiation Therapy: A Clinical Perspective" By Arno J. Mundt and John C. Roeske, Hamilton, Ontario: BC Decker, Inc., (2005) p. 216.

79 "Compilation of the Social Security Laws" Social Security Administration, 2009, http://www.socialsecurity.gov/OP_Home/ssact/title18/1800.htm (Accessed 6/19/09).

80 *Ibid.*

81 "Medicare's End Stage Renal Disease Program" By Paul W. Eggers, Health Care Financing Review, Vol. 22, No. 1, (Fall 2000), p. 55.

82 "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. 430, 432-433.

83 "Compilation of the Social Security Laws" Social Security Administration, 2009, http://www.socialsecurity.gov/OP_Home/ssact/title18/1800.htm (Accessed 6/19/09); "Electronic Booklet: Medicare" Social Security Administration, http://www.ssa.gov/pubs/10043.html (Accessed 11/02/09).

84 "From Patient to Payment: Insurance Procedures for the Medical Office, Third Edition" By Cynthia Newby, Columbus, Ohio: Glencoe/McGraw-Hill, 2002, p. 141-142.

85 "From Patient to Payment: Insurance Procedures for the Medical Office, Third Edition" By Cynthia Newby, Columbus, Ohio: Glencoe/McGraw-Hill, 2002, p. 140.

86 *Ibid.*

87 *Ibid.*

88 "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. 433.

89 "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. 430, 432.

90 "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. 440.

91 "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. 444.

92 "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. 65, 72.

93 "Prompt Payment by MA Organization" 42 C.F.R. § 422.520 (2009).

94 *Ibid.*

95 "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. 101.

96 "Medicare Benefit Policy Manual" Centers for Medicare and 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.

97 "Centers for Medicare and Medicaid Services Data Compendium" Centers for Medicare and Medicaid Services, December 2008, http://www.cms.hhs.gov/DataCompendium/16_2008_Data_Compendium.asp#TopOfPage (Accessed 08/18/09).

98 "From Patient to Payment: Insurance Procedures for the Medical Office, Third Edition" By Cynthia Newby, Columbus, Ohio: Glencoe/McGraw-Hill, 2002, p. 142.

99 "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. 437.

100 "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. 430.

101 "Hospital Acute Inpatient Services Payment System" MedPAC Payment Basics, October 2008, http://www.medpac.gov/documents/MedPAC_Payment_Basics_08_hospital.pdf (Accessed 09/24/09).

102 *Ibid.*

103 *Ibid.*

104 "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).

105 "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.

106 "Final 2009 Policy, Payment Changes for Hospital Outpatient Departments and Ambulatory Surgery Centers," Centers for Medicare and 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).

107 "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.

108 "Proposed 2010 Policy, Payment Changes for Hospital Outpatient Departments and Ambulatory Surgery Centers" Centers for Medicare and Medicaid Services, July 1, 2009, http://www.cms.hhs.gov/apps/media/fact_sheets.asp (Accessed 9/24/09).

109 "Final 2009 Policy, Payment Changes for Hospital Outpatient Departments and Ambulatory Surgery Centers," Centers for Medicare and 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).

110 "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.

111 "2009 Final ASC Payments: Policies and Rate" American Surgery Center Association, http://www.ascassociation.org/medicare2009 (Accessed 09/24/09).; "Calculation of the ASC Payment Rates" 74 Fed. Reg. 60628, (November 20, 2009).60628; "Effect of OPPS Changes in This Final Rule With Comment Period" 74 Fed. Reg. 60663, (November 20, 2009).

112 "Final 2009 Policy, Payment Changes for Hospital Outpatient Departments and Ambulatory Surgery Centers," Centers for Medicare and 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).

113 "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.

114 *Ibid.*

115 *Ibid.*

116 *Ibid.*

117 "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).

118 "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.

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

120 "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.

121 *Ibid.*

122 *Ibid.*

123 *Ibid.*

124 "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. 23.

125 "Medicare Physician Fee Schedule (MPFS)" American College of Radiology, http://www.acr.org/Hidden/Economics/FeaturedCategories/mps/mpfs.aspx (Accessed 09/15/09).; "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. 23.

126 "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. 23.

127 "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. [?].

128 "Physician Services Payment System" MedPAC Payment Basics, October 2008, http://www.medpac.gov/documents/MedPAC_Payment_Basics_08_Physician.pdf (Accessed 9/24/09).

129 *Ibid.*

130 "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).

131 "Physician Services Payment System" MedPAC Payment Basics, October 2008, http://www.medpac.gov/documents/MedPAC_Payment_Basics_08_Physician.pdf (Accessed 9/24/09).

132 "Development of the Relative Value System" 70 Fed. Reg. 70120 (November 21, 2005).

133 "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).

134 "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).

135 "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).

136 "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).

137 *Ibid.*

138 *Ibid.*

139 "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).

140 *Ibid.*

141 "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).

142 "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).

143 "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).1

144 "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).11

145 "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).; "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).

146 "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).11

147 "Physician Fee Schedule Look-Up, Overview" Centers for Medicare and 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. [?].

148 "Physician Reimbursement Under Medicare" By Alan M. Scarrow, Neurosurgical Focus, Vol. 12, no. 4, (April, 2002), p. [?].

149 "2009 Master Medicare Guide" CCH Health Editorial, Chicago, IL: Wolters Kluwer, 2009, p. 898-900.

150 "Physician Reimbursement Under Medicare" By Alan M. Scarrow, Neurosurgical Focus, Vol. 12, no. 4, (April, 2002), p. [?].

151 "2009 Master Medicare Guide" CCH Health Editorial, Chicago, IL: Wolters Kluwer, 2009, p. 901.

152 "2009 Master Medicare Guide" CCH Health Editorial, Chicago, IL: Wolters Kluwer, 2009, p. 900.

153 "CMS Proposes Payment, Policy Changes for Physicians Services to Medicare Beneficiaries in 2010" Centers for Medicare and Medicaid Services, Press Release (July 1, 2009), http://www.cms.hhs.gov/apps/media/press/release.asp?Counter=3469 (Accessed 10/09/09).

154 "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).

155 *Ibid.*

156 "CMS Proposes Payment, Policy Changes for Physicians Services to Medicare Beneficiaries in 2010" Centers for Medicare and Medicaid Services, Press Release (July 1, 2009), http://www.cms.hhs.gov/apps/media/press/release.asp?Counter=3469 (Accessed 10/09/09).; "Congress May Strike Doc-Pay Cuts" By Matthew DoBias, Modern Health Care, December 7, 2006, http://www.modernhealthcare.com/apps/pbcs.dll/article?AID=/20061207/REG/61207017# (Accessed 05/20/10). ; "Investor Presentation" Radiation Therapy Services, Inc., November 2006, p. 21.

157 "2009 CCH Medicare Explained" Edited By Pam Carron et al., Chicago, IL:Wolters Kluwer, 2009, p. 306.

158 *Ibid.*

159 "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).

160 "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.

161 "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.

162 *Ibid.*

163 "Physician Self Referral Issues" 72 Fed. Reg. 66307 (Nov. 27, 2007).

164 "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. 277-278.

165 "Changes to Reassignment Rules Related to Diagnostic Tests (Anti-Markup Provision)" 73 Fed. Reg. 69800 (November 19, 2008).

166 "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, p. 24.

167 "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).

168 *Ibid.*

169 *Ibid.*

170 "Centers for Medicare and Medicaid Services Data Compendium" Centers for Medicare and Medicaid Services, December 2008, http://www.cms.hhs.gov/DataCompendium/16_2008_Data_Compendium.asp#TopOfPage (Accessed 08/18/09).

171 "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. 436.

172 "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. 437.

173 *Ibid.*

174 *Ibid.*

175 *Ibid.*

176 *Ibid.*

177 *Ibid.*

178 "Essentials of Heath Care Finance" By William O. Cleverley and Andrew E. Cameron, 6th Edition, Sudbury, MA: Jones and Bartlett Publishers, Inc., 2007, p. 45.

179 "Medicaid Program-General Information: Overview" Centers for Medicare and Medicaid Services, http://www.cms.hhs.gov/MedicaidGenInfo/ (Accessed 10/06/09).

180 "Medicaid: An Overview of Spending on 'Mandatory' vs. 'Optional' Populations and Services" Kaiser Commission on Medicaid and the Uninsured, June 2005, http://www.kff.org/medicaid/upload/Medicaid-An-Overview-of-Spending-on.pdf (Accessed 10/06/09).

181 *Ibid.*

182 *Ibid.*

183 *Ibid.*

184 *Ibid.*

185 *Ibid.*

186 "From Patient to Payment: Insurance Procedures for the Medical Office, Third Edition" By Cynthia Newby, Columbus, Ohio: Glencoe/McGraw-Hill, 2002, p. 132.

187 "Medicaid: An Overview of Spending on 'Mandatory' vs. 'Optional' Populations and Services" Kaiser Commission on Medicaid and the Uninsured, June 2005, http://www.kff.org/medicaid/upload/Medicaid-An-Overview-of-Spending-on.pdf (Accessed 10/06/09).

188 *Ibid.*

189 "The Children's Health Insurance Program (CHIP): Overview" Centers for Medicare and Medicaid Services, http://www.cms.hhs.gov/LowCostHealthInsFamChild/ (Accessed 10/6/09).

190 "Monthly CHIP Enrollment" The Henry J. Kaiser Family Foundation, 2009, http://www.statehealthfacts.org/comparemaptable.jsp?ind=236&cat=4&st=3 (Accessed 10/06/09).

191 "The Children's Health Insurance Program (CHIP): Overview" Centers for Medicare and Medicaid Services, http://www.cms.hhs.gov/LowCostHealthInsFamChild/ (Accessed 10/6/09).

192 "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).

193 "Children's Health Insurance Program Reauthorization Act of 2009 (CHIPRA): Key Facts" Kaiser Commission on Medicaid and the Uninsured, http://www.kff.org/medicaid/upload/7863.pdf (Accessed 10/06/09).; "Children's Health Insurance Program Reauthorization Act of 2009 (CHIPRA): Key Facts" Kaiser Commission on Medicaid and the Uninsured, http://www.kff.org/medicaid/upload/7863.pdf (Accessed 10/06/09).

194 "Children's Health Insurance Program Reauthorization Act of 2009 (CHIPRA): Key Facts" Kaiser Commission on Medicaid and the Uninsured, http://www.kff.org/medicaid/upload/7863.pdf (Accessed 10/06/09).

195 *Ibid.*

196 "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. 478.

197 "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.

198 "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. 482.

199 "From Patient to Payment: Insurance Procedures for the Medical Office, Third Edition" By Cynthia Newby, Columbus, Ohio: Glencoe/McGraw-Hill, 2002, p. 135.

200 "Timely Claims Payment" 42 C.F.R. § 447.45(d) (October 1, 2007).

201 *Ibid.*

202 "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. 478.

203 "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. 479.

204 "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. 478, 480, 483.

205 "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. 478, 480.

206 "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. 479.

207 *Ibid.*

208 *Ibid.*

209 "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).1

210 *Ibid.*

211 *Ibid.*

212 *Ibid.*

213 "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).2

214 "Adjustment in Payment for Inpatient Hospital Services Furnished by Disproportionate Share Hospitals" Social Security Administration, 2009, http://www.socialsecurity.gov/OP_Home/ssact/title19/1923 (Accessed 10/5/09).; "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).

215 "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).3

216 *Ibid.*

217 "What is TRICARE?" TRICARE Management Activity, TRICARE.com, July 8, 2009, http://www.tricare.mil/mybenefit/home/overview/WhatIsTRICARE (Accessed 07/24/09).

218 *Ibid.*

219 "From Patient to Payment: Insurance Procedures for the Medical Office, Third Edition" By Cynthia Newby, Columbus, Ohio: Glencoe/McGraw-Hill, 2002, p. 152-153; "What is TRICARE?" TRICARE Management Activity, TRICARE.com, July 8, 2009, http://www.tricare.mil/mybenefit/home/overview/WhatIsTRICARE (Accessed 07/24/09).

220 "From Patient to Payment: Insurance Procedures for the Medical Office, Third Edition" By Cynthia Newby, Columbus, Ohio: Glencoe/McGraw-Hill, 2002, p. 152-153.

221 "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. 514.

222 "From Patient to Payment: Insurance Procedures for the Medical Office, Third Edition" By Cynthia Newby, Columbus, Ohio: Glencoe/McGraw-Hill, 2002, p. 155; "TRICARE- Authorized Providers" TRICARE Management Activity, TRICARE.mil, July 8, 2009, http://www.tricare.mil/mybenefit/home/Medical/FindingAProvider/AuthorizedProviders (Accessed 8/11/09).

223 "From Patient to Payment: Insurance Procedures for the Medical Office, Third Edition" By Cynthia Newby, Columbus, Ohio: Glencoe/McGraw-Hill, 2002, p. 157; "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. 513.

224 "From Patient to Payment: Insurance Procedures for the Medical Office, Third Edition" By Cynthia Newby, Columbus, Ohio: Glencoe/McGraw-Hill, 2002, p. 153.

225 "From Patient to Payment: Insurance Procedures for the Medical Office, Third Edition" By Cynthia Newby, Columbus, Ohio: Glencoe/McGraw-Hill, 2002, p. 155.

226 "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. 514.

227 "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. 515.

228 "From Patient to Payment: Insurance Procedures for the Medical Office, Third Edition" By Cynthia Newby, Columbus, Ohio: Glencoe/McGraw-Hill, 2002, p. 155.

229 "Becoming a TRICARE Provider- Things to Consider" TRICARE Management Activity, http://tricare.mil/tma/thingstoconsider.aspx (Accessed 08/11/09).

230 "From Patient to Payment: Insurance Procedures for the Medical Office, Third Edition" By Cynthia Newby, Columbus, Ohio: Glencoe/McGraw-Hill, 2002, p. 156.

231 *Ibid.*

232 "CHAMPVA Policy Manual" U.S. Department of Veterans Affairs, VA.gov, December 31, 2008, http://www.va.gov/hac/forbeneficiaries/champva/policymanual/index.asp (Accessed 08/11/09).

233 *Ibid.*

234 "Fact Sheet 01-11, Payment Methodology" Department of Veterans Affairs Health Administration Center, VA.gov, July 2008, http://www.va.gov/hac/factsheets/factsheets.asp (Accessed 8/18/09).

235 "From Patient to Payment: Insurance Procedures for the Medical Office, Third Edition" By Cynthia Newby, Columbus, Ohio: Glencoe/McGraw-Hill, 2002, p. 157.

236 "CHAMPVA Policy Manual" U.S. Department of Veterans Affairs, VA.gov, December 31, 2008, http://www.va.gov/hac/forbeneficiaries/champva/policymanual/index.asp (Accessed 08/11/09).

237 "Fact Sheet 01-15, Participating Providers" Department of Veterans Affairs Health Administration Center, VA.gov, July 2008, http://www.va.gov/hac/factsheets/factsheets.asp (Accessed 8/18/09).

238 *Ibid.*

239 "Benefits Limitations/Exclusions" 38 CFR § 17.272 (b) (2) and (3) (July 1, 2005).

240 "A Handbook for the CHAMPVA Program: Helping You Take An Active Role In Your Health Care" Department of Veterans Affairs Health Administration Center, http://www.va.gov/hac/forbeneficiaries/champva/handbook.asp (Accessed 08/18/09).

241 *Ibid.*

242 "Fact Sheet 01-16, For Outpatient Providers and Office Managers" Department of Veterans Affairs Health Administration Center, VA.gov, July 2008, http://www.va.gov/hac/factsheets/factsheets.asp (Accessed 8/18/09).

243 "From Patient to Payment: Insurance Procedures for the Medical Office, Third Edition" By Cynthia Newby, Columbus, Ohio: Glencoe/McGraw-Hill, 2002, p. 156.

244 *Ibid.*

245 "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. 532.

246 *Ibid.*

247 *Ibid.*

248 "Workers' Compensation" United States Department of Labor, DOL.gov, http://www.dol.gov/dol/topic/workcomp/ (Accessed 8/10/09).

249 "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. 534; "Workers' Compensation" United States Department of Labor, DOL.gov, http://www.dol.gov/dol/topic/workcomp/ (Accessed 8/10/09).

250 "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. 535.

251 "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).

252 *Ibid.*

253 *Ibid.*

254 *Ibid.*

255 "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. 538, 543.

256 "From Patient to Payment: Insurance Procedures for the Medical Office, Third Edition" By Cynthia Newby, Columbus, Ohio: Glencoe/McGraw-Hill, 2002, p. 132.

257 "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. 544.

258 "From Patient to Payment: Insurance Procedures for the Medical Office, Third Edition" By Cynthia Newby, Columbus, Ohio: Glencoe/McGraw-Hill, 2002, p. 132.

259 "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. 544.

260 "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.

261 "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. 544.

262 "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).

263 "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).; "Indian Health Service: A Quick Look" Indian Health Service, June 2009, http://info.ihs.gov/QuickLook09.asp (Accessed 8/10/09).

264 "Indian Health Service: A Quick Look" Indian Health Service, June 2009, http://info.ihs.gov/QuickLook09.asp (Accessed 8/10/09).

265 *Ibid.*

266 *Ibid.*

267 "CHS 101" Contract Health Services Data Quality Work Group, http://www.ihs.gov/NonMedicalPrograms/dqwg/dqwg-section1-home.asp (Accessed 08/27/09).

268 "Contract Health Services" Indian Health Services, IHS.gov, June 2009, http://info.ihs.gov/CHS.asp (Accessed 08/26/09).

269 "Section 506 of the Medicare Prescription Drug, Improvement, and Moderization Act of 2003—Limitation on Charges for Services Furnished by Medicare Participating Inpatient Hospitals to Individuals Eligible for Care Purchased by Indian Health Programs" 72 Fed. Reg. 30706 (June 4, 2007).

270 "About Us" Blue Cross Blue Shield of New Mexico, 2009, http://www.bcbsnm.com/about/whoweare.htm, (Accessed 08/28/09).

271 "CHS 101" Contract Health Services Data Quality Work Group, http://www.ihs.gov/NonMedicalPrograms/dqwg/dqwg-section1-home.asp (Accessed 08/27/09).

272 "IHS/CHS Fiscal Intermediary: What Can It Do For Tribes" Blue Cross Blue Shield of New Mexico, 2007, http://www.npaihb.org/images/policy_docs/medicarelike/FI%20Overview%20for%20Tribes%20-Brenda%20Smith%20-%20Sept%20%202007.ppt#304,18,FI Timeline (Accessed 08/28/09).

273 "OECD Health Data 2009: How does the United States Compare" By Organization for Economic Co-operation and Development, 2009, http://www.oecd.org/dataoecd/46/2/38980580.pdf (Accessed 11/23/09).

274 "Health Care Economics, Sixth Edition" By Paul J. Feldstein, Clifton Park, NY: Thomson Delmar Learning, 2005, p. 184.

275 "Healthcare Finance: An Introduction to Accounting and Financial Management" By Louis C. Gapenski, Third Edition, Chicago, IL: Health Administration Press, 2004, p. 35.

276 *Ibid.*

277 "Introduction to Health Services" By Stephen J. Williams and Paul R. Torrens, Seventh Edition, Clifton Park, NY: Thomson Delmar Learning, 2008, p. 113.

278 "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. 393.

279 "Introduction to Health Services" By Stephen J. Williams and Paul R. Torrens, Seventh Edition, Clifton Park, NY: Thomson Delmar Learning, 2008, p. 114.

280 *Ibid.*

281 "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. 399.

282 "About the Blue Cross and Blue Shield Association" Blue Cross Blue Shield Association, 2009, http://www.bcbs.com/about/ (Accessed 08/12/09).

283 "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. 399.

284 "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. 400.

285 *Ibid.*

286 "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. 402-406.

287 *Ibid.*

288 "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. 407.

289 *Ibid.*

290 "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. 408.

291 "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. 407.

292 *Ibid.*

293 "For Physicians, Other Health Care Professionals and Facilities: The Blue Card Program" Regence Blue Cross Blue Shield of Utah, http://www.ut.regence.com/physician/blueCard/ (Accessed 8/31/209). ; "How the Blue Cross Blue Shield Settlement Agreement Helps the Physician Practice" American Medical Association, 2008, http://www.ama-assn.org/ama1/pub/upload/mm/368/bcbsflyer.pdf (Accessed 08/31/09).

294 "Healthcare Finance: An Introduction to Accounting and Financial Management" By Louis C. Gapenski, Third Edition, Chicago, IL: Health Administration Press, 2004, p. 37.

295 "A Guide to Consulting Services for Emerging Healthcare Organizations" By Robert J. Cimasi, New York, NY: John Wiley & Sons, Inc., 1999, p. 24-25.

296 "Healthcare Finance: An Introduction to Accounting and Financial Management" By Louis C. Gapenski, Third Edition, Chicago, IL: Health Administration Press, 2004, p. 37.

297 "Fundamentals of Health Law" By Daniel J. Schwartz, Fourth Edition, Washington, DC: American Health Lawyers Association, 2008, p. 247.

298 "Introduction to Health Services" By Stephen J. Williams and Paul R. Torrens, Seventh Edition, Clifton Park, NY: Thomson Delmar Learning, 2008, p. 126.

299 *Ibid.*

300 "Fundamentals of Health Law" By Daniel J. Schwartz, Fourth Edition, Washington, DC: American Health Lawyers Association, 2008, p. 247.

301 "Healthcare Finance: An Introduction to Accounting and Financial Management" By Louis C. Gapenski, Third Edition, Chicago, IL: Health Administration Press, 2004, p. 38.

302 "Fundamentals of Health Law" By Daniel J. Schwartz, Fourth Edition, Washington, DC: American Health Lawyers Association, 2008, p. 248-250.

303 "Employers: Understanding HMOs" Pacific Care Health Systems, Inc., 2004, http://www.pacificareasia.com/English/employers/E_4_4_1.htm (Accessed 7/10/09).

304 "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.

305 "Introduction to Health Services" By Stephen J. Williams and Paul R. Torrens, Seventh Edition, Clifton Park, NY: Thomson Delmar Learning, 2008, p. 124.

306 "Introduction to Health Services" By Stephen J. Williams and Paul R. Torrens, Seventh Edition, Clifton Park, NY: Thomson Delmar Learning, 2008, p. 124-125.

307 "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.

308 "Healthcare Finance: An Introduction to Accounting and Financial Management" By Louis C. Gapenski, Third Edition, Chicago, IL: Health Administration Press, 2004, p. 37.

309 "Fundamentals of Health Law" By Daniel J. Schwartz, Fourth Edition, Washington, DC: American Health Lawyers Association, 2008, p. 245.

310 "Introduction to Health Services" By Stephen J. Williams and Paul R. Torrens, Seventh Edition, Clifton Park, NY: Thomson Delmar Learning, 2008, p. 127.

311 "Fundamentals of Health Law" By Daniel J. Schwartz, Fourth Edition, Washington, DC: American Health Lawyers Association, 2008, p. 258.

312 *Ibid.*

313 *Ibid.*

314 "Point of Service (POS)" All Insurance Info, AllInsuranceInfo.org, 2007, http://allinsuranceinfo.org/health/pos.html (Accessed 7/13/09).

315 *Ibid.*

316 *Ibid.*

317 *Ibid.*

318 "The Managed Health Care Handbook" By Peter R. Kongstvedt, Third Edition, Gaithersburg, MD: Aspens Publishers, Inc., 1996, p. 120.

319 "A Guide to Consulting Services for Emerging Healthcare Organizations" By Robert J. Cimasi, New York, NY: John Wiley & Sons, Inc., 1999, p. 11, 16.

320 "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.

321 *Ibid.*

322 "The Capitation Sourcebook: A Practical Guide to Managing At-Risk Arrangements" By Peter Boland, Berkeley, CA: Boland Healthcare, Inc., 1996, p. 107.

323 "Dictionary of Health Insurance and Managed Care" By David Edward Marcinko and Hope Rachel Hetico, New York, NY: Springer Publishing Company, 2006, p. 126.

324 "The Capitation Sourcebook: A Practical Guide to Managing At-Risk Arrangements" By Peter Boland, Berkeley, CA: Boland Healthcare, Inc., 1996, p. 107.

325 *Ibid.*

326 *Ibid.*

327 "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.

328 "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.

329 "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.

330 "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.

331 "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. 1258, 1263.

332 "Insurance Programs: Glossary" U.S. Office of Personnel Management, http://www.opm.gov/insure/glossary/index.asp (Accessed 10/05/09).

333 "The Managed Health Care Handbook" By Peter R. Kongstvedt, Third Edition, Gaithersburg, MD: Aspens Publishers, Inc., 1996, p. 139, 143.

334 *Ibid.*

335 "The Managed Health Care Handbook" By Peter R. Kongstvedt, Third Edition, Gaithersburg, MD: Aspens Publishers, Inc., 1996, p. 207-208.

336 "The Managed Health Care Handbook" By Peter R. Kongstvedt, Third Edition, Gaithersburg, MD: Aspens Publishers, Inc., 1996, p. 181.

337 "The Managed Health Care Handbook" By Peter R. Kongstvedt, Third Edition, Gaithersburg, MD: Aspens Publishers, Inc., 1996, p. 179-187.

338 "From Patient to Payment: Insurance Procedures for the Medical Office, Third Edition" By Cynthia Newby, Columbus, Ohio: Glencoe/McGraw-Hill, 2002, p. 112.

339 "From Patient to Payment: Insurance Procedures for the Medical Office, Third Edition" By Cynthia Newby, Columbus, Ohio: Glencoe/McGraw-Hill, 2002, p. 113; "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. 39.

340 "From Patient to Payment: Insurance Procedures for the Medical Office, Third Edition" By Cynthia Newby, Columbus, Ohio: Glencoe/McGraw-Hill, 2002, p. 113.

341 *Ibid.*

342 *Ibid.*

343 "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. 40.

344 *Ibid.*

345 "From Patient to Payment: Insurance Procedures for the Medical Office, Third Edition" By Cynthia Newby, Columbus, Ohio: Glencoe/McGraw-Hill, 2002, p. 112.

346 "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. 39.

347 *Ibid.*

348 "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).

349 *Ibid.*

350 "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.

351 "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.

352 "Defined Contribution: From Managed Care to Patient-Managed Care" By E. Haavi Morreim, Cato Journal, Vol. 22, No. 1 (Spring/Summer 2002), p. 112.

353 "Defined Contribution: From Managed Care to Patient-Managed Care" By E. Haavi Morreim, Cato Journal, Vol. 22, No. 1 (Spring/Summer 2002), p. 111.

354 "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. [?].

355 *Ibid.*

356 "HSA Frequently Asked Questions" Department of Treasury, May 15, 2007, http://www.ustreas.gov/offices/public-affairs/hsa/faq_eligibility.shtml (Accessed 8/18/09).

357 *Ibid.*

358 *Ibid.*

359 "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. [?].

360 "President Bush Signs Bill to Make Health Care More Affordable, Accessible" U.S. Treasury Department, Press Release, Dec. 20, 2006, Accessed at http://www.treas.gov/press/releases/hp209.htm (Accessed 7/1/09).

361 "Health Savings Accounts Come Under Fire" By Victoria E. Knight, The Wall Street Journal Online, June 26, 2009, http://blogs.wsj.com/wallet/2009/06/26/health-savings-accounts-come-under-fire/ (Accessed 07/01/09).

362 "January 2009 Census Shows 8 Million People Covered By HSA/High-Deductible Health Plans" America's Health Insurance Plans, ahipresearch.org, May 2009, http://www.ahipresearch.org/pdfs/2009hsacensus.pdf (Accessed 08/27/09).

363 "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).

364 "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).

365 "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).

366 *Ibid.*

367 "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.

368 "Healthcare Finance: An Introduction to Accounting and Financial Management" By Louis C. Gapenski, Third Edition, Chicago, IL: Health Administration Press, 2004, p. 36.

369 "Introduction to Health Services" By Stephen J. Williams and Paul R. Torrens, Seventh Edition, Clifton Park, NY: Thomson Delmar Learning, 2008, p. 113.

370 *Ibid.*

371 *Ibid.*

372 *Ibid.*

373 *Ibid.*

374 *Ibid.*

375 *Ibid.*

376 *Ibid.*

377 *Ibid.*

378 *Ibid.*

379 *Ibid.*

380 *Ibid.*

381 *Ibid.*

382 *Ibid.*

383 "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.

384 *Ibid.*

385 "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.

386 *Ibid.*

387 "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. 780.

388 "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.

389 "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).

390 "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).

391 "Basics of Financial Management for the Medical Practice" By Marcel Frenkel, Phoenix, MD: Greenbranch Publishing, 2003, p. 24.

392 "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.

393 *Ibid.*

394 "Basics of Financial Management for the Medical Practice" By Marcel Frenkel, Phoenix, MD: Greenbranch Publishing, 2003, p. 24.

395 *Ibid.*

396 *Ibid.*

397 "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).

398 "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).

399 *Ibid.*

400 "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).

401 *Ibid.*

402 "Alternative Quality Contract" BlueCross BlueShield Massachusetts, 2009, http://www.qualityaffordability.com/solutions/alternative-quality-contract.html (Accessed 08/04/09).

403 "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, mass.gov., July 16, 2009, http://www.mass.gov/Eeohhs2/docs/dhcfp/pc/Final_Report/Final_Report.pdf (Accessed 8/4/09).

404 *Ibid.*

405 *Ibid.*

406 "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 08/06/09).

407 *Ibid.*

408 "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).

409 "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 08/06/09).; "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 08/06/09).; "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).

410 *Ibid.*

411 "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 08/06/09).

412 *Ibid.*

413 "Pay-for-Performance in Health Care" By Jim Hahn, CRS Report for Congress, Washington, D.C.: 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.

414 "Pay-for-Performance in Health Care" By Jim Hahn, CRS Report for Congress, Washington, D.C.: Congressional Research Service, November 2, 2006, p. CRS-2.

415 "Pay-for-Performance in Health Care" By Jim Hahn, CRS Report for Congress, Washington, D.C.: Congressional Research Service, November 2, 2006, p. CRS-4.

416 "Pay-for-Performance in Health Care" By Jim Hahn, CRS Report for Congress, Washington, D.C.: Congressional Research Service, November 2, 2006, p. CRS-1, 13.

417 "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).

418 *Ibid.*

419 "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).2140

420 *Ibid.*

421 "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.

422 *Ibid.*

423 "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), Accessed at http://content.healthaffairs.org/cgi/content/abstract/hlthaff.26.3.w405 (Accessed 5/25/10) p. w406-w407.

424 "Gainsharing Arrangements" 73 Fed. Reg. 23692 (April 30, 2008).

425 "Medicare Program: Summary" 73 Fed. Reg. 38502 (July 7, 2008).

426 "General Considerations With Respect to the Proposed Exception" 73 Fed. Reg. 38502, 38548, (July 7, 2008); "Shared Savings Programs" 73 Fed. Reg. 38550 (July 7, 2008).

427 "General Considerations With Respect to the Proposed Exception" 73 Fed. Reg. 38552 (July 7, 2008).

428 "Gainsharing Arrangements" 73 Fed. Reg. 23692 (April 30, 2008).

429 *Ibid.*

430 "OIG Advisory Opinion No. 08-21" Office of Inspector General, Advisory Opinion (November 25, 2008), Accessed at http://www.oig.hhs.gov/fraud/docs/advisoryopinions/2008/AdvOpn08-21.2.pdf (Accessed 12/19/08), p. 1.

431 *Ibid.*

432 "OIG Advisory Opinion No. 08-21" Office of Inspector General, Advisory Opinion (November 25, 2008), Accessed at http://www.oig.hhs.gov/fraud/docs/advisoryopinions/2008/AdvOpn08-21.2.pdf (Accessed 12/19/08), p. 4.

433 "OIG Advisory Opinion No. 08-21" Office of Inspector General, Advisory Opinion (November 25, 2008), Accessed at http://www.oig.hhs.gov/fraud/docs/advisoryopinions/2008/AdvOpn08-21.2.pdf (Accessed 12/19/08), p. 10, 12.

434 "Requirments Related to the Design of an Incentive Payment or Shared Savings Program" 73 Fed. Reg. 38552-58 (July 7, 2008).

435 *Ibid.*

436 *Ibid.*

437 *Ibid.*

438 "American Recovery and Reinvestment Act of 2009" Pub. L. No. 111-5 (February 17, 2009).

439 "Health Information Technology for Economic and Clinical Health Act" Pub. L. No. 111-5 (February 17, 2009).

440 "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).

441 "American Recovery and Reinvestment Act of 2009" Pub. L. No. 111-5 (February 17, 2009).3018

442 "American Recovery and Reinvestment Act of 2009" Pub. L. No. 111-5 (February 17, 2009).4101(a)

443 *Ibid.*

444 "American Recovery and Reinvestment Act of 2009" Pub. L. No. 111-5 (February 17, 2009).4101(b)

445 *Ibid.*

446 "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).

447 *Ibid.*

448 "American Recovery and Reinvestment Act of 2009" Pub. L. No. 111-5 (February 17, 2009).4101(a)(2)

449 "Summary of HHS Recovery Operational Plan" HIMSS, May 2009, http://www.himss.org/advocacy/d/HIMSS_Summary_HHS_RecoveryProgram_May2009.pdf (Accessed 6/3/09).

450 *Ibid.*

451 "American Recovery and Reinvestment Act of 2009" Pub. L. No. 111-5 (February 17, 2009).3013h

452 "National Clearinghouse of Plastic Surgery Statistics: 2009 Report of the 2008 Statistics" The American Society of Plastic Surgeons, 2009, http://www.plasticsurgery.org/Media/stats/2008-US-cosmetic-reconstructive-plastic-surgery-minimally-invasive-statistics.pdf (Accessed 10/05/09).5

453 *Ibid.*

454 "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).

455 *Ibid.*

456 *Ibid.*

457 "Cosmetic and Reconstructive Surgery Procedures" Priority Health, September 1, 2007, http://www.priorityhealth.com/provider/manual/policies/91535.pdf (Accessed 10/05/09).

458 "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).

459 "Insurance Coverage: A Patient's Guide" The 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).

460 *Ibid.*

461 "Medicare and You 2009" Centers for Medicare and Medicaid Services, 2009, http://www.medicare.gov/Publications/Pubs/pdf/10050.pdf (Accessed 10/05/09).; "Reconstructive and Cosmetic Surgery Clinical Coverage Policy No.: 1-0-1," Division of Medical Assistance, North Carolina Department of Health and Human Services, January. 1, 1985, http://www.ncdhhs.gov/dma/mp/1-0-1.pdf (Accessed 10/5/09).

462 "Boutique Medicine" Medstar.com, June 14, 2003, http://news14.com/charlotte-news-104-content/30947/boutique-medicine (Accessed 02/16/04).

463 "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 08/10/09).

464 "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 05/24/10).

465 "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.

466 "Medicare Demonstrations: Details for Medicare Medical Home Demonstration" Centers for Medicare and 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 08/10/09).; "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 08/10/09).

467 "Fact Sheet: Medical Home Demonstration Fact Sheet" Centers for Medicare and 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 and 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 08/10/09).

468 "The Managed Health Care Handbook" By Peter R. Kongstvedt, Third Edition, Gaithersburg, MD: Aspens Publishers, Inc., 1996, p. 187.

469 "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).

470 "Acute Care Episode Demonstration Fact Sheet" Centers for Medicare and Medicaid Services, March 20, 2009, http://www.cms.hhs.gov/DemoProjectsEvalRpts/downloads/ACEFactSheet.pdf (Accessed 06/01/09).

471 "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.

472 "Acute Care Episode Demonstration Fact Sheet" Centers for Medicare and Medicaid Services, March 20, 2009, http://www.cms.hhs.gov/DemoProjectsEvalRpts/downloads/ACEFactSheet.pdf (Accessed 06/01/09); "Medicare Acute Care Episode Demonstration for Orthopedic and Cardiovascular Surgery" Centers for Medicare and Medicaid Services, 2009, http://www.cms.hhs.gov/DemoProjectsEvalRpts/downloads/ACE_web_page.pdf (Accessed 06/03/09).

473 "Medicare Acute Care Episode Demonstration for Orthopedic and Cardiovascular Surgery" Centers for Medicare and Medicaid Services, 2009, http://www.cms.hhs.gov/DemoProjectsEvalRpts/downloads/ACE_web_page.pdf (Accessed 06/03/09).

474 "Effects of Bundled Payment Policy Options" RAND, 2009, http://www.randcompare.org/analysis/mechanism/bundled_payment (Accessed 11/12/09).

475 "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.

476 *Ibid.*

477 "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.

478 "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. 5.

479 "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.

480 "Fostering Accountable Health Care: Moving Forward in Medicare" By Elliot Fisher, et al, Health Affairs Vol.28, No.2, (January. 27, 2009), p. w219.

481 "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.

482 "MedPAC Probes Effectiveness of Accountable Care Organizations" By Jane Norman, Washington Health Policy Week in Review, April 20, 2009, http://www.commonwealthfund.org/Content/Newsletters/Washington-Health-Policy-in-Review/2009/Apr/April-20-2009/MEDPAC-Probes-Effectiveness-of-Accountable-Care-Organizations.aspx (Accessed 11/13/09).

483 "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.

484 "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. 97.

3 Regulatory Environment

"In all science, error precedes the truth, and it is better it should go first than last."

Henry Walpole, 1801

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
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," John W. Jones, Esq., Physician's News Digest, June 2007, www.physiciansnews.com/law/607jones.html, (accessed July 9, 2009); People v. United Medical Services, 362 Ill. 442, 200 N.E. 157, 163 (1936).
Health Insurance Portability and Accountability Act of 1996 (HIPPA)	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 transmit 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.	45 C.F.R. 160.103; 45 C.F.R. 164; "Summary of the HIPAA Privacy Rule," OCR Privacy Brief, United States Department of Health and Human Services, May 2003, p. 4, www.hhs.gov/ocr/privacy/hipaa/understanding/summary/privacysummary.pdf (accessed June 17, 2009).
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.	"False Claim Act" 31 U.S.C. 3729; "Health Care Fraud Report: Fiscal Year 1998," Department of Justice, justice.gov, 1998, www.justice.gov/dag/pubdoc/health98.htm#national (accessed December 9, 2009); "False Claims Act" 31 U.S.C.A. §3730(d)(1).
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 June 17, 2009).
Office of the Inspector General (OIG)	"The mission of the Office of Inspector General (OIG), as mandated by Public Law 95-452 (as amended), is to protect the integrity of Department of Health and Human Services (HHS) programs, as well as the health and welfare of the beneficiaries of those programs. OIG has a responsibility to report both to the Secretary and to the Congress program and management problems and recommendations to correct them. OIG's duties are carried out through a nationwide network of audits, investigations, evaluations and other mission-related functions performed by OIG components."	"Mission." U.S Department of Health Services, Office of the Inspector General, http://oig.hhs.gov/ (accessed July 14, 2009).
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 July 14, 2009).
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 acts, "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.	Sec. 4 Clarifications to the False Claims Act to Reflect the Original Intent of the law," United States Senate, Fraud Enforcement and Recovery Act S.386, April 2009, http://thomas.loc.gov/cgi-bin/query/F?c111:3:./temp/~c111f3yFGF:e10867: (accessed May 1, 2009); "Fraud Enforcement and Recovery Act of 2009 (FERA)," Anne Sharamitaro, Esq. and Kelly Gordon, Health Capital Topics, Vol. 2, No. 5, May 2009.

Key Concept	Definition	Citation
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.	"Title IV of Public Law 99-660: The Health Care Quality Improvement Act of 1986."
Medicare and Medicaid Patient & Program Protection Act of 1987 (MMPPPA)	Amended the 1987 antikickback statute by including an alternative civil remedy to violation: exclusion from the Medicare Program.	"Medicare and State Health Care Programs: Fraud and Abuse," OIG Anti-Kickback, Department of Health and Human Services, July 29, 1991, 42 CFR Part 1001.; "Medicare and Medicaid Patient & Program Protection Act of 1987," Pub. L. 100-93 (Aug. 18, 1987).
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, Jan. 4, 1975, § 1501; Frank A. Sloan, et. al., Cost, Quality, and Access In Health Care: New Roles for Health Planning In A Competitive Environment, p. 31 (Josey-Bass Publishers 1988).
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 antikickback statute.	"The Balanced Budget Act of 1997," Pub. L. 105-33, Section 4304 (Aug. 5, 1997).
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" 42 CFR Part 3, Center for Medicare and Medicaid Services, November 21, 2008, p. 70732.
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," found in "American Recovery and Reinvestment Act of 2009," Pub. L. No. 111-5 (Feb. 17, 2009), Title XIII.
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.	42 U.S.C. 1395nn(a)(1)(A); 60 Fed. Reg. 41914 (Aug. 14, 1995); 69 Fed. Reg. 16054 (Mar. 26, 2004); "Phase III Regulations Result in Dramatic Changes to Stark Law," J. Kelly Barnes, et al., BNA Health Law Reporter, Vol. 16, No. 40, October 11, 2007, p. 1220; 72 Fed. Reg. 51028 (Sept. 5, 2007).
Antikickback Statute	Enacted in 1972, the federal antikickback 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.A. § 1320a-7b(b).
Centers for Medicare and Medicaid Services (CMS)	Regulate Medicare and Medicaid reimbursements and services in an attempt to "ensure effective, up-to-date health care coverage and to promote quality care for beneficiaries."	"Mission, Visions & Goals," Department of Health and Human Services, Centers for Medicare and Medicaid Services, www.cms.hhs.gov/MissionVisionGoals/ (accessed July 14, 2009).

(continued)

Key Concept	Definition	Citation
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 July 14, 2009).
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.	"Medicare Prescription Drug, Modernization, and Improvement Act of 2003" §507(a)(1)(B); "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.
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 July 14, 2009).
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, Oct. 6, 2008, www.ama-assn.org/amednews/2008/10/06/gvsb1006.htm, (accessed June 22, 2009).
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.	15 U.S.C. § 1; "Health Care Fraud: Enforcement and Compliance," By Robert Fabrikant, et al., Law Journal Press, 2007, p. 2-59-2-60.
Racketeer Influenced and Corrupt Organizations Act	Federal law which 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." 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., Law Journal Press, 2007, p. 3-84, quoting 115 Cong. Rec. 9566, 9568 (April 18, 1969), statement of Sen. McClellan; 18 U.S.C. 1962.
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.	"Individual Providers and Caregivers," "Problems in Health Care Law, Ninth Edition," Robert D. Miller, Jones and Bartlett Publishers, 2006, p. 184–85.
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.	"Overview: Clinical Laboratory Improvement Amendments" Centers for Medicare and Medicaid Services, May 07, 2009, www.cms.hhs.gov/clia/, (accessed June 30, 2009); "Clinical Laboratory Improvement Amendments" United States Food and Drug Administration, June 16, 2009.
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, June 02, 2008, www.nrc.gov/materials/medical.html, (accessed June 30, 2009); The Atomic Energy Act of 1954, Public Law 83-703, 68 Stat. 919 Sec. 274 August 30, 1954.

Key Concept	Definition	Citation
Section 1122 of the 1972 Social Security Amendments	Allowed the secretary of Health, Education, and Welfare to enter into agreements with states that had a "designated planning agency," an agency responsible for determining whether healthcare facilities could make capital expenditures. States failing to institute health policy planning programs could lose Medicare and Medicaid cost reimbursement.	"Compilation of the Social Security Laws: Limitation on Federal Participation for Capital Expenditures," United States Government, Sec. 1122, 2009, www.socialsecurity.gov/OP_Home/ssact/title11/1122.htm (accessed January 4, 2010).
Medical Injury Compensation Reform Act	California legislation that caps pain and suffering and malpractice damages.	Cal. Civ. Code § 3333.2.
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.	"H.R. 4600: Help Efficient, Accessible, Low-Cost, Timely Healthcare (HEALTH) Act of 2002: Related Legislation," govtrack.us, www.govtrack.us/congress/bill.xpd?bill=h107-4600&tab=related (accessed September 8, 2009).
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.	15 U.S.C. § 1.
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.	"Moratorium on Specialty Hospitals Expires" by Jennifer Gordon, Dallas Business Journal, http://assets.bizjournals.com/dallas/stories/2005/06/20/story8.html (accessed June 25, 2009).

Overview

The U.S. healthcare industry is replete with overlapping state and federal regulations which 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 nonphysician 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, that is, 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: professional liability, financial liability, and tax liability (see chapter 1 in *Professional Practices*).[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 (see *IRS Tax Status*).[3] Practitioners with ownership interest may be financially liable for any violations related to business practices

and, as a result, may suffer personal losses (see *Fraud and Abuse Laws*).[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 (see *Tort Reform*).[5] As healthcare grows in complexity, both medically and entrepreneurially, the liability that practitioners and practices face likely will increase in complexity as well.

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 (see chapter 1, *Shift to Managed Care*). 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.[6] 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."[7]

The CPOM is regulated by the states.[8] Although restrictions vary by jurisdiction, forty-eight states and the District of Columbia have some form of regulation that follows a CPOM standard.[9] Of these forty-eight states, eight have statutory provisions restricting the CPOM.[10] In thirty states, the CPOM has been restricted or outlawed by case law, opinions of the state attorney general, or state licensing boards.[11] Although, in eight of the states where the CPOM is regulated, the trend is less restrictive, and corporations are allowed to employ physicians as long as they do not interfere with the physician's independent medical judgment.[12] Currently, five states affirmatively permit the CPOM.[13] 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 doctrine.[14] Further, some states exempt nonprofit healthcare entities under the rationale that the lack of profit incentive eliminates the dangers associated with the CPOM.[15]

As a result of CPOM, new practice areas have surfaced that may be prone to running afoul of current statutes. A new practice area that may violate existing CPOM restrictions is the growth in "quick clinics," or physician offices generally found in large "doc-in-a-box" stores or pharmacies.[16] 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.[17]

Another growing trend in CPOM violation is the practice of nonphysician-owned spas offering Botox injections and other medical procedures with physicians staffed as medical directors.[18] Under this arrangement, unlicensed spa owners may be involved in the unlicensed practice of medicine, and the physician may be aiding and abetting.[19] At least one state, California, has issued regulations prohibiting this practice.[20]

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.[21] 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.[22] The defendant corporation argued that it should be reimbursed because all its patients received care from licensed providers.[23] However, because the corporation was owned by nonphysicians, the court found the organization to be in clear violation of state law.[24]

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 consultation. Examples of this trend include companies that provide medical consultation services by phone or e-mail and "quick clinics" that generally are found in larger "big box" stores and can take advantage of the store's clientele while allowing patient consumers to do efficient one-stop shopping (that is, they can shop while they wait for a physician to see them). These particular types of entities should be cognizant of the most recent CPOM in their states to avoid running afoul of restrictions.

"Demand Growing for Corporate Practice of Medicine," By Devon Herrick, Consumer Driven Health Care, National Center for Policy Analysis, Jan. 1, 2006, http://healthcare.ncpa.org/commentaries/demand-growing-for-corporate-practice-of-medicine (accessed June 24, 2009).

Healthcare Regulation at Federal and State Levels

Healthcare can be regulated at both the state and federal level. State legislation and enforcement measures actually may stem from federally elicited incentives or compliance standards (that is, Medicaid reimbursement (see chapter 2, *Medicaid and State Children's Health Insurance Program*). Conversely, some issues are federally regulated, which constitutionally binds states in compliance. Under these circumstances, federal guidelines are preserved but tailored through supplemental state law to meet state-specific needs.

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.[25] However, the domination of professional licensure boards by the professionals themselves also has been criticized as serving the interests of the profession more than the interests of the public.[26] Licensure of the various provider types is discussed in the corresponding sections of chapters 3, 4, 5, 6, and 7 in *Professional Practices*.

Individual Professional Licensure

Every state and the District of Columbia require licensure of all allopathic (M.D.) and osteopathic (D.O.) physicians.[27] Although the exact requirements for licensure vary by state, each state requires candidates to submit proof of "good moral character, adequate educational preparation [at an accredited medical school], appropriate practical experience, and successful completion of a licensure exam."[28]

A physician applying for licensure typically is found to be of good moral character absent his or her involvement in illegal activities.[29] Most physicians satisfy the exam requirement by submitting to the licensure board proof of their successful completion of the United States Medical Licensing Examination or the Comprehensive Osteopathic Medical Licensing Examination.[30] However, because some practicing physicians may have been licensed under a previously administered exam, some state licensing boards may consider a combination of other examinations as sufficient for licensure, as long as those exams were completed prior to 2000.[31] Once licensed, most states' scope of practice definitions allow physicians to perform almost all healthcare related activities, as the practice of medicine is the broadest definition in healthcare licensure.

As part of the Health Care Quality Improvement Act of 1986, the United States Congress established the National Practitioner Data Bank to improve the availability of information obtained during the peer review process.[32] The Department of Health and Human Services (HHS) is responsible for overseeing the system. The act requires state medical and dental licensing boards to report disciplinary action taken against a licensed professional, in regard to his or her professional competence and professional conduct.[33] Hospitals also are required to periodically check the status of the database for each member of their medical staff, and individual practitioners may request their own records, however, the general public does not have access the data bank.[34]

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.[35] Frequently, physician assistants, midwives, psychologists, social workers, opticians, physical therapy assistants, audiologists, and speech pathologists also are subject to state licensure laws.[36] As with physician licensing, state rules vary on licensure requirements for these professions.

Physician Versus Nonphysician Scopes of Practice

Because the licenses issued to nonphysician 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. 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 nonphysician professionals.[37]

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, as well as which services are covered.[38] 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 nonphysician practitioners, reimbursement rates are dictated by incident-to policies, which state the percentage of a service cost that a nonpractitioner may be reimbursed through Medicare.[39] These rates vary based on the level of supervision required (if at all) and the type of services provided (see chapter 4 in *Professional Practices*).[40] Further, the final rule of the 2010 Medicare physician fee schedule (MPFS) modified supervision requirements for in-hospital outpatient services to allow certain nonphysician practitioners (for example, clinical psychologists, physician assistants, nurse practitioners, clinical nurse specialists, certified nurse-midwives, and licensed clinical social workers) to be direct supervisors for all outpatient therapeutic services allowable under state laws.[41]

In some cases, Medicare rules and state laws overlap, which may be cause for controversy. For example, Certified Registered Nurse Anesthetists are authorized to administer anesthesia, without supervision, to Medicare patients if a state's governor petitions CMS on the basis of state need (see chapter 4 in *Professional Practices*).[42] 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.[43]

As the overlap between the scope of practice for physicians and nonphysicians increases, malpractice liability, which jeopardizes the licenses of both the supervising physician and the nonphysician professional, may increase as well.[44] For more information on mid-level provider competition with physicians see chapter 4 in *Professional Practices*.

Specialty Licensure and Certification

Technological advances during the past forty years have led to an increase in the specialization of healthcare personnel.[45] Accompanying this rise in specialization is the development of new categories of providers within the traditional healthcare professions, including pediatric nephrologists and hospitalists, physicians whose primary focus is the delivery of care in hospitals.[46] The creation of these specialties has been mirrored by a rise in various professional medical associations, which have created their own systems for credentialing specialists.[47] Although certification requirements vary by specialty, they typically include additional educational attainment, examinations, and work experience.[48] 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.[49]

Advances in technology also have led to the development of new categories of healthcare providers, including radiological technologists and speech pathologists, as well as the state licensing programs and private certifying agencies governing these providers.[50]

Healthcare Facility and Practice Licensure

Although the licensing of healthcare entities typically is 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.[51] As with other types of professional licensure, the licensure of healthcare facilities is intended to ensure that patients receive quality healthcare.

State regulation designates which healthcare facilities must be licensed. All states require hospitals to be licensed, and most states also require nursing homes to be licensed.[52] In addition, many states require further licensure of specialized areas within an already licensed facility, including hospital pharmacies, clinical laboratories, and hospital-based **ambulatory surgery centers (ASCs)**.[53]

In order to maintain licensure, facilities may need to meet certain building requirements and limit the number of beds allowed.[54] In addition, regulations, such as locally adopted zoning laws, occupancy permits, building codes, and building permits, may place increased demands on healthcare entities.

Physicians typically are not required to license their solo or group practices, because the state exercises control over these facilities through control of each physician's license.[55] 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.

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 and other requirements.[56] If a participating institution or program fails to maintain the requisite standards, they may not incur penalties other than the loss 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.[57]

Accreditation can be beneficial to organizations for purposes of federal compliance. Medicare grants deemed status to hospitals accredited by the Joint Commission[58] or the American Osteopathic Association (AOA).[59] 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.[60] Accreditation is also important because some payors will only contract with accredited providers.[61]

Major accrediting bodies in the United States include the **Joint Commission on Accreditation of Healthcare Organizations (JCAHO)**, the AOA, and the National Committee for Quality Assurance (NCQA).

The Joint Commission

JCAHO is a nongovernmental organization that strives to ensure the safety and quality of healthcare services provided to the public.[62] The Joint Commission pursues this goal by conducting on-site reviews and setting standards for institutional governance, support services, and patient care.[63] Facilities seek Joint Commission accreditation because it helps ensure the provision of quality services, attract quality staff, qualifies them to receive Medicare reimbursement, and in some states, is a licensure requirement.[64] The Joint Commission provides accreditation for ambulatory care centers, behavioral health centers, critical access hospitals, home health services, general hospitals, laboratory services, long-term care facilities, office-based surgery centers, and international healthcare providers.[65]

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.[66] The AOA strives to promote the practice of osteopathic medicine by ensuring quality in education, research, and the delivery of health-care services. In terms of accreditation, the AOA functions much like the Joint Commission.[67]

National Committee on Quality Assurance

The **National Committee for Quality Assurance (NCQA)** is a nonprofit organization that works with employers, doctors, policymakers, patients and health plans to improve the quality of healthcare through the accreditation of managed care plans.[68] NCQA performs this duty, much like other accrediting bodies, through the setting of standards and collection of outcome and performance data.[69]

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.[70] CON is based on the theory that, in an unregulated market, healthcare providers will provide the latest costly technology and equipment, regardless of duplication or need.[71] Despite CON's aim to reduce healthcare costs by preventing duplication of services, healthcare costs have continued to rise.[72]

Despite CON's aim to reduce healthcare costs by preventing duplication of services, healthcare costs have continued to rise.

"Improving Health Care: A Dose of Competition: Chapter 8: Miscellaneous Subjects," A Report by the Federal Trade Commission and Department of Justice, July 2004, p. 2.

Overview: The Federal Certificate of Need Program

CON statutes and regulations specify those healthcare facilities, medical equipment, and services which require applications and approval to operate. 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. While federal regulations provided legislation and enforcement provisions, however, program development and implementation generally took place at the state or local level.[73]

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.

"Beyond Health Care Reform: Reconsidering Certificate of Need Laws in a "Managed Competition" System," Patrick John McGinley, 23 Fla. St. U. L. Rev. 141, 145-148 (1995).

The National Health Planning and Resources Development Act of 1974 pushed CON regulations to the forefront of government healthcare cost containment efforts.[74] The act required that federal agencies pass health policy planning guidelines and establish "a statement of national health planning goals."[75] 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.[76] It also specified that state CON programs must meet federal guidelines in order to receive federal funding.[77] In response to the act, all fifty states developed some form of CON review program.[78]

Congress repealed the 1974 legislation in 1987, which caused fourteen states to discontinue their CON programs.[79] Despite the discontinuation of a formal CON program, all fourteen states retain certain regulatory mechanisms intended to prevent duplication of services.[80]

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.[81] State CON programs are administered according to statutes and regulations controlling market entry for regulated facilities, services, and equipment. Hospitals, nursing homes, certain freestanding clinics, home health agencies, and ASCs are often among the healthcare facility providers covered by CON.[82] CON also often applies to healthcare services, including the change of one service to another, the purchase of medical equipment, and new technology. 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.[83]

CON regulatory policy has been highly contentious in the state legislative arenas for many years, 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. In the four decades that CON has existed, approximately 800 reported legal cases have involved CON issues.[84] 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.

One argument against CON regulatory policy is that its intervention disrupts natural market forces and limits competition.[85] Seeking to preserve competition in healthcare markets, the Federal Trade Commission (FTC) consistently has criticized CON as a failed public health regulatory policy that creates barriers to new market competitors.[86]

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.[87]

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.

"The Effect of State Certificate-of-Need Laws on Hospital Costs: An Economic Policy Analysis," By Daniel Sherman, Federal Trade Commission, Jan. 1988, p. vi, www.ftc.gov/be/econrpt/232120.pdf (accessed October 10, 2009).

In November, 2002, FTC Chairman Timothy J. Muris announced that the FTC would hold joint hearings with the Department of Justice (DOJ) on competition in healthcare in the following year.[88] 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.[89] 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."[90] In addition to raising prices, the FTC has condemned CON regulation as causing lower quality and reduced innovation in healthcare markets.[91]

The FTC and DOJ stated their belief that ASCs are beneficial for consumers and that state CON laws pose an anticompetitive barrier to entry. In response to ASC provider allegations that general hospitals have attempted to use CON laws to prevent ASCs from entering the market, the agencies committed to aggressively pursue activities of anticompetitive conduct.[92] However, they acknowledged that antitrust laws do not prevent individual hospitals from unilaterally approaching state governments in connection with CON proceedings.[93]

Currently, thirty-six states and the District of Columbia retain some sort of CON program.[94] See box 3-1 for a complete list of states with CON legislation.

As of mid-2008, thirty-six states and the District of Columbia retained some sort of CON program.

"Certificate of Need: State Health Laws and Programs," By National Conference of State Legislatures, April 30, 2009, www.ncsl.org/IssuesResearch/Health/CONCertificateofNeedStateLaws/tabid/14373/Default.aspx (accessed June 24, 2009).

The Application Process

Every state has its own unique CON application process. However, general procedures tend to guide the application process in all states. 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.[95] If an application is approved, the project must typically begin within a specified amount of time.[96] If a CON holder fails to fulfill the requirements of the CON, the state may retain the right to revoke it.[97] In some states, a CON may be transferable, but laws governing such rights differ from state to state.

Box 3-1: States With Certificate of Need Legislation

1. Alabama	20. Montana
2. Alaska	21. Nebraska
3. Arkansas	22. Nevada
4. Connecticut	23. New Hampshire
5. Delaware	24. New Jersey
6. District of Columbia	25. New York
7. Florida	26. North Carolina
8. Georgia	27. Ohio
9. Hawaii	28. Oklahoma
10. Illinois	29. Oregon
11. Iowa	30. Rhode Island
12. Kentucky	31. South Carolina
13. Louisiana	32. Tennessee
14. Maine	33. Vermont
15. Maryland	34. Virginia
16. Massachusetts	35. Washington
17. Michigan	36. West Virginia
18. Mississippi	37. Wisconsin
19. Missouri	

Source: "National Directory State Certificate of Need Programs: Health Planning Agencies," By American Health Planning Association, 2008, p. 5.

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.[98]

Privacy Laws

Because practitioners, providers, and organizations have regular access to patient medical records, the handling of confidential healthcare information must be regulated to protect patients and ensure that their privacy is secure. Specifically, the Health Insurance Portability and Accountability Act of 1996 (HIPAA) regulates access to medical information, and the Red Flags Rules regulate access to financial information. With 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

Although HIPAA serves many purposes, it is most widely used for safeguarding the privacy of **protected health information (PHI)**, or individually identifiable health information.[99] This 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."[100] The HIPAA Privacy Rule provides standards for the use and disclosure of PHI by covered entities, as well as rights for individuals to control how their PHI is used.[101] The Privacy Rule governs such covered entities as, "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."[102] Transactions by healthcare providers falling under the HIPAA Privacy Rule include claims, benefit eligibility inquiries, referral authorization requests, and other transactions for which HHS has established particular standards.[103] 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.[104] When a covered entity contracts with a third-party entity to perform billing or other business associate activities, including, among other activities, claims processing, data analysis, and utilization review, the covered entity must impose specific safeguards of PHI.[105] The business associate agreement and the covered entity cannot authorize the business associate to use PHI in a way that would violate the Privacy Rule.[106] Even the proper destruction of PHI is protected under HIPAA. Approved technologies and methods of destroying records are listed in 74 Fed. Reg. 42742.

Health Information Technology for Economic and Clinical Health (HITECH) Act

Recently, the American Recovery and Reinvestment Act of 2009 (ARRA) made changes to HIPAA's health information privacy and security provisions.[107] The ARRA used the Health Information Technology for Economic Clinical Health (HITECH) Act in order to promote widespread adoption of health information technology, particularly **electronic health records (EHR)**.[108] 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.[109] 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.[110] Though these new notification requirements were effective as of September 23, 2009, enforcement was delayed until February 17, 2010.[111] The exceptions to the HITECH Act for PHI include

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;
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.[112]

Medicare National Provider Identifiers (NPI)

Originally, all providers seeking reimbursement under Medicare were given a unique physician identification number (UPIN). UPINs were discontinued as of June 2007 and replaced by National Provider Identifiers (NPI) to meet the "Administrative Simplification Standard" required under HIPAA.[113] The NPI is a ten-digit unique identification number required for all covered healthcare providers expecting reimbursement under Medicare, Medicaid, or any federal health program.[114] NPIs contain an entity type code, one being used for individual practitioners (for example, physicians, dentists, nurses, chiropractors, pharmacists, and physical therapists) and two being for healthcare provider organizations (for example, hospitals, group practices, ambulance companies, medical suppliers, etc.).[115] Mid-level providers who "furnish healthcare but do not necessarily conduct covered transactions" also are eligible for NPIs.[116] The use of NPIs is intended to improve, "the effectiveness and efficiency of the health care industry in general, by simplifying . . . administration . . . and enabling the efficient electronic transmission of certain health information."[117]

Red Flags Rules

On November 9, 2007, the FTC and other agencies published a list of "red flags," which indicate the possibility of identity theft, and mandated the implementation of an identity theft prevention program.[118] The deadline for required, written compliance programs has since been deferred until June 1, 2010.[119] This rule is intended to include all businesses defined as creditors (a "business or organization that . . .

provide[s] good or services and bill[s] customers later") that deal with covered accounts. Under the Red Flags Rules, a covered account includes:

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."[120]

Healthcare institutions will have to (1) review their billing practices and payment procedures and (2) create a program to ensure compliance.[121] 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.[122] Although varying degrees of detail are required depending on organizational complexity, all enterprises, healthcare and otherwise, are subject to regulation under the Red Flags Rules.[123]

The Patient Safety and Quality Act of 2005

The Patient Safety and Quality Act (PSQIA) of 2005 effective 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.[124] 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.[125] *Patient safety work product* includes any information that is collected while reporting and analyzing patient safety events.[126] Under PSQIA, Patient Safety Organizations are charged with collecting and analyzing data under the supervision of the Agency for Healthcare Research and Quality.[127]

Fraud and Abuse Laws

The corporatization of healthcare triggered a surge of fraud and abuse regulation of practice and practitioner arrangements.

False Claims Act (FCA)

The False Claims Act (FCA) is a federal law 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 payment or approval."[128] Since Congress amended the FCA in 1986, it has become one of the primary weapons used to combat healthcare fraud, particularly when used in conjunction with the federal physician self-referral (Stark) law and the federal antikickback statute.[129] The 1986 amendments strengthened the statute's qui tam, or whistleblower provision.[130] Under the statute's qui tam provisions, any private citizen can enforce the FCA by filing a complaint alleging fraud against the federal government.[131] **Qui tam actions** are often brought by former employees, but they can also be brought by competitors.[132] The DOJ assumes primary responsibility for prosecuting the claim if it believes the claim has merit.[133] The whistleblower is entitled

to share in a portion of any recovery the government makes.[134] Because the FCA provides for **treble damages** plus an additional penalty for each false claim, potential liability can be tremendous.[135]

Although potential violations of the FCA include **upcoding** and billing for unnecessary services, recent DOJ enforcement actions have shifted from targeting intentional criminal activity to targeting legitimate providers. For example, an action was brought in 2002 against a Kentucky orthopedic surgeon for failing to properly supervise residents.[136] However, in 1998, the Office of the Inspector General (OIG) and the DOJ issued guidelines limiting enforcement actions.[137] Still, qui tam actions pose a significant threat to providers, as the potential to share in the recovery of any ill-gotten funds creates a strong incentive for private individuals to bring these actions.

In addition to direct violations, the FCA is also used to prosecute violations of Stark laws (see *Stark Law*) and the federal antikickback statute (see *Antikickback Statute*). In particular, physician acceptance of **kickbacks** (that is, monetary bribes, free travel, and various other prerequisites) from pharmaceutical and medical device manufacturers recently have come under increased scrutiny as violations of the FCA.[138]

> Recently, the Physician Payments Sunshine Act of 2009 has been introduced to address illegal kickback activities. If passed, the act will require makers of pharmaceuticals, medical devices, and biologics to issue public statements concerning the money they give to doctors that exceeds $100 every year. Penalties for knowingly failing to disclose information under the act could be as high as $1 million per violation. Senators Chuck Grassley (R-IA) and Herb Kohl (D-WI) have been working on getting the Physician Payments Sunshine Act passed for a couple of years, and they seem confident that it will be passed by the 111th Congress.
>
> *"Grassley, Kohl Continue Campaign to Disclose Financial Ties Between Doctors and Drug Companies," Press Release, United States Senate Special Committee on Aging, Jan. 22, 2009, http://aging.senate.gov/record.cfm?id=307097 (accessed June 25, 2009).*

Fraud Enforcement and Recovery Act of 2009 (FERA)

In 2009, the federal government enacted the Fraud Enforcement and Recovery Act of 2009 (FERA), which focuses on expanding government resources to combat fraud in the housing and mortgage arena and expands the scope of the FCA.[139] FERA 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.[140] Under the new definition, 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."[141] In addition, FERA reduces the government's burden of proof, no longer requiring it to show specific intent to defraud. It now requires only a showing by a preponderance of the evidence of "deliberate ignorance" or "reckless disregard of the truth or falsity" of information.[142]

FERA also expanded the definition of "claim" to include any request for money or property offered to a government employee or official, as well as requests to contractors working on behalf of the government.[143] The expanded definition also includes any attempt to defraud the government regardless of

Box 3-2: States With False Claims Act Legislation

1. California
2. Delaware
3. Florida
4. Georgia
5. Hawaii
6. Illinois
7. Indiana
8. Louisiana
9. Massachusetts
10. Michigan
11. Minnesota
12. Montana
13. Nevada
14. New Hampshire
15. New Jersey
16. New Mexico
17. New York
18. North Carolina
19. Oklahoma
20. Rhode Island
21. Tennessee
22. Texas
23. Virginia
24. Washington, D.C.
25. Wisconsin

Source: "State False Claims Acts," The False Claims Act Legal Center, Taxpayers Against Fraud Education Fund, http://www.taf.org/statefca.htm (Accessed February 10, 2010).

whether the government is currently in possession of the money or whether the accused party intended to defraud the government.[144] Further, organizations are only liable if they "knowingly" retain improper payments.[145]

State False Claims Acts

Twenty-three states, the District of Columbia, and the individual cities of New York and Chicago have enacted false claims acts.[146] For the complete list, see box 3-2.

Additionally, some other states may have false claims acts that apply specifically to healthcare fraud, but which may or may not have qui tam provisions. See box 3-3.

Violations of state false claims acts can result in fines as high as $15,000 per false claim.[147] Although the state statutes commonly mirror the federal FCA, some differences can include expanded liability provisions in state false claims acts, jurisdictional bars not found in the federal FCA, and damage and penalty provisions that may differ from the federal law.[148]

It is projected that the number of states with false claims acts will grow in the coming years, as Congress passed legislation in 2005 creating financial incentives for states to create their own acts.[149] In the Deficit Reduction Act (DRA),[150] the federal government 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.[151] Prior to DRA, that money would have gone to the federal government.[152] Since its implementation in January 2007, the incentive has compelled many states to amplify their existing false claims laws, and it has encouraged more states to develop new false claims acts.[153]

The OIG for HHS is charged with reviewing state false claims laws to ensure they meet the requirements for the DRA incentive program. Programs must[154]

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 the Social Security Act,
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.[155]

Box 3-3: States With False Claims Act Legislation and no Qui Tam Provision

1. Arkansas
2. Michigan
3. North Carolina
4. Oklahoma
5. Utah
6. Washington

Source: "Health Care Fraud: Enforcement and Compliance," By Robert Fabrikant, et al., Law Journal Press, 2007, p. 4-72.4, n.1.

To date, the OIG has reviewed the false claims acts of twenty states, finding fourteen to be in compliance with the requirements of the DRA.[156] The OIG found that the false claims laws of the other six states were not as effective at facilitating and rewarding qui tam actions as the federal FCA.[157]

In addition, the DRA also requires that entities receiving more than $5 million annually from Medicaid establish an employee education plan covering state and federal false claims laws and whistleblower protections.[158] The education plan must provide information on the federal FCA, administrative remedies for false claims and statements, any civil or criminal penalties under state false claims laws, and whistleblower protections under federal and state law.[159] The DRA made this education requirement a prerequisite of Medicaid participation for entities making or receiving payments totaling more than $5 million a year from participation in Medicaid; failure to comply with the January 2007 deadline meant possible exclusion from the program.[160]

Antikickback Statute

Enacted in 1972, the federal antikickback statute makes it a felony for any person (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 healthcare program.[161] Violations of the antikickback statute are punishable by up to five years in prison, criminal fines up to $25,000, or both.[162]

The original statute was amended in 1987 with the passage of the Medicare and Medicaid Patient and Program Protection Act of 1987 (MMPPPA) to include an alternative civil remedy: exclusion from the Medicare program.[163] 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.[164] Civil penalties are believed to be a more effective way of enforcing the statute because the government need not prove the violation by the criminal standard of beyond a reasonable doubt.[165] Instead, to impose a civil penalty, the government need only prove the violation by the lesser standard of a preponderance of the evidence, meaning at least 51 percent of the evidence points to a certain conclusion.[166]

Regulatory and Court Interpretations of Statute

The OIG periodically issues "Special Fraud Alerts" providing 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 and rental agreements for space in physician offices.[167]

Both the OIG and case law have adopted expansive interpretations of the statute.[168] Therefore, many financial relationships, such as the exchange of anything of value between providers, could result in a potential violation.[169]

Thornton Letter—Office of the Inspector General

In 1992, the OIG Associate General Counsel D. McCarty Thornton launched a direct attack against physician owners of specialty care practices.[170] He sent a letter to the Internal Revenue Service (IRS) regarding kickback concerns related to an acquisition involving a charitable 501(c)(3) buyer.[171] Thornton claimed that any amount paid to physicians in excess of the fair market value of the practice's hard assets was suspect and could be considered inducement for referrals.[172] Effectively, this prohibited payments for goodwill, value of an ongoing business unit, covenants not-to-compete, exclusive dealing

arrangements, patient lists, and patient records.[173] In many cases, the Thornton letter resulted in a diminution of practice asset value considered by some to be an unconstitutional taking of property, as the effect of the letter made it difficult for specialists to sell their practices for a reasonable amount.[174]

> The Thornton letter resulted in a diminution of practice asset value considered by some to be an unconstitutional "taking of property," which made it impossible for specialists to sell their practices for a reasonable amount.

"Aspects of Fraud in Healthcare Valuation," by Robert James Cimasi, Speech to National Association of Certified Valuation Analysts, June 2, 2006, p. 12.

"One Purpose" Test

The "one purpose" test, established in *United States v. Greber*, is one of the most far reaching interpretations of the statute. Under the one purpose test, the antikickback statute is violated if even one purpose of the arrangement is to offer illegal remuneration.[175] Subsequently adopted by the OIG, under the one purpose test, providers reasonably can expect referrals to result from a business arrangement, but the expectation must not be a reason for entering into the arrangement.[176] 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.[177] Opponents also argue that it is impossible for providers to expect referrals and not consider referrals when entering into a business arrangement.[178]

Safe Harbors

Due to the broadness of the antikickback statute, legitimate business arrangements also may be prohibited. For example, if the statute was interpreted literally, 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.[179] Therefore, Congress created a number of statutory exceptions and gave HHS authority to protect other business arrangements through *safe harbors*.[180] Safe harbors detail specific regulatory criteria that must be met to shield an arrangement from liability, and they are meant to protect practices unlikely to result in fraud or abuse.[181] The failure to comply with every requirement does not mean that the arrangement is illegal,[182] if there is a low risk of fraud and abuse.[183]

The MMPPPA directed HHS to promulgate regulations specifying payment practices that did not violate the statute. Congress created the following statutory exemptions from the antikickback statute, protecting 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;
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.[184]

These safe harbors were intended to "permit physicians to freely engage in business practices and arrangements that encourage competition, innovation and economy."[185] HHS has created a number of safe harbors since 1989, and it 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.[186] In 1999, HHS added safe harbors protecting investments in healthcare entities located in underserved areas, investments in ambulatory surgical centers (ASCs), and investments in group practices.[187]

The most important safe harbors for the purposes of physician integration protect certain physician investment interests. Certain investment interests were protected because, "Congress did not intend to absolutely bar any investment by physicians in other health care entities."[188] Certain business investments "represent the extension of a physician's office space and not a means to profit from referrals."[189] Business arrangements which are "functionally an extension of a physician's office" pose less "risk of improper payments for referrals."[190] The OIG intended to protect these physician investment interests, because the OIG believed that the risk of improper referrals was relatively low when the physician personally performed services at, for example, the ASC on his or her own patients.[191] The OIG also was influenced by CMS's policy of promoting greater utilization of ASCs. Physicians were a natural source of capital for ASCs because hospitals were reluctant to invest in ASCs that might compete with their surgery departments.[192] These investment safe harbors were intended to protect arrangements that "can significantly reduce costs for Federal health care programs, while simultaneously benefiting patients."[193] In particular, HHS wanted to avoid "chill[ing] group practice integration that is crucial in an increasingly managed care *environment*."[194]

There are a total of twenty-five safe harbors under the antikickback statute. As used in section 1128B of the act, box 3-4 includes all of the twenty-five safe harbors and are not considered remuneration as long as the safe harbor's requirements are satisfied.

Box 3-4: Safe Harbor Regulations

The following twenty-five safe harbor regulations can be found in the antikickback statute:
1) Returns on investment interests. Payments that are in the form of a return on an investment.
2) Space rental. Payments for the use of premises made by a lessee to a lessor.
3) Equipment rental. Payments for the use of equipment made by equipment lessees to equipment lessors.
4) Personal services and management contracts. A principal's payments to an agent for the agent's services.
5) Sale of practice. A payment made by one practitioner for the purchase of the practice of another practitioner.
6) Referral services. Payments for the exchange of anything of value between a "participant" and a referral service.
7) Warranties. Payments or the exchange of anything of value under a manufacturer's or supplier's warranty.
8) Discounts. A discount given on an item or service for which a payment may be made in full or in part by Medicare, Medicaid, or other federal healthcare programs.

(continued)

Box 3-4: Safe Harbor Regulations *(continued)*

9) Employees. A payment made by an employer to an employee who has a bona fide employment relationship with the employer to deliver any item or service for which a payment may be made in full or in part by Medicare, Medicaid, or other federal healthcare programs.
10) Group purchasing organizations (GPO). Payments made by a vendor of goods or services to a GPO, pursuant to an agreement to furnish the goods or services.
11) Waiver of beneficiary coinsurance and deductible amount. A reduction or waiver of a Medicare or state healthcare program beneficiary's coinsurance or deductible.
12) Increased coverage, reduced cost-sharing amounts, or reduced premium amounts offered by health plans. The additional coverage of items or services offered by health plans to enrollees, reductions in the enrollee's obligation to pay the health plan or healthcare provider, or reductions in premiums for items and services covered by the health plan, Medicare, or a state healthcare program.
13) Price reductions offered to health plans. Price reductions found in a contract between a provider and a health plan for the provision of items or services to enrollees covered by the health plan, Medicare, or a state healthcare program.
14) Practitioner recruitment. Payments or the exchange of anything of value given by an entity to influence the relocation of a practitioner who has been practicing in his or her current specialty for less than one year, or to influence any other practitioner, to relocate their practice into a health professional shortage area (HPSA) for their specialty that is served by the entity.
15) Obstetrical malpractice insurance subsidies. Payments made by hospitals or entities that are providing malpractice insurance when the payments are used to subsidize or pay all of the costs of malpractice insurance premiums for practitioners who routinely engage in obstetrical practice as a part of their medical practice in a primary care HPSA.
16) Investments in group practices. Payments, in the form of a return on an investment, made to a practitioner investing in his or her own practice or a group practice.
17) Cooperative hospital service organizations (CHSO). Payments between a CHSO and its patron hospital, tax-exempt entities described in section 501(e) of the Internal Revenue Code of 1986, when the CHSO is owned by two or more patron hospitals.
18) Ambulatory surgery centers (ASC). Payment that is a return on an investment, as long as the entity is certified in accordance with part 416 of this title, its operating and recovery room space is exclusively dedicated to the ASC, all patients referred to the entity by an investor are fully informed of the investor's ownership interest, and all the following applicable standards are met within one of the following categories:
    a. *Surgeon-owned ASCs:* To fall within the safe harbor for surgeon-owned ASCs
        i. the investment terms offered to an investor may not be tied to the previous or expected number of referrals, services furnished, or the amount of business for the entity otherwise generated by the investor;
        ii. at least one-third of the surgeon investor's practice income for the prior fiscal year or the prior twelve-month period must come from the surgeon's performance of procedures;
        iii. neither the entity nor any investor can loan funds or guarantee a loan for an investor, if the investor uses any portion of the loan to acquire the investment interest;
        iv. an investor's payment in return for his or her investment must be directly proportional to the amount of capital he or she invested; and
        v. ancillary services performed for beneficiaries of federal healthcare programs must be related to the primary procedures performed at the entity and may not be billed separately to Medicare or other federal healthcare programs.
    b. *Single-Specialty ASCs:* To fall within the safe harbor for single-specialty ASCs
        i. the investment terms offered to an investor may not be tied to the previous or expected number of referrals, services furnished, or the amount of business for the entity otherwise generated by the investor;
        ii. at least one-third of the surgeon investor's practice income for the prior fiscal year or the prior twelve-month period must come from the surgeon's performance of procedures;
        iii. neither the entity nor any investor can loan funds or guarantee a loan for an investor, if the investor uses any portion of the loan to acquire the investment interest;
        iv. an investor's payment in return for his or her investment must be directly proportional to the amount of capital she or she invested;
        v. ancillary services performed for beneficiaries of federal healthcare programs must be related to the primary procedures performed at the entity and may not be billed separately to Medicare or other federal healthcare programs; and
        vi. patients receiving medical benefits or assistance under any federal healthcare program must not be discriminated against by the entity or any physician investor.
    c. *Multi-Specialty ASCs:* To fall within the safe harbor for multi-specialty ASCs
        i. the investment terms offered to an investor may not be tied to the previous or expected number of referrals, services furnished, or the amount of business for the entity otherwise generated by the investor;

Box 3-4: Safe Harbor Regulations *(continued)*

ii. at least one-third of the surgeon investor's practice income for the prior fiscal year or the prior twelve-month period must come from the physician's performance of procedures;
iii. physician investors must perform at least one-third of their procedures for the prior fiscal year or the prior twelve-month period at the investment entity;
iv. neither the entity nor any investor can loan funds or guarantee a loan for an investor, if the investor uses any portion of the loan to acquire the investment interest;
v. an investor's payment in return for his or her investment must be directly proportional to the amount of capital he or she invested;
vi. ancillary services performed for beneficiaries of federal healthcare programs must be related to the primary procedures performed at the entity and may not be billed separately to Medicare or other federal healthcare programs; and
vii. patients receiving medical benefits or assistance under any federal healthcare program must not be discriminated against by the entity or any physician investor.

d. *Hospital or Physician ASCs:* To fall within the safe harbor for hospital or physician ASCs
i. the investment terms offered to an investor may not be tied to the previous or expected number of referrals, services furnished, or the amount of business for the entity otherwise generated by the investor;
ii. neither the entity nor any investor can loan funds or guarantee a loan for an investor, if the investor uses any portion of the loan to acquire the investment interest;
iii. an investor's payment in return for his or her investment must be directly proportional to the amount of capital he or she invested;
iv. patients receiving medical benefits or assistance under any federal healthcare program must not be discriminated against by the entity, an investor in the entity, or any physician investor;
v. ancillary services performed for beneficiaries of federal healthcare programs must be related to the primary procedures performed at the entity and may not be billed separately to Medicare or other federal healthcare programs;
vi. the hospital's report, or any other claim for payment from a federal healthcare program, may not include any costs associated with the ASC unless the federal healthcare program requires their inclusion; and
vii. the hospital cannot directly or indirectly make or influence referrals to any investor or entity.

19) Referral arrangements for specialty services. Exchanges of value between individuals and entities, where one party has agreed to refer a patient for specialty care payable in full or in part by Medicare, Medicaid, or any other federal healthcare program in return for an agreement to refer the patient back at an agreed upon time or circumstance.
20) Price reductions offered to eligible Managed Care Organizations (MCOs). Payments in the form of price reductions offered between eligible MCOs and any first-tier contractor for providing for or arranging for items or services, or between a first-tier contractor and a downstream contractor or between two downstream contractors for the provision or arrangement of items or services.
21) Price reductions offered by contractors with substantial financial risk to MCOs. Payments in the form of price reductions offered between a qualified managed care plan and a first-tier contractor for the provision of or arrangement for items and services, or between a first-tier contractor and a downstream contractor or between two downstream contractors for the provision of or arrangement for items or services.
22) Ambulance replenishing. Gifts or transfers of drugs or medical supplies from a hospital or other receiving facility to an ambulance provider in order to restock the drugs and medical supplies used in connection with the transport of the patient. To qualify for this exception, the ambulance must be used to provide emergency ambulance services an average of three times per week.
23) Health centers. The transfer of any goods, items, services donations, loans, or a combination thereof from an individual or an entity to a health center.
24) Electronic prescribing items and services. Nonmonetary remuneration that is necessary for, and used solely to, send and receive electronic prescription information.
25) Electronic Health Record Items and Services. Nonmonetary remuneration that is necessary for, and used predominantly to, create, maintain, transmit, or receive electronic health records.

Source: "Exceptions" 42 C.F.R. 1001.952(a)-(x) (2004).

Although these exemptions allow federally funded healthcare programs to lessen their liability under the antikickback statute, many business interactions may still be suspect under 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 (DHS)**, defined by HHS, if the physician, or an immediate family member, has a financial relationship with that entity.[195] 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."[196] 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.

Prohibitions of physician self-referral are similar to the antikickback legislation, in that both laws prohibit conduct which induces physicians and allied health professionals to profit from referring patients to particular facilities. 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 antikickback statute is concerned with the financial relationship between providers.[197] The other important difference between the regulations is that the self-referral prohibitions apply only to Medicare and Medicaid, but the antikickback legislation applies to all federally funded state healthcare programs.[198]

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 antikickback statute, self-referrals were prevalent in the healthcare industry.[199] 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.[200]

Stark I

The Ethics in Patient Referrals Act (Stark I) was promulgated in 1989 and was implemented in various stages during the early 1990s.[201] Stark I 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.[202] Further, the lab was prohibited from billing for those services.[203]

Stark II

In 1993, Stark I was amended to expand the prohibition against referrals to clinical laboratories in which physicians had an ownership or investment interests, to ten additional categories of DHS (see definition of DHS).[204] Stark II was to be implemented in two phases, the first of which became effective on January 4, 2002.[205] In 2004, the second phase of Stark II was published, which implemented Stark II as an interim final rule to replace the 1995 Stark I final rule.[206]

Stark II, Phase III

On September 5, 2007, 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.[207] One requirement, as set out in the Phase I regulations, stipulated that there exist at least two financial relationships between the physician and the DHS entity in order for an indirect compensation arrangement to exist.[208] 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 compensation direct compensation arrangement as the physician organization itself.[209] As a result, a hospital that has a contract for professional services with a physician group, considered indirect under the Phase I regulations due to a financial relationship between individual physicians and their group practice as well as a relationship between the group practice and the hospital, is now considered to have a direct compensation arrangement.[210] Under this revision of the rule, a physician organization is no longer considered an intervening entity for purposes of establishing an indirect compensation arrangement, and arrangements between providers, and DHS entities may need to be structured differently to avoid Stark liability.[211]

This change applies to physician-owners, physician-employees, and physician-contractors of a physician organization.[212] However, other arrangements, such as an arrangement between a DHS entity, a leasing company, and a physician, are analyzed as an indirect compensation arrangement.[213]

Stark IV

Stark IV refers to the changes made to the Stark law in the 2009 Inpatient Prospective Payment System (see chapter 2, *Facility-Based Reimbursement Rates*).[214] 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

In Stark IV, CMS modified the stand in the shoes provision first introduced in Stark II Phase III. Under the final Stark IV version of the provision, physicians who have an ownership or investment interest in a physician organization are considered to stand in the shoes of the physician organization for the purpose of Stark laws.[215] Accordingly, the physician collapses into the physician organization, resulting in the physician organization no longer being considered an intervening entity for the purpose of establishing an indirect compensation arrangement with a DHS.[216] This mandatory provision applies only when the ownership or investment interest includes the ability or right to receive financial benefits.[217] However, in situations in which a physician organization employs both physician owners and nonowner physicians, DHS entities are allowed to treat the nonowner physicians as standing in the shoes of the physician organization so that two different compensation analyses are not required.[218] Exempted from the provisions are arrangements which meet the requirements of the academic medical centers exception.[219] Additionally, the rule refrained from finalizing stand in the shoes provisions originally proposed for DHS entities.[220]

Expansion of "Entity" to Include Under Arrangement Service Providers

CMS also changed the framework of under arrangements in Stark IV, such that both the physician-owned entity (which provides the service), as well as the hospital (which bills for the service), are considered DHS entities for purposes of Stark law.[221] The result of this provision is that it will preclude physician-owned entities from performing services on hospital patients under arrangements with the hospitals, unless the physician-owner(s) can satisfy the ownership exception under Stark. CMS concluded that any entity that performs a service under arrangement for a hospital which is then billed by the hospital is now considered a DHS entity, even if that service would not have been considered a DHS entity if the service was done outside the hospital setting. The only exception to this final conclusion is for lithotripsy services, procedures using shock waves to break up stones in urinary organs.[222]

Prohibition of "Per-Click" Arrangements and Percentage-Based Rent

Stark IV, effective October 1, 2009, 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, as they are seen as gainsharing agreements.[223] A **gainsharing** agreement is a pay-for-performance system that rewards employees for boosts in productivity and reductions in costs associated with poor quality.[224] This means that physicians and DHS entity lessors may not charge physician lessees rent based on the number of services provided by the lessees which are referred to them by the lessors. CMS concluded that on-demand time-based rental arrangements also are considered per-click arrangements and, therefore, fall under the limitation, as well.[225]

Similarly, CMS finalized a rule prohibiting 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.[226] Excluded from this prohibition are arrangements in which physicians pay on a percentage basis for management and billing services.[227] CMS also declared that the rule would not prohibit gainsharing arrangements, as long as they are properly structured incentive payment and shared saving programs.[228]

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.[229] Similar to concerns on the restrictive nature of the antikickback statute, Congress intended to protect group practices to avoid loss of integration.[230] There are thirty-five total exceptions to the Stark law, and the statute gives the secretary of HHS the authority to promulgate additional exceptions.[231] A significant difference between the antikickback 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.[232]

The thirty-five exceptions to the Stark law are divided between exceptions that apply to both ownership or investment interests and compensation arrangements,[233] exceptions that apply to only ownership or investment interests, and exceptions that apply to only compensation arrangements.[234] Exceptions which apply to both ownership and 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. qimplants 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
9. intrafamily rural referrals.[235]

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).[236]

There are a total of thirty-five 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(a)(1)(A).

The final subpart to this last exception, commonly known as the *whole hospital exception*, allows a physician to have an ownership interest in a hospital if the physician performs services at the hospital.[237]

Finally, exceptions that apply to only compensation arrangements can be found in box 3-5.

Federal and State Efforts to Eliminate Stark Whole Hospital Exception

The whole hospital exception allows physician self-referrals to hospitals in which they have an ownership stake as long as the physician is authorized to perform services at the hospital and the ownership or investment interest is in the entire hospital.[238] When proposed, there was little worry that this arrangement would create a risk of abuse, as it was believed that "ownership interests in an entire hospital would be so diluted that it would have no effect on referral decisions."[239]

Proponents of the whole hospital exception contend that it allows for the development of specialty and niche providers, which leads to healthcare services being provided in a more cost effective manner, while also maintaining and improving quality and beneficial outcomes.[240] However, the exception's opponents argue that because specialty hospitals are smaller in size, they are comparable to the individual departments within general hospitals.[241] Therefore, opponents argue, physician ownership of specialty hospitals raises the same concerns as does the ban on physician ownership in specialty departments within general hospitals: the risk that a physician's referral decisions and clinical judgment will be affected by the ability to influence his or her own income.[242]

Although healthcare has traditionally been regulated by the states, the federal government, as the largest payer of health care services, can mandate how these services are provided in the United States. Accordingly, opponents of the whole hospital exception repeatedly have lobbied the federal government to eliminate or mitigate the effects of the safe harbor. In 2001,

Box 3-5: Compensation Arrangement Exceptions

A list of Stark Law compensation arrangement exceptions include:

1. Rental of office space
2. Rental of equipment
3. Bona fide employment relationships
4. Personal service arrangements
5. Physician recruitment
6. Isolated financial transactions
7. Certain arrangements with hospitals
8. Group practice arrangements with hospitals
9. Payments by attending physicians
10. Charitable donations by attending physicians
11. Nonmonetary compensation
12. Fair market value compensation
13. Medical staff incidental benefits
14. Risk sharing arrangements
15. Compliance training
16. Indirect compensation arrangements
17. Referral services
18. Obstetrical malpractice insurance subsidies
19. Professional courtesy
20. Retention payments
21. Community-wide health information technology systems
22. Electronic prescription items and services
23. Electronic health records items and services

Source: "Exceptions to the Referral Prohibition Related to Ownership or Investment Interests" 42 C.F.R. 411.356 (October 1, 2008).

congressmen Pete Stark (D-CA) and Jerry Kleczka (D-WI) unsuccessfully introduced the Hospital Investment Act with the intention of limiting the whole hospital exception.[243] The act would have required newly formed specialty hospitals to undertake an initial public offering, instead of merely offering investment opportunities to the physicians practicing at the hospital, a requirement that would have rendered the startup of specialty hospitals too expensive to undertake.[244]

The Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (MMA) implemented an eighteen-month moratorium on the development of new specialty hospitals.[245] The moratorium represented a compromise between congressmen Kleczka and Stark, who believed that the whole hospital exception should be removed for all hospitals, and Senator Breaux, who advocated removing the exception only for specialty hospitals.[246] The moratorium officially ended on June 8, 2005.[247] However, the DRA, enacted on February 8, 2006, continued the suspension of CMS's enrollment of new specialty hospitals until six months after enactment of the DRA or the release of the final report on specialty hospitals by CMS required by the DRA, whichever came earlier.[248]

The eighteen-month moratorium on the development of new specialty hospitals, implemented by the MMA, lasted until June 8, 2005, only to be reinstated by the DRA on February 8, 2006.

"Medicare Prescription Drug, Modernization, and Improvement Act of 2003" §507(a)(1)(B); "Moratorium on Specialty Hospitals Expires" By Jennifer Gordon, Dallas Business Journal, http://assets.bizjournals.com/dallas/stories/2005/06/20/story8.html (accessed June 25, 2009); "Payment Provisions in Original Medicare Program Immediately Affected by The Deficit Reduction Act," Press Release, Centers for Medicare and Medicaid Services, February 10, 2006, www.cms.hhs.gov/apps/media/press/release.asp?counter=1779 (accessed March 2, 2005).

On August 8, 2006, CMS released its report on specialty hospitals, *Final Report to the Congress and Strategic Implementing Plan* (Report).[249] The report's recommendations included many aspects designed to make investing in specialty hospitals less attractive, such as a downward adjustment of specialty hospital reimbursement.[250] Additionally, the report recommended aligning physician and hospital interests to promote "better hospital physician collaboration," ensuring that all hospitals be in compliance with the Emergency Medical Treatment and Active Labor Act (EMTALA) (see *Emergency Medical Treatment and Active Labor Act*) when they provide services and requiring investment disclosure by physicians informing patients of their ownership interest before treatment.[251] Finally, the report recommended subjecting specialty hospitals to greater Stark and antikickback statute scrutiny.[252]

In recent years, efforts to eliminate or mitigate the effects of the whole hospital exception have continued at the federal level. For example, both Congressman Stark's proposed amendment to the Children's Health and Medicare Protection Act of 2007 and the U.S. House of Representatives' legislation, the Paul Wellstone Mental Health and Addiction Equity Act of 2008 (see chapter 6 in *Professional Practices*), unsuccessfully attempted to restrict physician ownership of hospitals.[253]

State law efforts to eliminate or mitigate the effects of the Stark law's whole hospital exception can take various forms including licensure, quality inspections, facility requirements, facility taxes, state CON laws, and state self-referral regulations.[254]

Licensure

Licensing provides a framework for the delivery of quality healthcare services, but it does not guarantee that quality care will be provided.[255] Historically, states have required that hospitals be licensed (see *Healthcare Facility and Practice Licensure*). Under the licensure schemes in most states, a specialty hospital is considered to be a general hospital for the purposes of licensure.[256]

Licensing legislation also has been proposed as an attempt to prevent competition by physician-owned specialty hospitals. In 2007, a community hospital CEO in California unsuccessfully pushed for a bill that would have prohibited the building of hospitals in the district if they did not have an emergency department.[257]

Quality Inspections and Facility Requirements

Quality inspections and facility requirements subject medical facilities to periodic inspections and the attainment of minimum standards.[258] For example, a New York law, the New York Patient Protection Bill, which took effect in July 2009, created a new rule requiring that physicians performing office-based surgery have their offices accredited.[259] The new bill forced many doctors, especially those in urban areas with offices not conducive to a remodel, to seek office space elsewhere.[260] Although New York's standards were enacted to ensure patient safety, it is reasonable to assume that opponents of the whole hospital exception may attempt to utilize rigid quality inspection and facility requirement standards in an effort to thwart competition from specialty hospitals.

Facility Taxes

Some states have attempted to level the playing field between general and specialty hospitals through certain tax initiatives. In June 2004, the New Jersey legislature imposed a tax on certain ambulatory care facilities, specifically excluding those owned by a hospital.[261] The measure places a 3.5 percent tax on gross revenues of ambulatory care centers and a 6 percent tax on gross receipts from cosmetic procedures, with the revenues raised to be used to compensate hospitals for charity care.[262] Facilities taxed include, ASCs, facilities providing diagnostic imaging services, and outpatient cancer centers.[263] The facility itself is taxed under the corporate business tax, and the physician-owners are taxed under the personal income tax code.[264]

Certificate of Need

CON regulation requires that health care providers obtain state approval before either developing new services, or expanding existing services (see *Certificate of Need* (*CON*)).[265] Because stringent CON regulation effectively can prevent or limit specialty and niche providers from entering a state, thereby protecting general hospitals from competition, the use of CON laws has become one of the primary attacks on physician-owned hospitals at the state level.[266] As of 2008, thirty-six states and the District of Columbia had CON laws.[267]

Antikickback 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 box 3-6.

Box 3-6: States With Self-Referral and Antikickback Legislation

1. Alabama (antikickback)	22. Missouri
2. Arizona	23. Montana
3. Arkansas	24. Nevada
4. California	25. New Hampshire
5. Colorado	26. New Jersey
6. Connecticut	27. New Mexico (antikickback)
7. Delaware (antikickback)	28. New York
8. Florida	29. North Carolina
9. Georgia (self-referral)	30. Ohio
10. Hawaii (self-referral)	31. Oklahoma
11. Illinois	32. Pennsylvania
12. Indiana (antikickback)	33. Rhode Island (antikickback)
13. Kansas	34. South Carolina
14. Kentucky	35. South Dakota
15. Louisiana	36. Tennessee (self-referral)
16. Maine (self-referral)	37. Texas (antikickback)
17. Maryland (self-referral)	38. Utah
18. Massachusetts	39. Virginia
19. Michigan	40. Washington
20. Minnesota (self-referral)	41. West Virginia
21. Mississippi (antikickback)	42. Wisconsin

Source: "Health Care Fraud: Enforcement and Compliance" By Robert Fabrikant, et al., Law Journal Press, New York, NY: 2007, p.2-64.

Updates to State Self-Referral Laws

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.[268] 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 Codey.[269]

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.[270] 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 which would allow self-referral to physician-owned ASCs.[271]

In 2009, New Jersey amended the Codey law to permit physician referrals to facilities in which they have a financial stake, if the physicians perform the procedure personally, their compensation as an owner is equal to their ownership interest, all patient related decisions at facilities with nonphysician owners are made by physicians, and the physicians inform the patients of their ownership share at the time of referral.[272] 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.[273]

Physician Compensation Restrictions

Generally

Increased regulatory scrutiny related to avoiding violations of federal fraud and abuse laws in transactions between healthcare providers affects the compensation paid to physicians for professional clinical, on-call, medical directorship, as well as administrative and executive related services. For example, physician compensation arrangements are scrutinized under the traditional concepts of fair market value (FMV), as well as under the related threshold of commercial reasonableness,[274] that is, compensation arrangement may be simultaneously at FMV and also be determined to be commercially unreasonable. A failure to meet these two standards may result in a violation of the FCA if the healthcare provider knowingly submits a claim for reimbursement to a government entity for services under compensation arrangements which are deemed to be Stark and antikickback violations.[275] Accordingly, compensation arrangements for physician clinical and executive services (for example, medical directorships) must

be both at FMV *and* commercially reasonable to avoid liability under the Stark law, the antikickback statute, and the FCA.[276] The impact of fraud and abuse regulation on structuring physician compensation plans is discussed further in chapter 3 of *Consulting with Professional Practices*.

> Compensation arrangements for physician and executive services must be both at FMV and commercially reasonable to avoid liability under the Stark law, the antikickback statute, and the FCA.

"All Eyes on Physician-Hospital Arrangements," By Lewis Lefko, HealthLeaders Media, Jan. 24, 2008, www.healthleadersmedia.com (Accessed September 18, 2008).

The test for commercial reasonableness is a threshold that is 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."[277]

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 general market value."[278]

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.[279] [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 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.[280]

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."[281] 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.[282] 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."[283] 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.[284] 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.[285] 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.[286]

However, 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 will continue to scrutinize the FMV of arrangements and indicated that "[p]arties to a transaction may calculate FMV 'using any commercially reasonable methodology that is appropriate under the circumstances and otherwise fits [within] the definition' of FMV for purposes of Stark."[287]

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.[288]

FMV is also a critical requirement under several antikickback safe harbors.[289] Although FMV is not specifically defined within the antikickback statute,[290] the OIG has provided guidance on this issue and stated in Thornton's widely circulated 1992 letter that

> When considering the question of FMV [Fair Market Value], we would note that the traditional methods of economic valuation do not comport with the proscriptions of the Anti-Kickback statute. Items ordinarily considered in determining the FMV may be expressly barred by the Anti-Kickback statute's prohibition against payments for referrals. Merely because another buyer may be willing to pay a particular price is not sufficient to render the price to be paid FMV. The fact that a buyer in the position to benefit from referrals is willing to pay a particular price may only be a reflection of the value of the referral stream that is likely to result from the purchase.[291]

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."[292] 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."[293]

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 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

(9) Salary ranges for equally qualified physicians in comparable organizations[294]

The IRS also will examine the independence of the board or committee that establishes a physician's compensation arrangement.[295]

Steps to Establishing Commercial Reasonableness

With regard to FMV under Stark law and the antikickback statute, a 2002 federal district court stated, "Payments exceeding FMV are in effect deemed 'payment for referrals.'"[296] Later courts have developed more analytical approaches to determining if a compensation arrangement will survive fraud and abuse scrutiny, particularly, by looking to whether physicians are actually performing the services outlined in the arrangement. As an example of the potential liability of hospitals and physicians for not abiding by commercial reasonableness standards, a 2009 case against an Iowa hospital system settled for $4.5 million after the DOJ alleged that Iowa's Covenant Medical Center compensated five referring physicians at rates far above FMV.[297]

The DOJ alleged that the Covenant physicians—specifically, two orthopedic surgeons, two neurosurgeons, and a gastroenterologist—were reportedly among the highest-paid physicians in the entire United States, making as much as $2.1 million, despite Covenant's nonprofit status.[298] In the *Covenant* case, the hospital asserted that the specialist physicians had been working in understaffed areas of the hospital.[299] However, the DOJ cited significant discrepancies between the compensation of the five Covenant physicians and other physicians in the region and around the country. These findings led the DOJ to conclude that the hospital was paying the physicians for referrals, in violation of the Stark law.[300] The *Covenant* settlement clearly reflects the government's increased vigilance against remuneration related to physician compensation arrangements that do not meet FMV and commercial reasonableness thresholds.

In those circumstances in which the physicians are not actually performing those services that are required within the scope of the compensation agreement, courts have found that the compensation arrangement does not meet standards of commercial reasonableness.[301] For this reason, a typical medical director agreement, for example, requires that contemporaneous logs are kept that document the number of actual hours worked, as well as the fulfillment of the tasks, duties, responsibilities, and accountabilities that are mandated in the compensation agreement for the medical director position.[302] It is important to note that several types of medical directorships may exist, including those related to quality management, patient care, clinical research, patient relations, business development and community outreach, clinical operations, and medical information services.

As part of the development of the commercial reasonableness threshold, a more specific test to determine whether an arrangement is commercially reasonable was proposed by a government expert.[303] In the 2004 case, *U.S. v. SCCI Hospital Houston*, a whistleblower suit which eventually was settled, the United States challenged the commercial reasonableness of the compensation paid by the hospital to three physician medical directors.[304] In this case, the government's financial expert stated that commercial reasonableness depends on the agreement being "essential to the functioning of the hospital."[305] The expert noted that in order to be commercially reasonable, there had to be "sound business reasons for paying medical director fees to referring physicians."[306]

The expert in the *SCCI Hospital Houston* case looked to several factors in assessing commercial reasonableness, including (1) the size of the hospital, number of patients, patient acuity levels, and patient needs; (2) the quality, activities, and involvement of medical staff and the need for medical direction; (3) the number of regular committees and meetings that require physician involvement; and (4) the quality of hospital management and interdisciplinary coordination of patient services.[307] The expert also stated that "commercial reasonableness . . . depends on the hospital performing a regular assessment of the actual duties performed by the medical director [, as well as assessing] how effectively the medical director is performing his duties and whether there is a bona fide need for continuing the services."[308]

Although medical director compensation may be based on an hourly payment (with the maximum number of hours specified in the contract) or an annual payment (determined by a projected number of hours multiplied by a FMV hourly rate), 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, as well as to make sure that the documentation is consistent with the hours outlined in the medical director contract.[309] Accordingly,

> [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.[310]

In 2000, the OIG issued a notice that suggested that a compliance program in which regular internal monitoring and auditing is conducted may be an effective way to both ensure that services provided are considered to be reasonable and necessary and to determine whether any incentives for unnecessary services exist.[311] Reflecting the importance of reasonable necessity, the OIG determined in a 2007 advisory opinion, that an on-call physician compensation arrangement that did not meet an antikickback safe harbor was nevertheless reasonable, because the structure of the arrangement was tailored to the specific unmet needs of the hospital.[312]

In summary, compensation arrangements will likely be deemed commercially reasonable if (1) the arrangements are at FMV, (2) the arrangements list the actual duties being performed by the physician, (3) services performed are reasonably necessary to the provider based on the details of the situation, and (4) the services could not be adequately provided for less compensation.

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).[313] In 2002, nonprofit hospitals nationwide saved an estimated $12.6 billion from tax exemptions.[314] Such benefits of federal tax exemption come with concordant burdens. To maintain tax-exempt status, an organization has to prove that it benefits the public in return for the public's foregoing of tax collections. To be tax-exempt under the IRC, an organization must be organized and operated exclusively for exempt purposes, and none of its earnings may be allocated to private shareholders or individuals.[315] Exempt purposes include those which are charitable, religious, educational, and scientific. The federal tax regulations 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.[316] Most healthcare organizations that are tax-exempt under federal law have that status because they are classified as charitable organizations.[317]

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).[318] The community benefit standard list several things that are important to section 501(c)(3) qualification for general acute care hospitals, such as 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.[319]

With at least $12.6 billion at stake, clear communication between tax-exempt organizations and the IRS is crucial. The IRS sought to ease the reporting process for nonprofit healthcare providers in 2007 by issuing 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.[320] 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."[321]

2010 IRS Audits and Compliance with Section 409A

Beginning in February 2010, 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. The IRS is seeking a thorough examination of all executive compensation and benefit arrangements, including executive retirement contracts and deferred compensation arrangements.[322] 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.

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*.[323] 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 a disqualified person, and the value of the economic benefit provided by the organization exceeds the value of the consideration received by the organization.[324]

The IRS is expected to examine up to 1,500 exempt organizations across all industries over a three-year period.[325] 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.[326]

Specific Application of Fraud Laws to Physician Compensation

On September 20, 2007, the OIG issued Advisory Opinion No. 07-10, regarding the compensation paid for physician services related to on-call coverage.[327] 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."[328]

The subject arrangement involved a nonprofit hospital experiencing a shortage of physicians to provide emergency department coverage and follow-up care due to the high volume of indigent patients unable to pay for services.[329] Some hospitals have responded to certain specialists' refusal to provide services without compensation by paying per diem rates to physicians who entered into a two year contract to provide care in the emergency department.[330]

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 (1) the per diem rates were at FMV without regard to referrals, the physicians were required to treat any patient who entered the emergency department until discharge with no additional compensation, and the physicians provided certain volunteer (uncompensated) services; (2) 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 (3) 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.[331]

Federal Antitrust Laws

Antitrust is a body of law which aims to combat anticompetitive behavior. The Sherman Antitrust Act (Sherman Act), which prohibits any "contract, combination . . . or conspiracy, in restraint of trade or commerce,"[332] and Section 5 of the FTC Act, which prohibits "unfair methods of competition in or affecting commerce. . .,"[333] are the federal government's two primary means of combating unfair competition and abuse of monopolistic power. Further, Section 2 of the Sherman Act prohibits the abuse of monopoly power.[334] The Sherman Act has been used to combat kickbacks and self-referral joint ventures, which have been recognized and an impediment to competition by providers outside the self-referral or kickback network.[335]

The Sherman Act also has been used to address concerns related to physician integration under physician–hospital organization models, independent practice associations (IPAs), and the ability of such organizations to negotiate on behalf of physician members.[336] The FTC typically examines such arrangements under a rule of reason analysis, balancing procompetitive and anticompetitive effects of the integration arrangement on the market.[337]

Recently, a FTC finding of illegal price fixing by a Texas IPA was upheld by a federal appellate court.[338] 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.[339]

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.[340] However, even under this latter exception, only two clinically integrated IPAs have successfully survived antitrust challenges.[341]

Additionally, many community hospitals have come under scrutiny by antitrust authorities for engaging in exclusionary practices in an effort to respond to the negative financial impact of **physician-owned facilities (POFs)**.[342] Many hospitals have attempted to shut POFs, particularly specialty hospitals, out of the market, which has resulted in some POFs initiating antitrust suits, claiming that such exclusionary behavior violates the Sherman Act.[343] Many of these cases have failed because antitrust authorities generally are protective of general hospitals that have taken measures to combat, what they claim to be, **cream skimming** by specialty hospitals.[344] 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.[345]

While antitrust challenges by POFs will not always fail, still important and unresolved issues 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.[346] In a majority of these cases, the allegations of agreement are launched at hospital boards that are in supposed agreements with their medical staffs.[347] 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.[348] 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.[349] In the absence of an agreement by separate entities, unilateral activity, as long as it is not predatory, is legal.[350] However, 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.[351] 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 it 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.[352]

Racketeer Influenced and Corrupt Organizations Act (RICO)

The Racketeer Influenced and Corrupt Organizations Act (RICO)[353] 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."[354] 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 and (2) acquire or maintain control of any enterprise through a pattern of racketeering activity. Additionally, it is illegal (3) for any person employed by, or associated with any enterprise to conduct the affairs of the enterprise through a pattern of racketeering activity.[355] It is also a violation of RICO to conspire to engage in any of these three activities.[356] 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.[357]

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.[358] 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.[359]

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.[360] The act requires laboratories to regulate all laboratory testing performed on humans, except the testing performed for research purposes.[361] CMS assumes the responsibility for overseeing the CLIA program.[362] 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.[363]

United States Nuclear Regulatory Commission (NRC)

The United States Nuclear Regulatory Commission (NRC) is an independent agency created by Congress in 1974.[364] 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.[365] 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.[366] 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.[367]

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.[368]

Emergency Medical Treatment and Active Labor Act (EMTALA)

The Emergency Medical Treatment and Labor Act (EMTALA) was enacted in 1986 by the Consolidated Omnibus Budget Reconciliation Act of 1985 and applies only to hospitals that participate in the Medicare program and have an emergency room.[369] EMTALA requires covered hospitals to provide "medical screening" to any patient coming to the hospital's emergency department.[370] Anyone suffering harm as a "direct result" of a hospital's violation of EMTALA can bring a claim against the hospital.[371] Additionally, EMTALA provides for civil penalties against the hospital.[372]

Of note is that EMTALA does not require hospitals to have an emergency department. Some specialty hospitals, however, are required by state licensure laws to have an emergency department.[373]

Tort Reform

Malpractice, defined as "professional misconduct or unreasonable lack of skill," has always been a risk inherent in the practice of medicine.[374] Medical malpractice litigation became popular in the 1970s, and since then, medical malpractice litigation has been a recurring problem in healthcare, as physicians have been forced to practice defensive medicine, leading to the overprovision of care and increased healthcare costs.[375] As malpractice litigation has increased due to improved technology and increased volume of patients, physicians have been forced to pay higher premiums for malpractice insurance, causing some physicians to move out of states with high premiums, close their medical practices, take early retirement, or choose to go naked, that is, practice without malpractice coverage.[376] While many physicians have not had to take such drastic action, high malpractice premiums have led to increases in the cost of services, and, therefore, to increased costs of consumer health insurance premiums.[377]

Tort reform proponents have alleged that the United States has the most expensive tort system in the world, with costs per citizen of about $845 per person in 2003.

"Tort excess: the necessity for reform from a policy, legal and risk management perspective." by David Dial, et al., p.1, http://server.iii.org/yy_obj_data/binary/727182_1_0/tortreform.pdf (accessed September 8, 2009).

Malpractice litigation stems from the U.S. tort system, which allows patients who are injured in some way, to sue the wrongdoer, or tortfeasor.[378] If found liable, the tortfeasor is held accountable for his or her actions, and the injured party is able to recover for damages incurred as a result of the tort.[379] Damages in a malpractice suit generally are classified as economic (loss of wages, etc), noneconomic (pain and suffering, etc), or punitive damages (intended to punish and deter future behavior).[380] Tort

reform proponents have alleged that the United States has the most expensive tort system in the world, with costs per citizen of approximately $845 per year in 2003.[381] Despite the fact that the vast majority of cases are settled out of court, an estimate of the 2001 direct costs of the U.S. tort system was $205.4 billion.[382]

State Tort Reform

In response to this problem, there have been multiple tort reform initiatives, at both the state and federal level, aimed at capping malpractice damages.[383] Many states have caps already in place.[384] Such caps, often modeled after California's Medical Injury Compensation Reform Act (MICRA), place limits on pain and suffering awards to plaintiffs.[385] Similarly, in 2003, the Texas legislature passed a $750,000 cap on damages ($250,000 per defendant).[386] As of 2009, thirty-seven states had passed laws that place limits on noneconomic or punitive damages in medical malpractice suits.[387] Of the thirteen states that do not place caps on damages, five have determined such caps to be unconstitutional, and four have constitutional provisions which outlaw caps on damages.[388]

In addition to damages caps, another method used to provide limits on financial risk to insurers has been the establishment of statutes of limitations on claims made by plaintiffs.[389] Other methods of tort reform called for by proponents would enable or enhance the ability of defendants to countersue claimants who file frivolous lawsuits.[390] Another way to lower malpractice premiums would be to create compensation programs outside of the court system to handle malpractice cases.[391] Additionally, a more proactive and preventative approach to prevent lawsuits by lowering medical malpractice awards (and therefore premiums) would include building rapport with patients, reducing medical errors, and establishing honesty policies for full disclosure of errors.[392]

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.[393] 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.[394] 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.[395] Similar bills have repeatedly passed in the House, however, no version of the bill has yet to be passed in the United States Senate.[396]

Proponents of tort reform historically have pushed for caps on punitive damage awards.[397] 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.[398] 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.[399]

Conclusion

The healthcare regulatory environment is constantly changing. As physicians and other providers find it more and more difficult to survive under crippling regulations and reimbursement rates, they are being forced to find ways around regulations directed at limiting the ways in which they may receive remuneration for services provided. The numerous modifications of the Stark law are a good example of how CMS has had to continuously modify existing regulations in an effort to keep up with providers who are finding new ways to join together and use new technologies to survive in a regulation-ridden environment.

As healthcare reform pushes forward, it is unlikely that providers will be faced with fewer regulations. It is more likely that reform efforts will focus on increased regulation and increased prosecution of regulatory violations. Notable recent events have demonstrated that agencies such as the HHS, the DOJ, and the FTC are cracking down on any activity that could have the potential to drive up the cost of healthcare services. All of these agencies have demonstrated their commitment to combating healthcare fraud and are likely to continue to promulgate new regulations to accomplish this task in the future.

Key Sources

Key Source	Description	Citation	Hyperlink
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 September 22, 2009).	http://thomas.loc.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, www.jointcommission.org AboutUs (accessed September 21, 2009).	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 September 21, 2009).	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 September 22, 2009).	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.	"Mission, Vision & Goals: Overview," Centers for Medicare and Medicaid Services, U.S. Department of Health and Human Services, www.cms.hhs.gov/MissionVisionGoals (accessed September 22, 2009).	www.cms.hhs.gov

Associations

Type of Association	Professional Association	Description	Citation	Hyperlink	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 October 1, 2009).	www.healthlawyers.org/Pages/Default.aspx	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
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.	"Customize your ABA membership by joining a Section, Division or Forum today!" American Bar Association, www.abanet.org/sections/home.html#health (accessed October 1, 2009).	www.abanet.org/health	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
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).	www.ama-assn.org	American Medical Association 515 N. State Street Chicago, IL 60654 Phone: 800-621-8335 Fax: n/a E-mail: n/a
National	American Osteopathic Association	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).	www.osteopathic.org	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

Type of Association	Professional Association	Description	Citation	Hyperlink	Contact Information
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, www.aha.org/aha/about/index.html (accessed December 4, 2009).	www.aha.org	American Hospital Association One North Franklin Chicago, IL 60606 Phone: 312-422-3000 Fax: n/a E-mail: n/a
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).	www.asc association.org	Ambulatory Surgery Center Association 1012 Cameron Street Alexandria, VA 22314 Phone: 703-836-8808 Fax: 703-549-0976 E-mail: ASC@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).	www.ahpanet.org/	American Health Planning Association 7245 Arlington Boulevard, Suite 300 Falls Church, Virginia 22042 Phone: 703-573-3103 Fax: n/a E-mail: info@ahpanet.org

Endnotes

1 "Oxford American Dictionary: Liable" Avon Books, New York, NY: Oxford University Press, Inc., 1980, p. 510.

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, Accessed at http://www.modernmedicine.com/modernmedicine/article/articleDetail.jsp?id=108814 (Accessed 7/30/09).

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).

5 "S Corp, C Corp, LLC, LLP—Which is Best?" By Dennis Murray, Medical Economics, March 5, 2004, Accessed at http://www.modernmedicine.com/modernmedicine/article/articleDetail.jsp?id=108814 (Accessed 7/30/09).

6 "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).

7 "The People of the State of Illinois v. United Medical Service, Inc" 200 N.E. 157, 163 (1936).163

8 "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).

9 "Corporate Practice: State by State Listing of Relevant Statutes, Cases, and Opinions" American Academy of Emergency Medicine, 2009, http://www.aaem.org/corporatepractice/states.php (Accessed 02/02/10).

10 "Corporate Practice of Medicine Doctrine: 50 States Survey Summary" By Mary Michal, Meg Pekarse, and Matthew McManus, National Hospice and Pallative Care Organization, September 2006, http://www.nhpco.org/files/public/palliativecare/corporate-practice-of-medicine-50-state-summary.pdf (Accessed 06/17/09).

11 *Ibid.*

12 *Ibid.*

13 *Ibid.*

14 "Corporate Law for the Healthcare Provider: Organization, Operation, Merger and Bankruptcy" By Ann Huckstep, James C. Wilson, Jr., and Richard P. Carmody, The National Health Lawyers Association: Washington, D.C. 1993, p. 123.

15 *Ibid.*

16 "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).

17 "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.

18 "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).

19 *Ibid.*

20 "Corporate Practice of Medicine" The Medical Board of California, Department of Consumer Affairs, 2007, http://www.mbc.ca.gov/licensee/corporate_practice.html (Accessed 07/09/09).

21 "State Farm Mutual Automobile Insurance Co. v. Robert Mallela et al." 827 N.E.2d 758 (N.Y. 2005).

22 "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 NE2d 758 (N.Y. 2005).

23 "State Farm Mutual Automobile Insurance Co. v. Robert Mallela et al." 827 N.E.2d 758 (N.Y. 2005).

24 *Ibid.*

25 "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.

26 "Health Law: Cases Materials and Problems" By Barry R. Furrow, et al., Third Edition, St. Paul, MN: West Publishing, 1997, p. 92.

27 "Health Care Law: A Practical Guide" By Scott Beckeret al., New York, NY: Matthew Bender and Co., 2008, p. 16-4.

28 "Health Care Law: A Practical Guide" By Scott Beckeret al., New York, NY: Matthew Bender and Co., 2008, p. 16-11.

29 "Legal Medicine" By S. Sandy Sanbar et al., Sixth Edition, Philadelphia, PA: Mosby, 2004, p. 81.

30 "About NBOME" National Board of Osteopathic Medical Examination, 2008, http://www.nbome.org/about.asp (Accessed 07/09/09); "Medical Licensure" American Medical Association, 2009, http://www.ama-assn.org/ama/pub/education-careers/becoming-physician/medical-licensure.shtml (Accessed 07/09/09).

31 "Medical Licensure" American Medical Association, 2009, http://www.ama-assn.org/ama/pub/education-careers/becoming-physician/medical-licensure.shtml (Accessed 07/09/09).

32 "Health Care Quality Improvement Act of 1986" 42 U.S.C. 11111 et seq. (2006).; "Hospital Peer Review and Clinical Privileges Actions: To Report or Not Report" By Troyen A. Brennan, Journal of the American Medical Association, Vol. 281, No. 4 (July 28, 1999), p. 381.

33 "Health Care Quality Improvement Act of 1986" 42 U.S.C. 11132-33, 11151 (2006).

34 "Health Care Quality Improvement Act of 1986" 42 U.S.C. 11135 (2006).

35 "Health Care Law: A Practical Guide" By Scott Becker et al., Albany, NY: Matthew Bender Co., 2008, p. 16-4,16-4.1.

36 "Health Care Fraud: Enforcement and Compliance" By Robert Fabrikant, et al., New York, NY: Law Journal Press, 2007, p. 3-84; "Health Care Law: A Practical Guide" By Scott Beckeret al., New York, NY: Matthew Bender and Co., 2008, p. 16-4.1.

37 "Health Care Law: A Practical Guide" By Scott Beckeret al., New York, NY: Matthew Bender and Co., 2008, p. 16-22.1.

38 "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).

39 "The Ins and Outs of "Incident-To" Reimbursement" By Alice G. Gosfield, Family Practice Management, Vol. 8, No. 10 (November/December 2001), p. 24.

40 "The Ins and Outs of "Incident-To" Reimbursement" By Alice G. Gosfield, Family Practice Management, Vol. 8, No. 10 (November/December 2001), p. 25.

41 "Medicare Program: Changes to the Hospital Outpatient Prospective Payment System and CY 2010 Payment Rates; Changes to the Ambulatory Surgery Center Payment System and CY 2010 Payment Rates" 42 CFR parts 410, 416, and 419 (2000), p. 994.

42 "Condition of Participation: Anesthesia Service" 42 CFR 482.52(c) (July 31, 1992).

43 "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).

44 "Health Care Law: A Practical Guide" By Scott Beckeret al., New York, NY: Matthew Bender and Co., 2008, p. 16-23.

45 "Introduction to Health Services" By Stephen J. Williams and Paul R. Torrens, Seventh Edition, Clifton Park, NY: Thomson Delmar Learning, 2008, p. 268

46 *Ibid.*

47 "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.

48 *Ibid.*

49 *Ibid.*

50 "Occupational Outlook Handbook" Bureau of Labor Statistics, 2008-09 Edition Washington, D.C.: Government Printing Office, 2008, http://www.bls.gov/oco/ocos105.htm (Accessed 07/02/09).; "Introduction to Health Services" By Stephen J. Williams and Paul R. Torrens, Seventh Edition, Clifton Park, NY: Thomson Delmar Learning, 2008, p. 268

51 "Health Care Law: A Practical Guide" By Scott Beckeret al., New York, NY: Matthew Bender and Co., 2008, p. 8-4.

52 "Health Care Law: A Practical Guide" By Scott Beckeret al., New York, NY: Matthew Bender and Co., 2008, p. 8-6.

53 "Health Care Law: A Practical Guide" By Scott Beckeret al., New York, NY: Matthew Bender and Co., 2008, p. 8-7.

54 "Excluded Hospital Units: Common Requirements" 42 CFR 412.25(b)(1) (October 1, 2007).

55 "Health Care Law: A Practical Guide" By Scott Beckeret al., New York, NY: Matthew Bender and Co., 2008, p. 8-6.

56 "Problems in Health Care Law" By Robert D. Miller, Ninth Edition, Sudbury, MA: Jones and Bartlett Publishers, 2006, p. 73.

57 *Ibid.*

58 *Ibid.*

59 "Medicare and Medicaid Programs; Recognition of the American Osteopathic Association (AOA) for Continued Approval of Deeming Authority for Hospitals" 70 Fed Reg 15333 (March 25, 2005).

60 "JCAHO Federal Deemed Status and State Recognition" American Society for Healthcare Engineering of the American Hospital Association, 2009, http://www.ashe.org/ashe/codes/jcaho/deemed_status.html (Accessed 6/30/09).

61 "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 05/13/10).

62 "The Joint Commission: Code of Conduct" The Joint Commission, 2009, http://www.jointcommission.org/NR/rdonlyres/5B9CE6DD-FA09-465E-BDA8-C1FBCE03A555/0/TJCCodeofConduct09.pdf (Accessed 02/10/10).

63 "Facts About The Joint Commission" The Joint Commission, November 13, 2009, http://www.jointcommission.org/AboutUs/Fact_Sheets/joint_commission_facts.htm (Accessed 2/10/10).

64 "Health Care Law: A Practical Guide" By Scott Beckeret al., New York, NY: Matthew Bender and Co., 2008, p. [?]

65 "About The Joint Commission" Joint Commission on Healthcare Accreditation, 2009, http://www.jointcommission.org/AboutUs/ (Accessed 06/30/09).

66 *Ibid.*

67 "New Hospital Accreditation Program Offers Hospitals More Choices" American Hospital Association, October 7, 2008, http://www.ashrm.org/ashrm/advocacy/advisories/files/2008accreditation.pdf (Accessed 02/10/10).

68 "About NCQA" National Committee for Quality Assurance, http://www.ncqa.org/tabid/675/Default.aspx (Accessed 06/29/09).

69 "National Committee for Quality Assurance 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 02/10/10).

70 "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).

71 "Improving Health Care: A Dose of Competition" Report by the Federal Trade Commission and The Department of Justice, July 2004, p. 2.

72 *Ibid.*

73 "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).; "Health Regulation: Certificate of Need and 1122" By Herbert Harvey Hyman, Germantown, MD: Aspen Systems Corp., 1977, p. 7

74 "The National Health Planning and Resources Development Act of 1974" Pub. L. No. 93-641, (January 4, 1975).

75 *Ibid.*

76 "Beyond Health Care Reform: Reconsidering Certificate of Need Laws in a 'Managed Competition' System" By Patrick John McGinley, Florida State University Law Review, Vol. 23 (1995), p. 141, 147-148.

77 "Excess Capacity: Markets, Regulation, and Values" By Carolyn W. Madden, Health Services Research, Vol. 33, No. 6 (February 1999), p. 1658,1662

78 "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).

79 *Ibid.*

80 *Ibid.*

81 "The U.S. Healthcare Certificate of Need Sourcebook" By Robert James Cimasi, Washington, DC: BeardBooks, 2005, p. 30-33.

82 "Cost, Quality and Access in Health Care: New Roles for Health Planning in a Competitive Environment" By Frank A. Sloan, James F. Blumstein, and James M. Perrin, San Francisco, CA: Jossey-Bass Inc., Publishers, 1988, p. 31.

83 "The U.S. Healthcare Certificate of Need Sourcebook" By Robert James Cimasi, Washington, DC: BeardBooks, 2005, p. 8.

84 "The U.S. Healthcare Certificate of Need Sourcebook" By Robert James Cimasi, Washington, DC: BeardBooks, 2005, p. 1, 168.

85 "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://www.georgia.gov/vgn/images/portal/cit_1210/30/8/41941228Dr_Payne_Testimony.pdf (Accessed 2/10/10).

86 "Improving Health Care: A Dose of Competition" Report by the Federal Trade Commission and The Department of Justice, July 2004, p. 1.

87 "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.

88 "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) Accessed at www.ftc.gov/opa/2002/11/murishealthcare.htm (Accessed 8/5/04).

89 "Improving Health Care: A Dose of Competition" Report by the Federal Trade Commission and The Department of Justice, July 2004, p. 22.

90 "Improving Health Care: A Dose of Competition" Report by the Federal Trade Commission and The Department of Justice, July 2004, p. 2.

91 "Comment on Senate Bill 398" By Paul K. Davis: Federal Trade Commission, Letter To Senator Culver Kidd (March 4, 1988), Accessed at http://www.ftc.gov/opp/advocacy/1988/V880021.PDF (Accessed 10/29/09).

92 "Improving Health Care: A Dose of Competition" Report by the Federal Trade Commission and The Department of Justice, July 2004, p. 2.

93 "Improving Health Care: A Dose of Competition" Report by the Federal Trade Commission and The Department of Justice, July 2004, p. 27; "Improving Health Care: A Dose of Competition" Report by the Federal Trade Commission and The Department of Justice, July 2004, p. 2; "Improving Health Care: A Dose of Competition" Report by the Federal Trade Commission and The Department of Justice, July 2004, p. 28.

94 "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).

95 "Corporate Law for the Healthcare Provider: Organization, Operation, Merger and Bankruptcy" By Ann Huckstep, James C. Wilson, Jr., and Richard P. Carmody, The National Health Lawyers Association: Washington, D.C. 1993, p. 122.

96 *Ibid.*

97 *Ibid.*

98 *Ibid.*

99 "Definitions" 45 C.F.R. 160.103 (October 1, 2008).; "Health Insurance Portability and Accountability Act of 1996" Pub. L. No. 104-191 (August 21, 1996).

100 "Definitions" 45 C.F.R. 160.103 (October 1, 2008).

101 "Summary of the HIPAA Privacy Rule" United States Department of Health and Human Services, May 2003, http://www.hhs.gov/ocr/privacy/hipaa/understanding/summary/privacysummary.pdf (Accessed 6/17/09).4,9

102 "Summary of the HIPAA Privacy Rule" United States Department of Health and Human Services, May 2003, http://www.hhs.gov/ocr/privacy/hipaa/understanding/summary/privacysummary.pdf (Accessed 6/17/09).2

103 *Ibid.*

104 *Ibid.*

105 "Summary of the HIPAA Privacy Rule" United States Department of Health and Human Services, May 2003, http://www.hhs.gov/ocr/privacy/hipaa/understanding/summary/privacysummary.pdf (Accessed 6/17/09).3; "Uses and Disclosures of Protected Health Information: General Rules" 45 C.F.R. 164.502(e) (October 1, 2003).

106 *Ibid.*

107 "American Recovery and Reinvestment Act of 2009" Pub. L. No. 111-5 (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).

108 "Health Information Technology for Economic and Clinical Health Act" Pub. L. No. 111-5 (February 17, 2009); "Health Information Technology for Economic and Clinical Health Act" Pub. L. No. 111-5 (February 17, 2009).

109 "Health Information Technology for Economic and Clinical Health Act" Pub. L. No. 111-5 (February 17, 2009).

110 *Ibid.*

111 "Investigating Privacy Breaches Under HITECH and HIPAA" By Barry Herrin and Allyson Jones Labban, Smith Moore Leatherwood, 2008, p. 3.

112 "Investigating Privacy Breaches Under HITECH and HIPAA" By Barry Herrin and Allyson Jones Labban, Smith Moore Leatherwood, 2008, p. 17, 21, 24.

113 "HIPAA Administrative Simplification Standard Unique Health Identifier for Health Care Providers; Final Rule" 69 Fed. Reg. 3434, January 23, 2004.

114 "National Provider Identifier Standard: Overview" Centers for Medicare and Medicaid Services, 2009, http://www.cms.gov/NationalProvIdentStand/ (Accessed 02/09/10).

115 "HIPAA Administrative Simplification Standard Unique Health Identifier for Health Care Providers; Final Rule" 69 Fed. Reg. 3434, January 23, 2004.

116 *Ibid.*

117 *Ibid.*

118 "Identify Theft Red Flags and Address Discrepancies Under the Fair and Accurate Credit Transactions Act of 2003; Final Rule" 72 Fed. Reg. 63718, November 9, 2007.

119 "FTC Extends Enforcement Deadline for Identity Theft Red Flags Rule" Federal Trade Commission, News Release, (October, 30, 2009), p. [?]

120 "Fighting Fraud with the Red Flags Rule: A How-To Guide for Business" Federal Trade Commission, Accessed at http://www.ftc.gov/bcp/edu/pubs/business/idtheft/bus23.pdf (Accessed 05/06/10) p. 10.

121 "Fighting Fraud with the Red Flags Rule: A How-To Guide for Business" Federal Trade Commission, Accessed at http://www.ftc.gov/bcp/edu/pubs/business/idtheft/bus23.pdf (Accessed 05/06/10) p. 8.

122 "Fighting Fraud with the Red Flags Rule: A How-To Guide for Business" Federal Trade Commission, Accessed at http://www.ftc.gov/bcp/edu/pubs/business/idtheft/bus23.pdf (Accessed 05/06/10) p. 14.

123 "Fighting Fraud with the Red Flags Rule: A How-To Guide for Business" Federal Trade Commission, Accessed at http://www.ftc.gov/bcp/edu/pubs/business/idtheft/bus23.pdf (Accessed 05/06/10) p. 4.

124 "Patient Safety and Quality Improvement; Final Rule" 73 Fed. Reg. 70732 (November 21, 2008).70732; "Health Information Privacy: Understanding Patient Safety Confidentiality" U.S. Department of Health and Human Services, http://www.hhs.gov/ocr/privacy/psa/understanding/index.html (Accessed 2/4/10).

125 "Patient Safety and Quality Improvement; Final Rule" 73 Fed. Reg. 70734 (November 21, 2008). 70734

126 "Patient Safety and Quality Improvement; Final Rule" 73 Fed. Reg. 70739 (November 21, 2008). 70739

127 "Health Information Privacy: Understanding Patient Safety Confidentiality" U.S. Department of Health and Human Services, http://www.hhs.gov/ocr/privacy/psa/understanding/index.html (Accessed 2/4/10).

128 "Civil Actions for False Claims" 31 U.S.C. 3729(a) (July 5, 1994).

129 "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.

130 "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).

131 "Civil Actions for False Claims" 31 U.S.C.A. §3730(b)(2) (July 5, 1994).

132 "Qui Tam Actions Under the False Claims Act" By James G. Gumbert, Medical Journal-Houston, July 2003, p. 1.

133 "Civil Actions for False Claims" 31 U.S.C.A. §3730 (c)(1) (July 5, 1994).

134 "Civil Actions for False Claims" 31 U.S.C.A. §3730(d)(1) (July 5, 1994).

135 "False Claims" 31 U.S.C.A. § 3729(a) (July 5, 1994).

136 "Interventions and Suits Filed: Unsealed" Taxpayers Against Fraud, False Claims Act and Qui Tam Quarterly Review, Vol. 29 (January 2003), p. 47; "What is the False Claims Act and Why is it Important?" The False Claims Act Legal Center, 2009, http://www.taf.org/whyfca.htm (Accessed 09/8/09).

137 "Guidance on the Use of the False Claims Act in Civil Health Care Matters" By Eric H. Holder, Jr., Office of the Deputy Attorney General Washington, D.C.: U.S. Department of Justice, June 3, 1998, Accessed at http://www.usdoj.gov/dag/readingroom/chcm.htm (Accessed 9/2/09). ; "National Project Protocols—Best Practice Guidelines" By June Gibbs Brown, False Claims Act and Qui Tam Quarterly, Vol. 14 (July 1998), http://www.taf.org/PDF/jul98qr.pdf (Accessed 10/29/09), p. 46.

138 "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 09/02/09), p. 1.

139 "Fraud Enforcement and Recovery Act: Sec. 4 Clarifications to the False Claims Act to Reflect the Original Intent of the Law" Pub. L. No. 111-21 (January 6, 2009).

140 *Ibid.*

141 *Ibid.*

142 "Federal Program Participants: Beware the Amended False Claims Act" By Joseph De Simone, Marcia G. Madsen, and John J. Tharp, New York Law Journal, Aug. 17, 2009, http://www.mayerbrown.com/news/article.asp?id=7440&nid=20 (Accessed 9/2/09).; "Fraud Enforcement and Recovery Act: Sec. 4 Clarifications to the False Claims Act to Reflect the Original Intent of the Law" Pub. L. No. 111-21 (January 6, 2009).

143 "Fraud Enforcement and Recovery Act: Sec. 4 Clarifications to the False Claims Act to Reflect the Original Intent of the Law" Pub. L. No. 111-21 (January 6, 2009).

144 "Fraud Recovery Bill Has Healthcare Implications" By Ben Amirault, Health Leaders Media, April 29, 2009, http://www.healthleadersmedia.com/content/PHY-232249/Fraud-Recovery-Bill-Has-Healthcare-Implications.html (Accessed 5/6/10).

145 "Concerns with Proposed Amendments to the Fraud Enforcement and Recovery Act of 2009" By American Hospital Association et al., Letter 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).

146 "State False Claims Acts" The False Claims Act Legal Center, Taxpayers Against Fraud Education Fund, http://www.taf.org/statefca.htm (Accessed 6/30/09).

147 "Health Care Fraud: Enforcement and Compliance" By Robert Fabrikant, et al., New York, NY: Law Journal Press, 2007, p. 4-72.4

148 "Health Care Fraud: Enforcement and Compliance" By Robert Fabrikant, et al., New York, NY: Law Journal Press, 2007, p. 4-72.4-72.6

149 "False Claims Resource Center: State False Claims Act" Pietragallo, Gordon, Alfano, Bosick, & Raspanti, LLP, 2009, http://www.falseclaimsact.com/sfca_overview.php (Accessed 6/30/09).

150 "Deficit Reduction Act of 2005" Pub. L. No. 109-171 § 6031 (2006).

151 *Ibid.*

152 "The Deficit Reduction Act of 2005: New Medicaid Fraud and Abuse Provisions" Health Law Update, Nashville, TN: Bass, Berry & Sims, May 31, 2006, www.bassberry.com/.../Health%20Law%20Update%20May%2031%202006.pdf (Accessed 05/10/10).

153 *Ibid.*

154 "State False Claims Act Reviews" Office of Inspector General, http://oig.hhs.gov/fraud/falseclaimsact.asp (Accessed 6/30/09).

155 *Ibid.*

156 *Ibid.*

157 *Ibid.*

158 "Deficit Reduction Act of 2005" Pub. L. No. 109-171 § 6032 (2006).

159 *Ibid.*

160 "Deficit Reduction Act of 2005" Pub. L. No. 109-171 § 6032 (2006).; "State Plans For Medical Assistance" 42 USC §1396(a)(68).

161 "Medicare Benefit Policy Manual" Centers for Medicare and 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; "Criminal Penalties for Acts Involving Federal Health Care Programs" 42 U.S.C.A. § 1320a-7b(b) (1997).

162 "Criminal Penalties for Acts Involving Federal Health Care Programs" 42 U.S.C.A. § 1320a-7b(b) (1997).

163 "Medicare and Medicaid Patient & Program Protection Act of 1987" Pub. L. 100-93 (August 18, 1987).; "Medicare and State Health Care Programs: Fraud and Abuse OIG Safe Harbor Provisions" 56 Fed Reg 35952 (July 29, 1991).

164 "The Balanced Budget Act of 1997" Pub. L. No. 105-33 (Aug. 5, 1997).

165 "Health Care Administration: Planning, Implementing and Managing Organized Delivery Systems," By Lawrence F. Wolper, Sudbury, MA: Jones and Bartlett Publishers, Inc., 2004, p. 111

166 *Ibid.*

167 "Rental of Space in Physician Offices By Persons or Entities to Which Physicians Refer" Office of Inspector General, Special Fraud Alert (February 2000), Accessed at http://oig.hhs.gov/fraud/docs/alertsandbulletins/office%20space.htm (Accessed 2/27/05). ; "Special Fraud Alerts" 59 Fed. Reg. 31157 (Dec. 19, 1994).

168 "Advisory Opinions" Office of Inspector General, U.S. Department of Health and Human Services, http://oig.hhs.gov/fraud/advisoryopinions.asp (Accessed 10/06/09).

169 "OIG Advisory Opinion No. 04-08" Office of Inspector General, Advisory Opinion (June 30, 2004), Accessed at http://oig.hhs.gov/fraud/docs/advisoryopinions/2004/AdvOp04-08B.pdf (Accessed 5/10/10).

170 "Regarding Inquiry of Veiws on Medicare and Medicaid Anti-Kickback Statute" From D. McCarty Thorton: Associate General Counsel of the Office of the Inspector General, To T.J. Sullivan: Technical Assistant (Health Care Industries) of the Internal Revenue Services (Dec. 22, 1992) Accessed at http://www.oig.hhs.gov/fraud/docs/safeharborregulations/acquisition122292.htm (Accessed 09/24/2008).

171 *Ibid.*

172 *Ibid.*

173 "Guidance for Health Care Joint Ventures: A Comparison of the Requirements of the Antitrust, Fraud and Abuse, and Self-Referral Laws" By Peter M. Kazon, Washington, D.C.: Aspen Publishers Inc., 1994, p. 20.

174 "Aspects of Fraud in Healthcare Valuation" By Robert James Cimasi, Speech to 13th Annual Consultants' Conference, National Association of Certified Valuation Analysts, June 2, 2006, p. 12.

175 "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. ; "U.S. v. Greber" 760 F.2d 68 (3d Cir. 1985).

176 "Fraud and Kickbacks and Other Prohibited Activity" 42 C.F.R. § 1001.951(a)(2)(i) (2005).

177 "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).

178 "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.

179 "Medicare and Medicaid Programs; Fraud and Abuse OIG Anti-Kickback Provisions: Supplementary Information; II. Provisions of the Proposed Rule" 54 Fed. Reg. 3088 (July 23, 1989).

180 "Exceptions" 42 C.F.R. § 1001.952 (June 11, 2009).

181 "Exceptions" 42 C.F.R. § 1001.952 (June 11, 2009).; "New CMS Stark Regulations Tighten Referral Rules October 2008 Compliance Deadline for 'Stand in the Shoes'" By Lawrence A Mason and Leeanne R Coons, ABA Health eSource, Vol. 5, No. 1 (September 2008), http://www.abanet.org/health/esource/Volume5/01/manson-coons.html (Accessed 05/17/10).

182 "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" 64 Fed. Reg. 63518 (November 19, 1999).63518

183 "OIG Advisory Opinion 09-07" Office of the Inspector General, Advisory Opinion (June 30, 2009), Accessed at http://oig.hhs.gov/fraud/docs/advisoryopinions/2009/AdvOpn09-07.pdf (Accessed 5/7/10) p. 6.

184 "Criminal Penalties for Acts Involving Federal Health Care Programs" 42 U.S.C. § 1320a-7b(b)(3) (1997).

185 "Medicare and Medicaid Programs; Fraud and Abuse OIG Anti-Kickback Provisions: Supplementary Information; II. Provisions of the Proposed Rule" 54 Fed. Reg. 3088 (July 23, 1989).

186 "Medicare and State Health Care Programs: Fraud and Abuse OIG Safe Harbor Provisions" 56 Fed Reg 35952 (July 29, 1991).

187 "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" 64 Fed. Reg. 63518 (November 19, 1999).63518

188 "Medicare and Medicaid Programs; Fraud and Abuse OIG Anti-Kickback Provisions: Supplementary Information; II. Provisions of the Proposed Rule" 54 Fed. Reg. 3088 (July 23, 1989).

189 "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" 64 Fed. Reg. 63518 (November 19, 1999).63535-63536

190 *Ibid.*

191 "Commentary and Responses; Ambulatory Surgical Centers" 64 Fed. Reg. 63535 (November 19, 1999).

192 *Ibid.*

193 "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" 64 Fed. Reg. 63518 (November 19, 1999).63536

194 "Medicare and Medicaid Programs; Physicians' Referrals to Health Care Entities With Which They Have Financial Relationships; Final Rule" 66 Fed. Reg. 895 (January 4. 2001).

195 "Limitation on Certain Physician Referrals" 42 U.S.C. 1395nn(a)(1)(A) (2007).

196 "Prohibition on Certain Physciains and Limitations on Billing" 42 C.F.R. 411.353 (October 1, 2008).

197 "Financial Relationships Between Physicians and Entities Furnishing Designted Health Services; Definitions" 42 C.F.R § 411.351 (July 1, 2009).; "Limitation on Certain Physician Referrals" 42 U.S.C. 1395nn (2007).; "Criminal Penalties for Acts Involving Federal Health Care Programs" 42 U.S.C.A. § 1320a-7b(b) (1997).

198 "Limitation on Certain Physician Referrals" 42 U.S.C. 1395nn (2007).; "Criminal Penalties for Acts Involving Federal Health Care Programs" 42 U.S.C.A. § 1320a-7b(b) (1997).

199 "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.

200 "Financial Arrangements Between Physicians and Health Care Businesses" By Richard P. Kusserow, Report to Congress, Washington, D.C.: Office of Inspector General, May 1989.

201 "Legislation and Regulations—Chronological Background" 60 Fed. Reg. 41915 (August 14, 1995).

202 *Ibid.*

203 *Ibid.*

204 *Ibid.*

205 "Background" 69 Fed. Reg. 16055 (March 26, 2004).

206 "General Prohibition Under Section 1877 of the Act" 69 Fed. Reg. 16056 (March 26, 2004).

207 "Medicare Program; Physicians' Referrals to Health Care Entities with Which They Have Financial Relationships (PhaseIII); Final Rule" 72 Fed. Reg, 51012 (September 5, 2007).

208 "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.

209 *Ibid.*

210 *Ibid.*

211 *Ibid.*

212 *Ibid.*

213 *Ibid.*

214 "Medicare Program" 73 Fed. Reg. 48433 (August 19, 2008).

215 "Financial Relationship, Compensation, and Ownership or Investment Interest" 72 Fed. Reg. 51028 (September 5, 2007).51028

216 "Financial Relationship, Compensation, and Ownership or Investment Interest" 72 Fed. Reg. 51028 (September 5, 2007).51028; "Physician Self-Referral Provisions" 73 Fed. Reg. 23690 (April 30, 2008).

217 "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).

218 *Ibid.*

219 "IPPS Rule Finalizes Certain Physician Self-Referral Provisions" AHANews.com, August 4, 2008, http://www.ahanews.com/ahanews_app/jsp/display.jsp?dcrpath=AHANEWS/AHANewsNowArticle/data/ann_080804_niche&domain=AHANEWS (Accessed 8/20/08).

220 "Medicare Program; Changes to the Hospital Inpatient Prospective Payment Systems and Fiscal Year 2009 Rates; Final Rule" 73 Fed. Reg. 48723-48724, 48730 (August 19, 2008).48599

221 "Medicare Program; Changes to the Hospital Inpatient Prospective Payment Systems and Fiscal Year 2009 Rates; Final Rule" 73 Fed. Reg. 48723-48724, 48730 (August 19, 2008).48721

222 "Medicare Program; Changes to the Hospital Inpatient Prospective Payment Systems and Fiscal Year 2009 Rates; Final Rule" 73 Fed. Reg. 48723-48724, 48730 (August 19, 2008).48723-48724, 48730; "Lithotripsy" Medline Plus Medical Encyclopedia, December 18, 2009, http://www.nlm.nih.gov/medlineplus/ency/article/007113.htm (Accessed 2/5/10).

223 "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).

224 "Improving Plant Performance Through Gainsharing" By Woodruff Imberman, The Minerals, Metals, and Materials Society, 1995, http://www.tms.org/pubs/journals/JOM/matters/matters-9507.html, (Accessed 07/07/09).

225 "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).

226 *Ibid.*

227 *Ibid.*

228 *Ibid.*

229 "Health Law: Cases Materials and Problems" By Barry R. Furrow, et al., Third Edition, St. Paul, MN: West Publishing, 1997, p. 997.

230 "Medicare and Medicaid Programs; Physicians' Referrals to Health Care Entities With Which They Have Financial Relationships; Final Rule" 66 Fed. Reg. 895 (January 4. 2001).

231 "General Exceptions to the Referral Prohibition Related to both Ownership/Investment and Compensation" 42 C.F.R. 411.355-411.357 (October 1, 2008).; "Limitation on Certain Physician Referrals" 42 U.S.C. 1395nn(a)(1)(A) (2007).

232 "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.

233 "General Exceptions to the Referral Prohibition Related to both Ownership/Investment and Compensation" 42 C.F.R. 411.355 (October 1, 2008).

234 "Exceptions to the Referral Prohibition Related to Ownership or Investment Interests" 42 C.F.R. 411.356 (October 1, 2008).

235 "General Exceptions to the Referral Prohibition Related to both Ownership/Investment and Compensation" 42 C.F.R. 411.355 (October 1, 2008).

236 "Exceptions to the Referral Prohibition Related to Ownership or Investment Interests" 42 C.F.R. 411.356 (October 1, 2008).

237 "Scope of Benefits" 42 U.S.C. 1395(d)(3) (2009).

238 *Ibid.*

239 "Specialty Versus Community Hospitals: What Role For The Law?" By Sujit Choudhry, Niteesh K. Choudry, and Troyen A. Brennan, Health Affairs, Web Exclusive (August 9, 2005), http://content.healthaffairs.org/cgi/content/full/hlthaff.w5.361/DC1 (Accessed 5/10/10), p. W5-364.

240 "Congress Proposes Legislation Targeting Physician-Owned Specialty Hospitals" By Anthony H. Choe, Orthopedics Today, 2008, http://www.orthosupersite.com/view.asp?rID=29375 (Accessed 11/02/09).; "The Attack on Specialty and Niche Providers" By Robert James Cimasi, Second Annual Physician Agreements & Ventures, Chicago, IL, November 3, 2005, p.

241 "Specialty Versus Community Hospitals: What Role For The Law?" By Sujit Choudhry, Niteesh K. Choudry, and Troyen A. Brennan, Health Affairs, Web Exclusive (August 9, 2005), http://content.healthaffairs.org/cgi/content/full/hlthaff.w5.361/DC1 (Accessed 5/10/10), p. W5-364.

242 *Ibid.*

243 "Trends and Issues" By Cherilyn G. Murer, Rehab Management, October 2003, www.rehabpub.com/rehabec/102003/1.asp (Accessed 06/21/09).

244 *Ibid.*

245 "Medicare Prescription Drug, Improvement and Modernization Act of 2003: Clarifications to Certain Exceptions to Medicare Limits on Physician Referrals " Pub. L. No 108-173 (December 8, 2003), p. § 507(a)(1)(B).

246 "The Attack on Specialty and Niche Providers" By Robert James Cimasi, Second Annual Physician Agreements & Ventures, Chicago, IL, November 3, 2005, p. 42.

247 "Moratorium on Specialty Hospitals Expires" By Jennifer Gordon, Dallas Business Journal, June 17, 2005, http://assets.bizjournals.com/dallas/stories/2005/06/20/story8.html (Accessed 06/25/09).

248 "Payment Provisions in Original Medicare Program Immediately Affected by The Deficit Reduction Act" Centers for Medicare and Medicaid Services, Press Release (February 10, 2006), Accessed at http://www.cms.hhs.gov/apps/media/press/release.asp?counter=1779 (Accessed 3/2/05).

249 "Final Report to the Congress and Strategic Implementing Plan Required under Section 5006 of the Deficit Reduction Act of 2005" Centers for Medicare and Medicaid Services of the United States Department of Health and Human Services, August 8, 2006, http://www.cms.gov/apps/media/press/factsheet.asp?Counter=1941 (Accessed 5/10/10).

250 *Ibid.*

251 *Ibid.*

252 *Ibid.*

253 "Hospital Syndications: Opportunities and Options, or Poised for Extinction" By Leigh Walton, Nashville, TN: Bass, Berry & Sims PLC., March 31, 2009, http://www.bassberry.com/files/upload/LW%20-%20Hospital%20Syndications.pdf (Accessed 06/23/09).

254 "The Attack on Niche Providers" By Robert J. Cimasi, American Association of Ambulatory Surgery Centers 27th Annual Meeting, (2005), p. [?]

255 "Limited State Efforts to Assure Quality of Care Outside Hospitals" Testimony of Lawrence H. Thompson: General Accounting Office, Before the Subcommittee on Regulation, Business Opportunities, and Energy Committee on Small Business of the House of Representatives (April 29, 1991), http://161.203.16.4/t2pbat7/143773.pdf (Accessed 03/02/05).

256 "The Attack on Niche Providers" By Robert J. Cimasi, American Association of Ambulatory Surgery Centers 27th Annual Meeting, (2005), p. 46.

257 "Fremont Hospital Battles Plan for 'Boutique' Rival" By Troy May, San Francisco Business Times, http://www.bizjournals.com/eastbay/stories/2002/08/26/story7.html (Accessed 6/2/09).

258 "The Attack on Niche Providers" By Robert J. Cimasi, American Association of Ambulatory Surgery Centers 27th Annual Meeting, (2005), p. 47.

259 "Office Based Surgery" N. Y. Pub. Health §230-d (January 14, 2008), Accessed at http://www.health.state.ny.us/professionals/office-based_surgery/law/230-d.htm (Accessed 5/10/10).

260 "New York Doctors Race to Abide by In-Office Surgery Law" By Alison Gregor, New York Times (June 17, 2009), http://www.nytimes.com/2009/06/17/business/17doctor.html (Accessed 06/22/09).

261 "The Attack on Specialty and Niche Providers" By Robert James Cimasi, Second Annual Physician Agreements & Ventures, Chicago, IL, November 3, 2005, p. 17.

262 "New Taxes in New Jersey Target Doctor Services" By Mike Norbut, American Medical Association, September 13, 2004, http://www.ama-assn.org/amednews/2004/09/13/bisb0913.htm (Accessed 07/09/09).

263 "New Jersey Assembly Bill" No. 3127, 211th Legislature, June 21, 2004.

264 "MSNJ Opposes A-3127, Tax on Ambulatory Care Centers" Medical Society of New Jersey, Press Release (June 22, 2004), p. 1.

265 "Health Care Law: A Practical Guide" By Scott Becker, New York, NY: Mathew Bender and Co., 1998, p.

266 "The Attack on Niche Providers" By Robert J. Cimasi, American Association of Ambulatory Surgery Centers 27th Annual Meeting, (2005), p. 3

267 "Certificate-of-Need Law in Illinois Slammed by Feds, AMA" By Amy Sorrel, American Medical News, October 6, 2008, http://www.ama-assn.org/amednews/2008/10/06/gvsb1006.htm (Accessed 06/22/09).

268 "New Jersey Code Act" N.J. Stat. Ann. §45:9-22.4 et seq., (1992).

269 "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 04/18/08).

270 "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 02/10/10).

271 "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 02/10/10).

272 "New Jersey Senate Bill" No. 787, 213th Legislature, November 24, 2008.

273 *Ibid.*

274 "The Commercial Reasonableness Standard" 63 Fed. Reg. 1700-1703 (January 09, 1998).

275 "False Claims" 31 U.S.C. § 3729 (2009).; "United States of America v. Peter Rogan" 459 F.Supp. 2d 692 (N.D. Ill. 2006).717

276 "All Eyes on Physician-Hospital Arrangements" By Lew Lefko, HealthLeaders Media, January 24, 2008, http://www.healthleadersmedia.com (Accessed 09/18/08).

277 "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), http://findarticles.com/p/articles/mi_m0CYD/is_21_38/ai_110804605/ (Accessed 05/17/10), p. 26.

278 "Fair Market Value" 66 Fed. Reg. 944 (January 04, 2001).

279 "Financial Relationships Between Physicians and Entities Furnishing Designted Health Services; Definitions" 42 C.F.R § 411.351 (2008), p. 34; "Fair Market Value: Analysis and Tools to Comply with Stark and Anti-kickback Rules" By Robert A. Wade and Marcie Rose Levine, Audioconference: HC Pro, Inc., Mar. 19, 2008, p. 34.

280 "Fair Market Value" 66 Fed. Reg. 944 (January 04, 2001).

281 "Fair Market Value" 69 Fed. Reg. 16107 (March 26, 2004).

282 "Personal Service Arrangements" 69 Fed. Reg. 16093 (March 26, 2004); "Successful Medical Practice Valuation" By Reed Tinsley, Physician's News Digest, July 2008, http://www.physiciansnews.com/business/708tinsley.html (Accessed 9/19/2008).

283 "Fair Market Value" 69 Fed. Reg. 16107 (March 26, 2004).

284 "Financial Relationships Between Physicians and Entities Furnishing Designted Health Services; Definitions" 42 C.F.R § 411.351 (July 1, 2009).; "Personal Service Arrangements" 69 Fed. Reg. 16092 (March 26, 2004).

285 "Personal Service Arrangements" 69 Fed. Reg. 16092 (March 26, 2004).

286 "Renal Physicians Association v. U.S. Department of Health and Human Services, et al." 489 F.3d 1267, 1270-71 (D.C. App. 2007).

287 "Fair Market Value" 72 Fed. Reg. 51015 (September 05, 2007).; "Fair Market Value: Analysis and Tools to Comply with Stark and Anti-kickback Rules" By Robert A. Wade and Marcie Rose Levine, HC Pro, Inc., Audioconference (Mar. 19, 2008) p. 39-41; "Over a Decade Later, the Third and Final Phase in the Rulemaking of the Stark Regulations is Finally Here!" By Andrew Wachler and Adrienne Dresevic, ABA Health eSource, Vol. 4, no. 1, (September 2007), Accessed at http://www.abanet.org/health/esource/Volume4/01/Wachler-Dresevic.html (Accessed 05/14/2010).

288 "Medicare Program: Definitions" 72 Fed. Reg. 51015 (September 5, 2007).51015-51016

289 "Exceptions" 42 C.F.R. 1001.952 (March 18, 2002); "Fair Market Value: The Lawyer's Perspective" By Kimberley Elting, et. al., Jones Day, Health Care Compliance Forum, October 2006.

290 "Fair Market Value: The Lawyer's Perspective" By Kimberley Elting, et. al., Jones Day, Health Care Compliance Forum, October 2006.

291 "Regarding Inquiry of Veiws on Medicare and Medicaid Anti-Kickback Statute" By D. McCarty Thorton: Associate General Counsel of the Office of the Inspector General, Letter To T.J. Sullivan: Technical Assistant (Health Care Industries) of the Internal Revenue Services (Dec. 22, 1992) Accessed at http://www.oig.hhs.gov/fraud/docs/safeharborregulations/acquisition122292.htm (Accessed 09/24/2008).

292 "The Commercial Reasonableness Standard" 63 Fed. Reg. 1700 (January 09, 1998).

293 "Personal Service Arrangements" 69 Fed. Reg. 16093 (March 26, 2004).

294 "Physician Compensation Arrangements: Management and Legal Trends" By Daniel K. Zismer, Gaithersburg, MD: Aspen Publishers, Inc., 1999, p. 204.

295 *Ibid.*

296 "American Lithotripsy Society and Urology Society of America v. Tommy G. Thompson" 215 F.Supp. 2d 23, 27 (D.D.C. July 12, 2002).

297 "Covenant Medical Center to Pay U.S. $4.5 Million to Resolve False Claims Act Allegations" U.S. Department of Justice, News Release August 25, 2009, http://www.usdoj.gov/opa/pr/2009/August/09-civ-849.html (Accessed 09/04/09).

298 "Covenant Medical Center to Pay U.S. $4.5 Million to Resolve False Claims Act Allegations" U.S. Department of Justice, News Release August 25, 2009, http://www.usdoj.gov/opa/pr/2009/August/09-civ-849.html (Accessed 09/04/09). ; "Covenant to Pay Feds $4.5M to Settle Fraud Allegations" By Courier Staff, Waterloo/Cedar Falls Courier, August 25, 2009, http://www.wcfcourier.com/articles/2009/08/25/news/breaking_news/doc4a94156271f78380125347.txt (Accessed 09/11/09).

299 "Covenant to Pay Feds $4.5M to Settle Fraud Allegations" By Courier Staff, Waterloo/Cedar Falls Courier, August 25, 2009, http://www.wcfcourier.com/articles/2009/08/25/news/breaking_news/doc4a94156271f78380125347.txt (Accessed 09/11/09).

300 "Covenant Medical Center to Pay U.S. $4.5 Million to Resolve False Claims Act Allegations" U.S. Department of Justice, News Release August 25, 2009, http://www.usdoj.gov/opa/pr/2009/August/09-civ-849.html (Accessed 09/04/09). ; "Iowa Hospital Pays $4.5 Million in Fraud Case" By Nigel Duara, Chicago Tribune, August 25, 2009, http://www.chicagotribune.com/news/chi-ap-ia-iowahospital-frau,0,7910766,print.story (Accessed 8/29/09).

301 "United States of America v. Peter Rogan" 459 F.Supp. 2d 692 (N.D. Ill. 2006).; "United States of America ex rel. Roberts v. Aging Care Home Health, Inc., et al." 474 F.Supp. 2d 810, 818 (W.D. La. 2007).818

302 "Fair Market Value in Health Care Transactions" By Lewis Lefko, Haynes and Boone, LLP, Posted on World Services Group: Member Publications, July 20, 2007, http://www.worldservicesgroup.com/publications.asp?action=article&artid=2086 (Accessed 9/18/2008).

303 Fair Market Value in Health Care Transactions" By Lewis Lefko, Haynes and Boone, LLP, Posted on World Services Group: Member Publications, July 20, 2007, http://www.worldservicesgroup.com/publications.asp?action=article&artid=2086 (Accessed 9/18/2008).

304 "United States ex rel. Darryl L. Kaczmarczyk, et al. v. SCCI Health Services Corp." Civ. No. H-99-1031 (S.D. Tex. 2004).; "Fair Market Value in Health Care Transactions" By Lewis Lefko, Haynes and Boone, LLP, Posted on World Services Group: Member Publications, July 20, 2007, http://www.worldservicesgroup.com/publications.asp?action=article&artid=2086 (Accessed 9/18/2008).

305 "Fair Market Value in Health Care Transactions" By Lewis Lefko, Haynes and Boone, LLP, Posted on World Services Group: Member Publications, July 20, 2007, http://www.worldservicesgroup.com/publications.asp?action=article&artid=2086 (Accessed 9/18/2008).

306 *Ibid.*

307 *Ibid.*

308 "United States ex rel. Darryl L. Kaczmarczyk, et al. v. SCCI Health Services Corp." Civ. No. H-99-1031 (S.D. Tex. 2004).; "Fair Market Value in Health Care Transactions" By Lewis Lefko, Haynes and Boone, LLP, Posted on World Services Group: Member Publications, July 20, 2007, http://www.worldservicesgroup.com/publications.asp?action=article&artid=2086 (Accessed 9/18/2008).

309 "Fair Market Value: Analysis and Tools to Comply with Stark and Anti-kickback Rules" By Robert A. Wade and Marcie Rose Levine, HC Pro, Inc., Audioconference (Mar. 19, 2008) p. 63-64.

310 "Fair Market Value: Analysis and Tools to Comply with Stark and Anti-kickback Rules" By Robert A. Wade and Marcie Rose Levine, HC Pro, Inc., Audioconference (Mar. 19, 2008) p. 45; "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. 281.

311 "OIG Compliance Program For Individual and Small Group Physician Practices" 65 Fed. Reg. 59434, (October 5, 2000).

312 "OIG Advisory Opinion No. 07-10" Office of Inspector General, Advisory Opinion (September 27, 2007), Accessed at oig.hhs.gov/fraud/docs/advisoryopinions/2007/AdvOpn07-10A.pdf (Accessed 5/10/10), p. 10.

313 "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).

314 "Nonprofit Hospitals and the Provision of Community Benefits" Congressional Budget Office, A CBO Paper (December 2006), http://www.cbo.gov/ftpdocs/76xx/doc7695/12-06-Nonprofit.pdf (Accessed 02/09/10).

315 "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).

316 *Ibid.*

317 "The Law of Tax-Exempt Healthcare Organizations" By Thomas K. Hyatt and Bruce R. Hopkins, Hoboken, NJ: John Wiley & Sons Publishers, 1995, p. 13.

318 "Health Care Provider Reference Guide" By Janet E. Gitterman and Marvin Friedlander, Internal Revenue Service, 2004, Accessed at http://www.irs.gov/pub/irs-tege/eotopicc04.pdf (Accessed 02/09/10).

319 "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).

320 "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).

321 "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; "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. 612.

322 "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) Accessed at http://news.bna.com/hlln/display/batch_print_display.adp (Accessed 12/28/09).

323 *Ibid.*

324 "Intermediate Sanctions—Excess Benefit Transactions" Internal Revenue Service, August 13, 2009, http://www.irs.gov/charities/charitable/article/0,,id=123303,00.html (Accessed 02/09/10).

325 "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 28, 2009).

326 *Ibid.*

327 "OIG Advisory Opinion No. 07-10" Office of Inspector General, Advisory Opinion (September 27, 2007), Accessed at oig.hhs.gov/fraud/docs/advisoryopinions/2007/AdvOpn07-10A.pdf (Accessed 5/10/10).

328 "OIG Advisory Opinion No. 07-10" Office of Inspector General, Advisory Opinion (September 27, 2007), Accessed at oig.hhs.gov/fraud/docs/advisoryopinions/2007/AdvOpn07-10A.pdf (Accessed 5/10/10), p. 6-7.

329 "OIG Advisory Opinion No. 07-10" Office of Inspector General, Advisory Opinion (September 27, 2007), Accessed at oig.hhs.gov/fraud/docs/advisoryopinions/2007/AdvOpn07-10A.pdf (Accessed 5/10/10), p. 2.

330 "OIG Advisory Opinion No. 07-10" Office of Inspector General, Advisory Opinion (September 27, 2007), Accessed at oig.hhs.gov/fraud/docs/advisoryopinions/2007/AdvOpn07-10A.pdf (Accessed 5/10/10), p. 3-4.

331 "Advisory Opinion No. 07-10" Office of Inspector General, U.S. Department of Health and Human Services, Advisory Opinon (September 27, 2007), p. 1, 12.

332 "Trust, etc., in Restraint of Trade, Illegal" 15 U.S.C. § 1 (2009).

333 "Unfair Methods of Competition Unlawful; Prevention by Commission" 15 U.S.C. § 45 (2009).

334 "Monopolizing Trade a Felony; Penalty" 15 U.S.C. § 2 (2009).

335 "Health Care Fraud: Enforcement and Compliance" By Robert Fabrikant, et al., Law Journal Press, New York, NY: 2007, p. 2-60.

336 "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.

337 "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).

338 "North Texas Specialty Physicians v. Federal Trade Commission" 528 F.3d 346 (5th Cir. 2008).

339 *Ibid.*

340 "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 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.

341 "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).; "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 04/18/08), p. 1, 11-12.

342 "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.

343 *Ibid.*

344 "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).

345 "Heartland Surgical Specialty Hospital, LLC v. Midwest Division, Inc." 527 F.Supp. 2d 1257 (D. Kan. 2007).

346 "Trust, etc., in Restraint of Trade, Illegal" 15 U.S.C. § 1 (2009).

347 "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.

348 "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. 5.

349 349 "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. 5-6.

350 "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. 5.

351 "Angel Yuh Williamson v. Sacred Heart Hospital of Pensacola" 1993 WL 543002 (N.D. Fla. 1993); "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.

352 *Ibid.*

353 "Racketeer Influenced and Corrupt Organizations Act; Definitions" 18 U.S.C. 1961 (2009).

354 "Health Care Fraud: Enforcement and Compliance," By Robert Fabrikant, et al., Law Journal Press, 2007, p. 3-83-84, quoting 115 Cong. Rec. 9566, 9568 (April 18, 1969), statement of Sen. McClellan.

355 "Racketeer Influenced and Corrupt Organizations Act; Prohibited Activities"18 U.S.C. 1962(a-c) (2009).

356 "Racketeer Influenced and Corrupt Organizations Act; Prohibited Activities"18 U.S.C. 1962(d) (2009).

357 "Health Care Fraud: Enforcement and Compliance" By Robert Fabrikant, et al., New York, NY: Law Journal Press, 2007, p. 3-90.

358 "Problems in Health Care Law" By Robert D. Miller and Rebecca C. Hutton, Eighth Edition, Sudbury, MA: Jones and Bartlett Publishers, 2004, p. 327.

359 "Problems in Health Care Law" By Robert D. Miller and Rebecca C. Hutton, Eighth Edition, Sudbury, MA: Jones and Bartlett Publishers, 2004, p. 328; "Radon in the Workplace, The OSHA Ionizing Radiation Regulations" By Robert K. Lewis, Bureau of Radiation Protection, http://www.aarst.org/proceedings/2004/2004_07_Radon_in_the_Workplace_The_OSHA_Ionizing_Radiation.pdf (Accessed 10/13/2009).

360 "Clinical Laboratory Improvement Amendments: Overview" Centers for Medicare and Medicaid Services of The U.S. Department of Health and Human Services, http://www.cms.hhs.gov/clia/ (Accessed 09/01/09).; "Clinical Laboratory Improvement Amendments" United States Food and Drug Administration, June 16, 2009, http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/IVDRegulatoryAssistance/ucm124105.htm (Accessed 06/30/09).

361 "Clinical Laboratory Improvement Amendments: Overview" Centers for Medicare and Medicaid Services of The U.S. Department of Health and Human Services, http://www.cms.hhs.gov/clia/ (Accessed 09/01/09).

362 *Ibid.*

363 "Clinical Laboratory Improvement Amendments" United States Food and Drug Administration, June 16, 2009, http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/IVDRegulatoryAssistance/ucm124105.htm (Accessed 06/30/09).; "CMS Initiatives To Improve Quality of Laboratory Testing Under the CLIA Program" Centers for Medicare and Medicaid Services, July 2006, http://www.cms.hhs.gov/CLIA/downloads/060630.Backgrounder.rlEG.pdf (Accessed 11/02/09).

364 "About NRC" United States Nuclear Regulatory Commission, April 28, 2009, http://www.nrc.gov/about-nrc.html (Accessed 09/01/09).

365 "Medical, Industrial, and Academic Uses of Nuclear Material" United States Nuclear Regulatory Commission, June 2, 2008, http://www.nrc.gov/materials/medical.html (Accessed 06/30/09).

366 "Atomic Energy Act of 1954: Section 274" U.S. Nuclear Regulatory Commission, Vol. 1, No. 6 (June 2002), http://www.nrc.gov/reading-rm/doc-collections/nuregs/staff/sr0980/ml022200075-vol1.pdf#pagemode=bookmarks&page=14 (Accessed 05/05/10).

367 "Agreement State Program" United States Nuclear Regulatory Commission, April 10, 2009, http://www.nrc.gov/about-nrc/state-tribal/agreement-states.html (Accessed 06/30/09).

368 "Medical Uses of Nuclear Material" United States Nuclear Regulatory Commission, February 12, 2007, http://www.nrc.gov/materials/miau/med-use.html (Accessed 06/30/09).

369 "The Public Health and Welfare" 42 U.S.C. §1395ee(e)(2) (2009).

370 "Medical Screening Requirement" 42 U.S.C. §1395dd(a) (2009).

371 "Personal Harm" 42 U.S.C. §1395dd (d)(2)(A) (2009).

372 "Agreements with Providers of Services" 42 U.S.C. §1395cc(d)(1)(A) and (B) (2009).

373 "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), Accessed at http://www.hschange.com/CONTENT/552/ (Accessed 5/10/10).

374 "Black's Law Dictionary" By Henry Black, 5th Edition, St. Paul, MN: West Publishing Co., 1979, p. 864.

375 "Health Law: Cases Materials and Problems" By Barry R. Furrow, et al., Third Edition, St. Paul, MN: West Publishing, 1997, p. 308; "Medical Malpractice Reform and Employer-Sponsored Health Insurance Premiums" By Michael A. Morrisey, Meredith L. Kilgore, and Leonard (Jack) Nelson, HSR: Health Services Research, Vol. 43, No. 6 (December 2008), p. 2125-2126.

376 "Health Law: Cases Materials and Problems" By Barry R. Furrow, et al., Third Edition, St. Paul, MN: West Publishing, 1997, p. 309-310; "Medical Malpractice Liability Crisis Meets Markets: Stress in Unexpected Places" By Robert A. Berenseon, Sylvia Kuo and Jessica H. May, Center for Studying Health System Change, September 2003, http://www.hschange.com/CONTENT/605/ (Accessed 09/30/03). ; "The U.S. Health Care System: Stakeholders and Politics" By Marcia Nielsen, Society of Actuaries Spring Meeting: New Orleans, LA, June 16, 2005, http://www.soa.org/files/pdf/066_nielsen-health05.pdf (Accessed 10/28/09).

377 "Medical Malpractice Reform and Employer-Sponsored Health Insurance Premiums" By Michael A. Morrisey, Meredith L. Kilgore, and Leonard (Jack) Nelson, HSR: Health Services Research, Vol. 43, No. 6 (December 2008), p. 2127; "Special Report: Hype Outraces Facts in Malpractice Debate: Degree of Crisis Varies Among Specialties and From State to State" By Peter Eisler, Julie Appleby and Martin Kasindorf, USA Today.com, March 5, 2003, http://www.saynotocaps.org/newsarticles/hype%20Outraces%20facts.html (Accessed 10/28/09).

378 "Black's Law Dictionary" By Henry Black, 5th Edition, St. Paul, MN: West Publishing Co., 1979, p. 352, 864, 1355.

379 "Justice for the Injured: Defending the Civil Justice System From the Corporate 'Tort Deform' Movement" Multinational Monitor, March 2003, http://www.multinationalmonitor.org/mm2003/032003/doroshow.html (Accessed 10/28/09).

380 "Ending the Confusion: Economic, Non-Economic and Punitive Damages" American College of Surgeons Professional Association, July 30, 2003, http://www.facs.org/acspa/damagedefined.html (Accessed 10/30/09).

381 "Tort Excess: The Necessity for Reform From a Policy, Legal and Risk Management Perspective" By David Dial et al., Weinberg Wheeler Hudgins Gunn and Dial, LLC, http://server.iii.org/yy_obj_data/binary/727182_1_0/tortreform.pdf (Accessed 09/08/09).

382 "The Economics of U.S. Tort Liability: A Primer" U.S. Congressional Budget Office, Washington, D.C.: Government Printing Office, October 2003, http://www.cbo.gov/ftpdocs/46xx/doc4641/10-22-TortReform-Study.pdf (Accessed 05/10/10), p. viii,10.

383 "Medical Malpractice Reform and Employer-Sponsored Health Insurance Premiums" By Michael A. Morrisey, Meredith L. Kilgore, and Leonard (Jack) Nelson, HSR: Health Services Research, Vol. 43, No. 6 (December 2008), p. 2125.

384 "Medical Liability/Malpractice Laws" National Conference of State Legislatures, September 4, 2009, http://www.ncsl.org/default.aspx?tabid=18516 (Accessed 10/28/09).

385 "Damages For Wrongs" Cal. Civ. Code § 3333.2.

386 "Limits of Liability" Tex. Civ.Prac. & Rem. Code Ann. §74.301 (2009), http://www.statutes.legis.state.tx.us/Docs/CP/htm/CP.74.htm#74.301 (Accessed 10/29/09).

387 "Medical Liability/Malpractice Laws" National Conference of State Legislatures, September 4, 2009, http://www.ncsl.org/default.aspx?tabid=18516 (Accessed 10/28/09).

388 *Ibid.*

389 "The New Medical Malpractice Crisis" By Michelle M. Mello, David M. Studdert, and Troyen A. Brennan, The New England Journal of Medicine, Vol. 348, No. 23 (June 5, 2003), p. 2283.

390 "Docs Return Fire: Countersuing in Frivolous Malpractice Cases" By Leigh Page, Modern Physician (September 2003), p. 6.

391 "Special Report: Hype Outraces Facts in Malpractice Debate: Degree of Crisis Varies Among Specialties and From State to State" By Peter Eisler, Julie Appleby and Martin Kasindorf, USA Today.com, March 5, 2003, http://www.saynotocaps.org/newsarticles/hype%20Outraces%20facts.html (Accessed 10/28/09).

392 "A New 'Malpractice Crisis'? Why Premiums Are Soaring Again" By Mark Crane, Medical Economics Magazine (July 9, 2001), http://medicaleconomics.modernmedicine.com/memag/article/articleDetail.jsp?id=118155 (Accessed 09/08/09).

393 "Confronting the New Health Care Crisis: Improving Health Care Quality and Lowering Costs By Fixing Our Medical Liability System" U.S. Department of Health and Human Services, (July 24, 2002), p. 17.

394 "H.R. 4600: Help Efficient, Accessible, Low-Cost, Timely Healthcare (HEALTH) Act of 2002: Related Legislation" Govtrack.us, http://www.govtrack.us/congress/bill.xpd?bill=h107-4600&tab=related (Accessed 9/8/09).

395 *Ibid.*

396 "Have State Caps on Malpractice Awards Increased The Supply of Physicians?" By William E. Encinosa and Fred J. Hellinger, Health Affairs, Web Exclusive (May 31, 2005), Accessed at http://content.healthaffairs.org/cgi/reprint/hlthaff.w5.250v1(Accessed 5/10/10), p. W5-251.

397 "Beyond MICRA: New Ideas for Liability Reform" American College of Physicians, Annals of Internal Medicine, Vol. 122, No. 6 (1995), p. 466; "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. 2.

398 "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.

399 *Ibid.*

4

Impact of Competitive Forces

There are perhaps few things upon which all men are so agreed as that the problems which beset them today surpass in difficulty those which confronted any previous generation. It is maintained that never has knowledge been so complex nor the pace of life so insistent; that never has it been so difficult to take thought on those larger considerations which allow men to appreciate the trend of events and the measures by which they might be controlled.

Harold Himsworth, 1953

KEY TERMS

- Cherry-pick or Cream-skim
- Economic Demand
- Economic Supply
- Monopsony
- Niche Providers
- Purple Pill

Key Concept	Definition	Citation
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
"Corporatization" of Medicine	The transformation of vertically organized bureaucracies into government-owned corporations that are exposed to market-like pressures. In healthcare, this means the establishment of publically owned hospitals as private corporations. Corporatization is usually seen along with autonomization.	"Understanding Organizational Reforms: The Corporatization of Public Hospitals" by April Harding and Alexander S. Preker, Health, Nutrition, and Population, The World Bank, September 2000, p. vii, 15.
"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.
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.	"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.
"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.
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. w34.
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 to begin merging 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.
Federal Specialty Hospital Moratorium of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003	Placed an eighteen-month moratorium on physician investment in, and referrals to, specialty hospitals in which the referring physician had an ownership or investment interest in order to study the impact of specialty hospitals on Medicare payment rates and referral practices. Expired in 2005.	"CMS Outlines Next Steps and Moratorium on New Specialty Hospitals Expires," Press Release, Centers for Medicare and Medicaid Services, June 9, 2005, www.cms.hhs.gov/apps/media/press/release.asp?Counter=1478 (accessed November 9, 2009).
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).
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.
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.	"Making Competition in Health Care Work." by Michael E. Porter, et al., Harvard Business Review, July/August, 1994.
Medical Tourism	The practice of patients traveling to countries to receive medical procedures at a fraction of what they would cost in the United States.	"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. 18.
Medicare Improvements for Patients and Providers Act of 2008	Includes a provision requiring accreditation of physicians who provide the technical component for advanced diagnostic imaging services (for example, magnetic resonance imaging , computed tomography, and nuclear medicine or single photon emission computed tomography) for which payment is made under the Medicare physician fee schedule. All suppliers of the technical component of advanced diagnostic imaging services will need to be accredited by January 2012.	"Medicare Improvements for Patients and Providers Act of 2008," Pub. L. 110-275, 122 Stat. 2494, July 15, 2008, Sec. 135(a).
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.

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.

As the relationship between price and quality of care generally is defined by providers rather than patients, consumers (that is, patients) are less equipped to make informed purchase decisions than they are in other markets. 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 (discussed in chapter 3, *Regulatory Environment*), the government's role as the single largest payor for healthcare services exerts enormous pressure on providers to reduce costs. 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. 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," just like if they were any other market commodity (for example, 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 [for example, independent diagnostic testing facilities (IDTFs) and ambulatory surgery centers (ASCs)], and large for-profit health insurance payors.

Economics of Healthcare

Healthcare costs are not just rising, they are growing at a proportionally greater rate compared to the rise in cost of other goods and services in the U.S. economy.[1] The percentage of the gross domestic product (GDP) devoted to healthcare services has grown from 6 percent in 1965 to almost 18 percent at the time of publication, and it is projected to surpass 20 percent by 2018.[2] 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, was more severe on GDP than it was on healthcare spending, though the growth rate of the latter did decline slightly.[3]

The percentage of the gross domestic product (GDP) devoted to healthcare services has grown from 6 percent in 1965 to almost 18 percent at the time of publication, and is projected to surpass 20 percent by 2018.

"Three Decades of Government-Financed Health Care in the United States," by Patrick Fleenor, Tax Foundation, August 1994, www.taxfoundation.org/files/bd006ece1a4b8166023dbc913175b7b7.pdf (accessed November 11, 2009); "Health Spending Projections Through 2018: Recession Effects Add Uncertainty to the Outlook," by Andrea Sisko, et al., Health Affairs, Web Exclusive, Feb. 24, 2009, p. w347.

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.[4] In reality, the rise in healthcare expenditures is, at least in large part, the result of much deeper economic forces. As economist William J. Baumol explains, "the relative increase in healthcare costs compared with the rest of the economy is inevitable and ineradicable part of a developed economy. The attempt [to control relative costs] may be as foolhardy as it is impossible."[5]

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.[6]

Second, unlike other labor-intensive industries, healthcare is local in nature and cannot be imported. Despite the technology advances described previously, healthcare services mainly are provided by skilled workers within a local market in which the providers compete locally and are compensated at higher levels.[7]

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.[8]

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."[9] Prior to the mid–twentieth century, healthcare was dominated by these providers who justified anticompetitive behavior under the guise of quality control

(see chapter 6 of *Professional Practices* for a discussion of the highly publicized *Wilk v. American Medical Association*, in which the American Medical Association (AMA) attempted to boycott chiropractic practices, stating that doctors of chiropractic were unscientific practitioners, as well as chapter 4 of *Professional Practices* regarding the highly contested 2008 Missouri Supreme Court decision to allow the independent practice of nurse midwives under constitutional law).[10] In the mid- to late-twentieth century, however, the stringency of competition policy was heightened in order to address such behavior among providers, and, as such, competition laws have begun to regulate the healthcare sector, as an economic market, more directly.[11]

Prior to the mid–twentieth century, healthcare was dominated by these providers that justified anticompetitive behavior under the guise of quality control.

"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.

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" (see chapter 3, *Federal Antitrust Laws*).[12]

Also unique to the healthcare sector is the widespread notion of providing services irrespective of the client's (that is, the patient's) ability to pay. Under laws such as the Emergency Medical Treatment and Labor Act (EMTALA), general hospital emergency departments are required to provide care under certain circumstances, even to patients who are uninsured and unable to pay for services rendered.[13] Additionally, the power of Medicare and Medicaid 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 nearly 60 percent of a hospital's revenue, the general relationship between cost and price found in other markets is not commonly followed in the healthcare sector.[14]

Medicare and Medicaid provide nearly 60 percent of a hospital's revenue.

"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. 14.

Further, competition in healthcare does not divide neatly between supply and demand, further contributing to the complexity that distinguishes competition within 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 services through the use of provider networks, and hospitals are incentivized to keep costs low by treating only what is necessary, knowing that readmission will mean additional reimbursement.[15]

Additionally, many community hospitals are finding it increasingly difficult to cross-subsidize expensive treatments due to competition from specialty providers and increased demands for price transparency by consumers.[16] Difficulties in accessing capital to support the provision of money-losing services have pushed many smaller hospital systems to consolidate with larger, for-profit systems.[17]

At the same time, insurers operate as consumers of healthcare services by paying for the services provided and deferring that cost from the actual consumer, the patient.[18] On this side of the equation, large insurance companies have been able to enjoy **monopsony** (that is, single purchaser; opposite of monopoly) power in the United States which has allowed them to demand "most favored nation" status in their contracts with providers; that is, the provider contractually agrees to not charge the insurance company any more than he or she charges any other customer.[19] This has allowed insurance companies to prevent competitors from entering the market, which, combined with numerous mergers, has led to a highly concentrated insurance market and paved the way for insurers to set malpractice premiums at rates so high, and reimbursement payments at rates so low, that they are driving physicians and small hospitals out of business or forcing them to join large hospital system conglomerations.[20]

At the same time, consumers enduring the repercussions of high insurance premiums are choosing 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.[21] (For more information about HSAs, see chapter 2, *Health Savings Accounts* (*HSA*)). 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 scrutinize more closely the procedures and services they purchase.[22] 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.[23]

Impact of Government Regulation

Healthcare institutions 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 (see chapter 3, *Stark Law*). State and federal fraud and abuse laws have profoundly affected the provision of healthcare services in the United States because they, in part, prohibit particular financial relationships between healthcare providers. Proponents of these laws contend that practitioner medical judgment is influenced by financial relationships with referral sources.[24] However, substantial regulation has the capacity to limit free market competition in the healthcare industry.[25] Additionally, the influence of the government as both regulator and purchaser of healthcare services has the potential to distort consumer responses to prices, as well as harm consumers directly by creating disincentives for the provision of quality care by reducing rewards for innovation, despite the aim of regulations to prevent market forces from running amok and hurting quality (for more information related to government regulation of the healthcare industry, see chapter 3, *Regulatory Environment*).[26]

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 and other related services to patients referred to the hospital in which the physicians enjoyed staff privileges.[27] Under this symbiotic dynamic, there was relatively little to no competition between physicians and hospitals.[28] 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 (for more detail related to the organizational structure of healthcare services in the current market, see chapter 1 of *Professional Practices*).[29]

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.[30] With 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.[31] Declining patient volumes also prompted hospitals to begin merging with each other so that they could leverage their consolidated bargaining power against private insurers.[32] As time progressed, concerns regarding access to capital have led to continued hospital consolidation, such that smaller, typically nonprofit, hospitals are faced with the grim choice of going bankrupt or joining larger, for-profit hospital systems to survive.[33]

A particular impact of competition on hospitals is that they are asked to provide money-losing services in an environment in which price-competitiveness is promoted. Traditionally, hospitals could cross-subsidize cost-ineffective services (for example, those falling under Medicare or Medicaid, services provided to indigent patients, etc.) by charging more to insured patients who were not price-sensitive and did not have the capacity to know the difference.[34] However, the rise of competition with specialty hospitals and niche providers (see *Threat of New Market Entrants*) has led to increased price transparency, which allows those insured patients who have been footing the bill for money-losing services to demand that prices reflect the services actually provided to them, and nothing more.[35] The potential decrease in demand for services that are priced too high could force hospitals to eliminate cost-ineffective services in the struggle to compete with other hospitals and specialty providers.[36]

Competition Between General and Specialty Hospitals

Although specialty and niche providers are not new providers, the increase in their number has led to concerns that more and more providers will be able to "**cherry-pick**" and "**cream-skim**" the most profitable patients and procedures away from community hospitals. Specialty hospitals focus on providing only cost-effective or profitable services, and they refuse to provide services that result in a net loss or treat patients who cannot pay.[37] Further, the development of new technology has made it possible for physicians to perform, in their office or ASC, services traditionally provided by hospitals.[38] Specialty hospitals and ASCs have been able to compete better than community hospitals for more profitable patients by (1) concentrating only on specific diagnosis-related groups (DRG), (2) treating far fewer costly Medicaid patients, and (3) opting out of emergency room facilities and services, the latter to forego

the related regulatory requirements under laws, such as EMTALA, that pertain to the provision of care regardless of a patient's ability to pay.[39]

Specialty hospitals and ASCs treat some of the most profitable diseases in a predominantly outpatient setting. These facilities have grown due to the increased incidence of these diseases, as well as changes in consumer demands and new technologies. "Specialty hospitals are also able to achieve economies of scale and scope by providing high volumes of a limited scope of services and lowering fixed costs by reengineering the care delivery process."[40] This narrow focus helps achieve profitability and makes such facilities more competitive than more generalized providers, because "greater diversification into a wider array of activities has the potential to lead to diminished financial performance."[41]

The ability to provide services at a reduced cost is a double-edged sword for ASCs. Under the Medicare system, reimbursement rates for hospital outpatient departments (HOPD) are substantially higher than reimbursement rates for the same procedures performed in an ASC or a physician's office.[42] For most services performed in an ASC, payment is made under a system that aligns ASC reimbursement rates at a percentage of the Outpatient Prospective Payment System (OPPS) rates.[43] Because of the need to ensure budget neutrality between the old ASC payment system and the revised system, the reimbursement rate for ASC procedures was set at 65 percent of the OPPS rate in 2008.[44] Centers for Medicare and Medicaid Services (CMS) cut this rate again in 2009,[45] with a zero percent adjustment for inflation,[46] and only increased the conversion factor for payments to ASCs by 1.2 percent for 2010, despite an increase of 2.1 percent for HOPDs for the same year.[47] Because CMS accounts for an average of 34 percent of ASC revenue, changes to CMS reimbursement rates greatly affect the ability of ASCs to provide quality patient care services (see chapter 1 of *Professional Practices*).[48]

Medicare and Medicaid account for an average of 34 percent of an ambulatory surgery center's (ASC's) revenue.

"10 interesting facts and statistics for ASCs," by S. Becker, Becker's ASC Review, January 2008, www.beckersasc.com/ambulatory-surgery-center/surgery-center-education/10-interesting-facts-and-statistics-for-ascs.html (accessed May 17, 2010).

Further, physicians who provide outpatient services in their offices only receive the physician fee component reimbursement rate under the Medicare physician fee schedule.[49] When procedures are performed in a 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.[50] Further, although the payment differential between HOPDs and ASCs is standardized for the most part, the payment differential between services provided in HOPDs or ASCs and services provided in physicians' offices varies substantially by payor and service (for more detail on Medicare reimbursement see chapter 2, *Medicare*).[51]

Campaign Against Physician Ownership

Competition between hospitals and physicians has been intensified by a growing tension between the American Hospital Association (AHA) on one side and the American Medical Association (AMA) and Physician Hospitals of America on the other side, a tension which has risen out of the debate over physician ownership of specialty hospitals.[52] At its heart, the controversy regarding specialty and niche providers is a turf war between physicians and hospitals related to the technical component revenues from procedures and diagnostic testing. Physicians, who have seen decreased reimbursement rates for

the professional fee component of their services under the Medicare physician fee schedule, have begun to invest in ancillary services and technical component (ASTC) revenue stream enterprises (for example, ASCs, IDTFs, and specialty hospitals) so that they may also be reimbursed for the procedure under the OPPS.[53]

As many also assert that the practice of physician investment in healthcare from which they seek to earn a profit is a practice that is normatively controversial and should be avoided, physician owners of ASTC revenue stream enterprises have come under attack at the hands of regulators that have been lobbied incessantly by powerful community hospital systems.[54] In particular, opponents of specialty hospitals consistently have lobbied for the elimination of the "whole hospital exception" to the Stark law (see chapter 3, *Stark Law*), which allows physicians to refer patients to facilities in which they have ownership or investment interest as long as the ownership or investment interest is in the whole hospital and not just a subdivision of it.[55]

Legislative proposals to remove the whole hospital exception in 2003 prompted the General Accounting Office (GAO) to investigate the development and effects of specialty hospitals.[56] In April 2003, GAO issued its first report on the market share and physician ownership of specialty hospitals.[57] The GAO found that specialty hospitals represented a growing share of the hospital market and that there has been rapid growth in the number of specialty hospitals.[58] The GAO also found that physicians owned 70 percent of all specialty hospitals.[59] The GAO issued a more detailed report in October 2003 analyzing the impact of specialty hospitals on general hospitals. The October report found that specialty hospitals were less likely to have emergency rooms than general hospitals, treated fewer Medicaid patients than general hospitals, and derived less income from inpatient services than general hospitals.[60]

In response to this report, the United States Congress, as part of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (MMA), placed an eighteen-month moratorium on physician investment in, and referrals to, specialty hospitals in which referring physicians had an ownership or investment interest in order to study the impact of specialty hospitals on Medicare payment rates and referral practices.[61] Typically, the whole hospital exception to the Stark law would have protected such physicians who have an ownership or investment interest in the whole hospital from violating the Stark law by referring patients to that facility. However, the MMA's eighteen-month moratorium on the development of new specialty hospitals[62] was the culmination of a multiyear battle against this perceived loop-hole in the Stark law allowing physicians to have ownerships interests in hospitals. The temporary moratorium appears to represent a compromise between the faction wanting to eliminate the whole hospital exception for all hospitals and the faction concerned only with the perceived threat from specialty and niche providers.

The AHA, a long-time supporter of restrictions limiting physician self-referrals and investment, supports extending the specialty hospital moratorium contained in the MMA.[63] Recognizing that it may be difficult for physicians to unite against the hospital industry, the AMA has demonstrated its support of specialty hospitals and a "level playing field" between general and specialty hospitals.[64] The AMA has stressed that it supports competition between healthcare providers because it "promotes delivery of high-quality, cost effective healthcare."[65] However, the AMA does not speak for all physicians on this issue. The American Academy of Family Physicians (AAFP) has announced its support for extending the specialty hospital moratorium. The AAFP has sided with the AHA, believing that specialty hospitals could cream-skim patients with profitable diagnoses.[66]

Although the specialty hospital moratorium expired without being perpetuated in 2005, the debate regarding physician ownership of specialty hospitals continues, with organizations such as the AHA

accusing specialty hospitals of leaving community hospitals with the brunt of uninsured and underinsured patients.[67] At the same time, physicians counter that physician-owned facilities (POFs) are able to offer improved competition leading to lower costs, higher quality, better outcomes, increased efficiency derived from more focus on specific services, more convenient services than offered by general hospitals, and better amenities. POFs also offer physicians greater control over delivery of services and the ability to supplement their otherwise decreasing revenues.[68]

Exclusionary Boycotts

In response to the threat from specialty hospitals, many community hospitals also have started to fight 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 POF out of the market. Some of these practices include refusing to assist or cooperate with specialty hospitals, pressuring other members of the medical staff or community physicians to not do business with the specialty hospital, pressuring payors to exclude specialty hospitals from the payors' networks, and limiting or terminating physician-investors' privileges and medical staff membership (conflict of interest credentialing).[69] In response to these practices, some POFs have initiated antitrust suits, claiming that general hospitals are engaging in illegal exclusionary boycotts.[70]

Although courts typically have favored general hospitals that have been trying 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.[71] 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.[72]

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.[73] This has incentivized physicians to join together in one of many types of emerging healthcare models (see chapter 2 of *Professional Practices*) so that they may improve their positioning vis-à-vis third-party payors. 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.[74] 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.[75] Managed care has placed pressure on these organizations to reduce costs, maintain quality, and protect market share.[76] A key driver of physician integration has been the potential negotiating power it merits, namely

for contracting with hospitals and Managed Care Organizations (MCOs).[77] The independent practice association (IPA) has been one of the more successful physician integration models.[78] Other forms of physician integration include group practices without walls, physician practice management companies (PPMCs), and consolidated medical groups.[79] These organizations have not achieved the success levels of IPAs.[80] However, management services organizations (MSOs) have been successful in the integration of both providers and healthcare institutions.[81] They generally offer an array of medical support services, including billing and administrative support.[82] They also help negotiate contracts with third-party payors.[83] For detail on each of these types of physician integration models see chapter 2 of *Professional Practices*.

Manpower Shortage

In 1980, the Graduate Medical Education National Advisory Committee projected a surplus of 70,000 physicians in the year 2000, which led to the implementation of a cap on medical school enrollment to control supply of physicians to the market. 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.[84] As economic recession hit in 2008, the physician workforce, like many other professions, experienced a shortage that is expected to continue through the next decades, reaching a possible a shortage of 159,000 physicians by the year 2025.[85] 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 two decades, reaching a possible a shortage of 159,000 physicians by the year 2025.
>
> *"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. 6.*

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.[86] Further exacerbating this particular shortage is the focus of medical schools on advanced specialization arising out of 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.[87] Additionally, many surgeons have specialized so much that they do not feel qualified to provide emergency services, with some surgeons only providing outpatient care.[88]

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 remember that the power of third-party payors as purchasers of healthcare services is significant. 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, as a result eliminating traditional demand forces that work in other markets to keep prices at reasonable levels.

Insurance and Managed Care

With regard to demand, 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.[89] 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 with benefits, resulting in an imperfect demand curve.[90] Conversely, insurance companies bear the costs associated with healthcare 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.[91]

Health insurance further affects 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.[92] As a result, physicians may be neither rewarded nor punished based on the quality of their work.[93] This has the effect of insulating physicians from traditional competitive forces which force low-performing participants out of other markets.[94]

MCOs, such as HMOs and preferred provider organizations (PPOs), also can distort the traditional competitive marketplace model by integrating the financing and delivery of healthcare services under the administration of one organization.[95] MCOs may be attractive to consumers because they offer lower premiums, deductibles, and co-payments than traditional third-party payors.[96] 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.[97] 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.[98]

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.[99] POS plans allow patients to use out-of-plan specialty physicians for some services as long as they start with an in-plan primary care gatekeeper; PPOs allow patients to choose out-of-plan providers listed as preferred providers without the need for a gatekeeper.[100]

MCOs are beginning to push their way into smaller markets, offering broader provider networks in the process. There is nothing new about mergers in the managed-care arena—consolidation has grown steadily for years. However, industry analysts and investment bankers predict that 2005 saw several new trends emerge to help accelerate the kinds of mergers and acquisitions that have become commonplace in the managed-care marketplace.[101] According to a recent AMA report, a single insurer dominates in most of the nation's markets.[102] In the combined HMO and PPO markets, 96 percent of metropolitan areas have few competing health insurers, with the dominant insurer having a market share of 30 percent or greater.[103] In 64 percent of the markets, the dominant insurer had a market share of 50 percent or greater.[104]

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.[105] Beginning in 1983, however, CMS adopted the hospital Inpatient Prospective Payment System (IPPS) as a means of combating rising costs associated with FFS.[106] 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 treating patients in that DRG.[107] 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.[108] 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 one of a number of Ambulatory Payment Classifications (APCs).[109]

Consumer-Driven Healthcare

The prevalence of third-party payors that deflect a substantial portion of the true cost of services away from the consumer (that is, the patient) is unique to the United States.[110] 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 (see chapter 2, *Consumer Driven Health Plans—The Shift From Demand Benefits to Defined Contributions*). A significant competitive trend in health insurance is the rise of individual, high-premium insurance plans coupled with HSAs.[111]

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.

"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. 16.

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 do insured individuals with low deductibles.[112] 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.[113] Generally, HSAs are personalized accounts into which an individual contributes. An individual's employer may contribute as well. The individual then may withdraw funds to cover healthcare expenses.[114] 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.[115] HDHPs are then used in the traditional insurance context to pay the costs associated with catastrophic events like trauma and chronic disease.[116]

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,[117] skeptics argue that there is not enough evidence to demonstrate that CDHC leads to better informed choices based on quality.[118] 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.[119]

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 often has been characterized as unique in its many 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:

- The nature of health creates an unpredictable, urgent, and infinite level of demand.
- The ubiquitous involvement of insurance, private and governmental, as an intermediary in the purchase of healthcare interferes with consumer motivations and consequently their choice of providers and services.
- The difficulties in measuring healthcare quality and beneficial outcomes (both of quantifying and qualifying) and the lack of information on the relative costs of healthcare providers and services also inhibits consumer selection, further removing incentives to providers to increase quality and lower costs.

Included among the many barriers to competition in healthcare delivery are the following:

1. Patients don't purchase services directly from providers.
2. Patients don't compare prices between providers.
3. The government is the largest purchaser of healthcare.
4. Private purchasers often lack market power.
5. Patients, purchasers, and providers lack information.
6. Many providers have monopoly or near monopoly power (yet antitrust laws prevent some potentially beneficial integration).
7. Providers are rewarded for increasing costs.
8. Capital investments are overly subsidized.
9. Certificates of Need, regulation, and licensing laws are entry barriers to competing and substitute providers and services.
10. Exit barriers protect low quality providers.

The government is the largest purchaser of healthcare services.

"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. 344.

The Application of Porter's Five Forces to Hospitals and Physician Groups

Harvard Business School Professor Michael Porter is considered by many to be one of the world's leading authorities on competitive strategy and international competitiveness. Porter argues 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, (4) the bargaining power of buyers, and (5) rivalry among existing firms.[120] 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.[121]

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. removal of consumers from the direct purchasing decisions because of employer driven insurance purchasing, and
5. difficulties in quantifying health and the quality and costs of care.

Yet 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 because of rising costs. Therefore, Porter's five forces model may well be applicable to healthcare just like any other industry.[122] Porter has further explored the value of his model as a process or framework for use when examining competition in healthcare.[123]

Porter's model applies to a company operating within a given industry, therefore, 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. This is not an easily quantifiable outcome, but 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. Each of these is a strategy that has a different set of ethical consideration related to its application by healthcare providers in a care and treatment environment.[124]

Threat of New Market Entrants

Historically, many hospitals and physicians have believed that there is 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. Traditionally, healthcare has differed from many industries because financial return does not always drive the decision process. However, the overall threat from evolving market entrants on a given healthcare industry sector may be related to the size of the financial return in that particular segment of the industry.

Rise of Niche Providers

The predominance in the market of limited-service providers, that is **niche** or **specialty providers**, has grown in recent years.[125] The AHA broadly defines niche providers to include "heart hospitals, orthopedic hospitals, surgical hospitals, ASCs, cancer hospitals and centers, dialysis clinics, pain centers, imaging centers, mammography centers, and a host of other narrowly focused providers."[126] The AHA does not include other types of specialty and niche services, such as trauma and intensive care, which require extensive specialization and are provided solely within the traditional inpatient community hospital setting. However, the definition of niche provider changes depending on who is attempting to classify this subjective and potentially broad range of limited-service providers. The definition may be expanded to include surgical hospitals, ASCs, specialty hospitals, and virtually all providers who provide a specialized service outside of a hospital setting. Alternately, the definition may be limited to only those providers treating patients with either a cardiac or orthopedic condition or those performing surgical procedures.[127]

Healthcare providers falling into the broad niche provider category focus on a section or group of buyers, a segment of a product line, or a specific area of a geographic market. The assumption is that by focusing on a narrow target, healthcare providers can provide value to customers more effectively than rivals who compete more broadly. The past decade has seen explosive growth in both inpatient and outpatient limited service providers, increasingly owned, at least in part, by the physicians who refer patients to them.

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.[128] Concierge medicine is basically a return to old fashioned medicine, in which physicians limit their client base and devote more time to each patient (for more information, see chapter 2, *Concierge Medicine*, and chapters 1 and 2 of *Professional Practices*). Patients usually can see their physician within a day of requesting an appointment, and most have twenty-four-hour access to their physician by beeper or 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 increased access to personalized physician care.[129] Physicians, tired of 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.[130] 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 $1,000 per year to $10,000 per year depending on the patient's age, benefits received, area of the country, and type of practice.[131] Amenities vary by practice, but some include more time with the physician (for example, a thirty-minute office visit), increased access to physicians, newsletters or condition-specific information sent by e-mail, accompaniment on medical visits to outside specialists, and house calls.[132]

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.[133] However, many physicians report that the bulk of their clients are middle-income people who are willing to pay more for this kind of care.[134] Boutique medicine is not a substitution for traditional insurance. Patients typically will keep their traditional health insurance to pay for any tests or scans ordered by the concierge physician.[135] Medicare beneficiaries cannot be charged more than 115 percent of the rate for services, and many politicians have said that the annual fee requirement is significantly greater than the Medicare rate and, consequently, is illegal billing.[136]

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.[137] By their very nature, CON programs are anticompetitive, a principle that serves as, *de minimis*, part of the rationale for the inception of 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.[138] CON is based on the theory that, in an unregulated market, healthcare providers will utilize the most up-to-date, costly technology and equipment, regardless of duplication or need.[139] However, various shifts in the healthcare industry in the years since CON legislation (see *Certificate of Need* (*CON*)) was introduced have fueled disputes against the implementation of CON programs in order to avoid excess capacity.[140]

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. In any industry, the underlying dynamic is the same, and competition compels companies to deliver increasing value to customers.[141] The fundamental driver of this effort in continuous quality improvement and cost reduction is innovation.[142] Without incentives to sustain innovation in healthcare, short-term cost savings soon will be overwhelmed by the desire to widen access to care, the growing health needs of an aging population, and a perceived resistance to receiving care that may be anything less than the best treatments available.[143] Inevitably, the failure to promote innovation will lead to lower quality or more rationing of care—two results viewed as equally undesirable.[144]

This bears semblance to the continuing consensus among health economic analysts that competition between providers drives patient quality of care and beneficial outcome, as well as 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.[145] Healthy competition appears to offer 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.

In markets that are competitive, attempts to promote the implementation of CON legislation are perceived as a notable shift from its original purpose of supporting competition by preventing overinvestment in healthcare facilities.[146] 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 POFs.[147]

For now, the federal specialty hospital moratorium (see *Campaign Against Physician Ownership*) has ended, and many states are moving forward with their own initiatives to prevent market entry of POFs through state CON regulations.[148] In light of continued evidence refuting the efficacy of CON legislation in reducing healthcare costs, arguments are now being made to support the use of CON in preventing physician self-referral and continuing the viability of community hospitals' charity care policies.[149]

Rise of Urgent Care Walk-In Clinics

Urgent care centers are becoming increasingly popular in the United States. 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 (for example, the extended hours, the availability of walk-in appointments, etc.).[150] With the supply of primary care physicians projected to dwindle during the next two decades, combined with many family physicians declining to accept new Medicare FFS patients and fewer emergency departments nationally, urgent care utilization may continue to rise.[151] However, research remains unclear regarding the impact of urgent care centers on cost, quality, and access to care.[152]

Medical Tourism

Another competitive force in the healthcare industry is the growing incidence of medical tourism. Medical tourism 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 the United States.[153] By avoiding structural, regulatory, and legal barriers that are present in the United States, foreign hospitals may be freer to innovate in ways that potentially can decrease the cost of many procedures.[154] Generally, these procedures are performed by skilled physicians, who sometimes trained in the United States, who may employ the latest technology with a risk of infection and mortality no higher than in the United States.[155] This trend demonstrates how globalization has reached 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 Suppliers

Healthcare suppliers are primarily professional services providers but can also include anyone or anything involved in the provision of improved quality patient care. Physicians are, in this sense, suppliers (as long as they are not employees of the organization in which they practice).[156] Other suppliers may include such entities, including medical supply companies, pharmaceutical companies, and outsourcers.[157] Suppliers may have the potential to affect healthcare professional practices if they are able to influence practice spending.[158] Healthcare supplier prices often are controlled or influenced by government fee

schedules for reimbursing certain products or services.[159] The bargaining power of suppliers is subject to increasing regulatory and reimbursement pressures. Healthcare is different from other industries in that the suppliers are often also the customers, as in hospital–physician relationships.[160]

Hospital Suppliers

The thrust of the campaign by community hospitals against specialty and niche providers is the desire to maintain monopoly or oligopoly power in the marketplace, as hospital consolidation continues to bolster the bargaining position of hospitals vis-à-vis insurers.[161] This position is supported by the argument that monopolistic hospitals may use that power to (1) maintain access for those who need it, (2) cross-subsidize uninsured patients and expensive procedures, and (3) maintain high quality standards through the intake of steady patient volumes.[162] Although community hospitals may need a substantial volume of patients to be able to make up the cost of money-losing procedures and patients, the separation between payor and consumer in the healthcare market also allows hospitals to use their monopoly power to set prices above what a monopoly might be able to charge in other markets.[163] In a marketplace in which elasticity of demand already is inhibited by necessity in many cases, the presence of insurance companies acts as a buffer between supplier and consumer and allows the supplier (that is, the hospital) to charge the insurer high prices that have no direct impact on the consumer.[164]

Physician or Provider Suppliers

In contrast to hospitals, the impact of physician providers on the healthcare competitive market continues to diminish due to regulatory (see chapter 3, *Regulatory Environment*) and reimbursement (see chapter 2, *Reimbursement Environment*) restraints, which include payment bundling, physician restrictions regarding group ventures under antitrust laws, and the decline of the primary care physician with the rise in MCOs and specialties.

The first reason for the declining effect of physician providers, is that "bundling" is a fairly new method of payment promoted by CMS (see chapter 2, *Payment Bundling*). Bundled payments change the way doctors and hospitals are reimbursed by Medicare; the FFS system would allocate two separate payments: one to the hospital for treating a patient and one to the physicians for their relative value units.[165] Using the bundled payment system, Medicare would allocate one payment to be split between the hospital and the physicians for services rendered.[166]

Although, in theory, bundled payments should improve the quality of care and streamline the reimbursement process by eliminating charges for unnecessary services, there is some backlash among physicians, mainly because hospitals would be determining how they get paid. For example, specialists could be compensated more favorably than primary care doctors.[167] In a 2009 letter to the Senate Finance Committee, the AHA voiced concerns, stating that the "bundling of hospital and post-acute payments is problematic" and "(p)roposals to bundle Medicare payments for general acute hospital and post-acute care (PAC) services call for a paradigm shift in health service delivery."[168] The AMA commented in a 2008 letter to the Committee on Ways and Means, stating that "bundling payments provides more incentives for efficient care but also carries the risk that appropriate services are withheld or limited."[169] The concerned parties agree bundling needs to be tested in many different venues and contexts before a reliable system can be managed.

Another reason for the waning physician provider impact is the many antitrust laws restricting physicians from joining together in groups such as IPAs. By definition, an IPA is a "legal entity organized and directed by physicians in private practice to negotiate contracts with insurance companies on their

behalf."[170] Although advantageous because they perform a variety of services for the medical practice, including negotiating contracts, organizing the delivery of care, and disbursing payments to physicians, IPAs have been attacked by antitrust legislation.[171] For example, a violation of Section One of the Sherman Antitrust Act could involve one of three things: (1) "an agreement between two or more independent physician practices regarding prices for medical services;" (2) "an agreement among two or more independent physician practices regarding patients they will treat and services they will offer;" or (3) "two or more independent physician practices agreeing not to deal with a particular competitor, healthcare entity, or managed care plan."[172] Because of these restrictions, some IPAs have violated antitrust laws.[173] As physician influence within independent or group practices exceeds that of physicians within organizations, the decline of the IPAs due to antitrust law has damaged their impact in the healthcare market.

The final reason for the drop in physician provider influence on the healthcare competitive marketplace is the decline of the primary care doctor due to the rise of MCOs and the emphasis on specialties. In a seminal 1994 report by the AMA, the organization indicated that enrollment in managed care plans had jumped from 12.5 million people in 1983 to 45 million ten years later.[174] In conjunction with this finding, the AMA found that between 1986 and 1993, "the proportion of US medical school graduates matched to residencies in one of three potential generalist streams (internal medicine, pediatrics, and family medicine) declined from 52 percent to 38 percent, and the majority of those in internal medicine and pediatrics became subspecialists."[175] Statistics from 2008 by the Association of American Medical Colleges suggest that this trend continues, "with the supply of primary care physicians that many already believe to be insufficient are likely to intensify as demand outpaces supply faster for primary care than any of the specialty groups."[176] The decline in general surgeons is no different. The promise of better working hours, less on-call time, and less involvement in the business end of the practice have attracted more students to specialties.[177] Notably, 70 percent of graduating surgical residents chose specialized instead of general surgery in 2007.[178]

As such, instead of building relationships with patients and focusing on preventative care, many doctors are now opting for the specialty track. Growing disparities in compensation likely affect this trend. A 2006 study showed primary care physicians at the bottom of the physician pay scale, making almost $300,000 less per year than radiologists—the highest paid specialty—in 2004.[179] However, a 2005 study by Barbara Starfield et al. indicated that a "greater supply of family physicians is associated with an earlier detection of breast cancer, colon cancer, cervical cancer, and melanoma."[180] The study also found that primary care physicians were better at managing health problems before the problems became serious enough to require hospitalization.[181]

Hospital System and Physician Practice Realignment

Due to economic incentives and changing legislation regarding competition, hospitals and physicians have increased their collaboration both through employment and joint ventures.

Hospital Acquisition of Physician Practices

Recently, hospitals have returned to the 1990s trend of directly employing physicians and increasingly competing for physicians' time and loyalty. As more physician-owned specialty hospitals open, this allows a growing number of physicians to refuse on-call emergency room duties and other traditional medical staff responsibilities.[182] Although hospitals mainly employed primary care physicians during the 1990s, the recent employment trend has seen a rise in the number of specialists employed by hospitals.[183]

Joint Ventures Between Community Hospitals and Niche Providers

In an attempt to strengthen relationships and align economic incentives to enhance market position and financial success between physicians and hospitals, many specialty providers, such as orthopedic surgeons, are entering into joint ventures with one another.[184] As competition for technical component revenue streams between physicians and hospitals remains intense, new forms of joint ventures and revenue-sharing options are developing in an attempt to repair their recently contemptuous relationship and to offer patients increased quality services and access.[185] "Ambulatory surgery centers and imaging centers are the most popular hospital–physician enterprises founding our communities. Threatened with potential loss of volume, hospitals have found innovative ways to share income streams with specialists that comply with Stark laws or other regulations."[186] Several key factors play a role in the growth of joint ventures between hospitals and physicians. As mentioned previously, in the past twenty years, physician incomes have decreased due to managed care and government reimbursement constraints. Consequently, many physicians have found hospital investments to be an enticing opportunity to supplement decreasing income.[187] The economic benefits of a physician and hospital joint venture, including the development of ASC joint ventures, are significant. Collaboration between physicians and hospitals creates an economy of scale not achieved if each continued to operate independently, thereby increasing hospital and health system interest.[188] Some hospital executives believe joint ventures with physicians increase their facility's quality of service, leading to increased profit for their hospital.[189]

According to Jay Klarsfeld, M.D., many advantages exist to a hospital–physician joint venture.[190] Hospitals make most of their money from inpatient services, and opening a separate outpatient surgery center often is not economically feasible; because ASCs perform outpatient procedures economically and safely, it behooves hospitals to form business relationships with physician-owners. When these hospitals send patients to their new surgery center affiliates, they share in the profit.[191] Additionally, when physicians have pull in the design process and ownership of an outpatient facility, things run smoother and more efficiently.[192] Studies have shown that when, "physicians have an economic stake [they] show up on time, don't waste minutes in the OR, and make smarter purchasing decisions."[193] Physicians have advantages as well. Most hospitals have a reputation in the community as being safe and reliable, and the physician-owner shares this good reputation in a joint venture, making his or her ASC more credible.[194] These physicians also gain exposure to hospital vendors, and association with hospitals can be helpful in purchasing.[195]

Threats from Substitute Products or Services

Nontraditional healthcare providers increasingly are competing with their traditional counterparts. Nontraditional providers, such as chiropractors, have taken a larger market share, and some healthcare systems and MCOs have embraced the changes in patient preferences and developed networks of these providers. Technology has fueled the entry of new competitors in many other industries, and healthcare is no exception. Patients searching for medical advice on the Internet is a trend that the industry must consider. With advances in medical imaging communication, technology groups of radiologists in remote locations can outsource x-ray film readings for hospitals at lower prices (see chapter 5, *Telemedicine and Telehealth*). The role of the pharmacy and pharmacist is changing and may become a threat to some portion of the service, advice, or monitoring business of medical offices. Competition can come in many forms and affect many subsets of healthcare services. Planning and analyzing potential substitute products and services requires creative thinking as well as in-depth, substantive research.

One of the primary differences between the healthcare industry and other industries in regard to substitute products and services may well be the regulation of medical professionals, treatments, and drugs that may delay or prohibit substitutes. The regulation, therefore, stymies innovation—previously discussed as the fundamental driver of quality improvement and the underlying dynamic of a company's ability to compete.

"Purple Pill"

Increasingly, drugs serve as alternative treatment options, and often at a lower cost, reducing hospital stays or need for costly surgeries or procedures. For example, the introduction of the **Purple Pill** revolutionized the treatment of bleeding ulcer patients. Administering a proton-pump inhibitor like Prilosec (omeprazole) prior to endoscopy stopped patients' bleeding faster than patients who took a placebo, thereby reducing both the need for surgery and the length of hospital stays.[196]

Battle Lines Among Providers

Competition exists not only among hospitals and physician-owned facilities but also among different types of providers (for example, ophthalmologists versus optometrists; anesthesiologists versus Certified Registered Nurse Anesthetists, obstetricians and gynecologists versus certified nurse midwives). As discussed in chapter 6 of *Professional Practices*, physician suppliers compete with allied health professionals for the provision of many primary care services. Similarly, as discussed in chapter 4 of *Professional Practices*, physicians also are experiencing competition from mid-level providers whose ability to practice without the supervision of a physician is growing due to less stringent regulations in certain states. For example, nurse practitioners (NPs) are capable of obtaining their own Medicare provider numbers, which allows them to bill Medicare directly for services provided without the need for a supervising physician.[197] This ability has resulted in a growing number of nurse practitioners who provide primary care services to patients who never actually see a physician until they need services which are beyond an NP's capability.[198]

One of the most prevalent areas of competition is related to providers of imaging services. The issue of in-office ancillary imaging pits radiologists against other physicians. Radiologists continue to face increased competition from referring physicians.[199] A study funded by the Radiological Society of North America in 2004 claimed that self-referral lead to increased utilization of diagnostic imaging.[200] The study recommended that the radiologist professional community lobby the federal government to enact regulations making self-referrals more difficult. According to the chief researcher, Dr. David C. Levin, "[o]rthopedic surgeons really don't belong in the business of owning MR [magnetic imaging] scanners."[201]

The result of such efforts was reflected in the passage of the Medicare Improvements for Patients and Providers Act of 2008 (MIPPA).[202] After the American College of Radiology announced plans to lobby for legislation requiring Medicare to define standards for physicians performing diagnostic imaging, and the Medicare Payment Advisory Commission (MedPAC) staff members stated "it's important for CMS to set national standards for each imaging modality . . . ," Congress included in the MIPPA a provision requiring accreditation of physicians who provide the technical component for advanced diagnostic imaging services (for example, magnetic resonance imaging, computed tomography, and nuclear medicine or single photon emission computed tomography) for which payment is made under the Medicare physician fee schedule.[203] After the secretary of the Department of Health and Human Services (HHS) designates accreditation organizations in 2010, all suppliers of the technical component of advanced diagnostic imaging services will need to be accredited by January 2012.[204]

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, because buyers are not. Corporate buyers have asserted substantial, if disproportionate, influence over healthcare companies but not necessarily always in the best interests of the consumers or the community at large.

Recently, however, payors have begun to shift toward P4P plans that assess certain performance outcomes and offer financial incentives to providers that attain them (see chapter 2, *Pay-For-Performance (P4P)*). P4P programs have been shown to improve quality of care,[205] and by offering financial incentives to providers, P4P also will allow consumers to recognize quality of care when making choices for provision of services.[206]

Power of the Insurance Lobby

The rise of antitrust law in the healthcare marketplace indirectly has led to support of insurance companies' preferences by the courts. As agents for the consumers protected under the laws (that is, 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 (that is, selective contracts with health professionals or onerous contractual requirements on network providers).[207]

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.[208] State legislation is preserved in the bill, but whether states are powerful enough to prevent insurance companies from engaging in price fixing, bid rigging, and market allocations, deterring competition, and impairing consumers has been questioned.[209]

Power of Medicare and Other Public Payors

The government is the country's largest third-party payor. 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.[210] 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.[211]

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.[212] Instead, negotiations are undertaken by private insurers and Pharmacy Benefit Managers (PBMs) that then offer prices they obtain through those negotiations to Medicare beneficiaries.[213] 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.[214] 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.[215]

Rivalry Amongst 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, poor performance of hospital managed physician practices [including physician-hospital organizations (PHOs)], the failure of capitated groups and IPAs in California, and the current trend toward divestiture of acquired practices would seem to indicate that EHOs have not been effective competitors. 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 (see chapter 2 of *Professional Practices*).

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 their expression 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.

Antitrust Issues

Antitrust law traditionally has been used to combat anticompetitive behavior arising from professional- and payer-imposed barriers to competition, as well as against consolidations (either by collaboration or merger) by provider groups and health systems.[216] However, at the beginning of this decade, strict antitrust enforcement in the healthcare sector tended to shift away from providers and toward pharmaceuticals in a larger shift away from strict application of antitrust law to the healthcare sector generally.[217] During that timeframe, antitrust jurisprudence began to shift to 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.[218] Additionally, federal enforcement agencies generally won cases against hospital mergers between the mid-1980s and the mid-1990s; those agencies lost all the hospital merger cases brought in federal court between 1995 and 2001.[219] During this timeframe, courts tended to take a purely economic look at elements of antitrust decisions, such as a provider's market share and price, ignoring other elements germane to healthcare, such as patients' personal and logistical considerations when choosing a provider.[220]

Promulgated by recent healthcare reform efforts, the Federal Trade Commission (FTC) and Department of Justice (DOJ) have expressed renewed concern regarding the adequacy of existing standards for horizontal mergers, maintaining that fortified measures of antitrust enforcement are crucial to cutting costs and improving quality of healthcare.[221] Most recently, the DOJ and FTC have focused their efforts on evaluating the affect of horizontal consolidation of certain healthcare organizations (for example, pharmaceutical giants, payors, outpatient clinics, and hospitals) to determine whether their respective market sectors experience a decrease in competition as a result.[222]

As legislators continue to focus on reducing the cost of healthcare while improving quality and access, antitrust enforcement is likely to take on a larger role in the healthcare sector. With the promotion of a public option as part of healthcare reform legislation, more focus has been placed on the benefits of competition in the healthcare insurance marketplace, and the proposed repeal of the McCarran-Ferguson Act (see *Power of the Insurance Lobby*) demonstrates how legislators will continue work to improve competition throughout the healthcare industry in an effort to reduce costs and improve quality.[223]

The FTC and DOJ have taken special interest in the impact of hospital consolidation on market competition. Most research conducted to date suggests a potential correlation between hospital consolidation and higher prices for hospital services; the magnitude of price increase estimated by these studies ranges from 5 percent to greater than 50 percent.[224] While some dispute exists on the impact of consolidation on quality of care, studies utilizing methods perceived to be robust tend to show a reduced level of quality.[225] Surmising a sudden surge of hospital consolidation as a result of impending reform initiatives 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.[226]

Clinical Integration

One area of antitrust enforcement that did not suffer as significant a decline toward the beginning of the new millennium involves collective actions by healthcare professionals that thwart competition and violate Section 1 of the Sherman Antitrust Act, which prohibits agreements between competitors in restraint of trade.[227] Commonly taking the form of IPAs and PHOs that wish to clinically integrate, these cartels generally are found to violate antitrust laws. In the wake of two FTC advisory opinions favorable toward clinical integration, however, it is likely that IPAs and PHOs will see a resurgence the near future.

Clinical integration among provider networks traditionally has been scrutinized by the FTC as generally being anticompetitive and in violation of antitrust laws. Part of the reason for this is that provider networks typically involve competing providers that agree to fix prices between them. Such practices are *per se* unlawful under antitrust law.[228] However, since the 2002 FTC Advisory Opinion for MedSouth[229] and the 2007 Advisory Opinion for the Greater Rochester Independent Practice Association Inc. (GRIPA), it has now become clear that clinical integration is not necessarily considered to be a *per se* violation of antitrust regulations.[230] 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, determining whether the arrangement would actually lead to procompetitive outcomes. The benefits of clinical integration are that it allows a network of competing providers to participate in both joint-pricing and risk sharing, therefore leading to improved efficiency that will benefit consumers.[231]

It is important to note, however, that the MedSouth and GRIPA opinions do not mean that all clinical integration programs will be approved by antitrust enforcement agencies. In fact, more recently than GRIPA, an FTC decision striking down a clinical integration program in Texas from 2005 was affirmed by the Fifth Circuit Court of Appeals in 2008.[232] When analyzing any clinical integration scheme, the FTC will first ask whether the proposed collaboration offers the potential for proconsumer cost savings or qualitative improvements in the provision of healthcare services, and then ask whether any price or other agreements exist among participants, in particular the terms on which they will deal with healthcare insurers, and if the terms are reasonably necessary to achieve those benefits.[233] If both questions are answered affirmatively, only then will the FTC consider the procompetitive and anticompetitive effects of the collaboration.[234] At that point, "as 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."[235]

Above all, it is important to note that the antitrust enforcement agencies support precompetitive clinical integration of provider networks as a means of increasing efficiency and reducing costs, especially in an environment where these two objectives are part of the overall goals of healthcare reform. Collaborations among providers often implement efficiency-producing tools, such as electronic health records, and collaboration among clinicians to create guidelines, measure performance, and develop remedial measures and consequences for failure to meet those guidelines.[236]

Antitrust enforcement agencies also will continue to carefully scrutinize hospital mergers to ensure that no one hospital gains enough market share such that patients are deprived of choices, and that the hospital is able to increase prices to both patients and insurers.[237]

Healthcare Reform and Its Effect on Competition

The fundamental debate that historically has impeded healthcare reform efforts has centered on the costs associated with providing universal, comprehensive care. In light of twenty-first-century healthcare reform, this debate has led to competition for the overall healthcare dollar, that is, there is only so much money to go around, and everyone in the industry is vying for it. As demonstrated in this chapter, the power of the insurance companies, pharmaceutical companies, and hospitals has subjugated the power of the independent physician or provider such that providers are no longer operating on a level playing field.

It is not an exercise in paranoia to view the overall effect of the attacks on physician ownership as being aimed not only at rolling back the calendar to an earlier time but also an attempt to severely diminish the overall role and status of physicians in the delivery of care continuum. This profoundly concerning onslaught against the professional stature and economic interests of physicians arises not only from hospital and insurance industry advocacy campaigns but even from widely cited purported supporters of physician independence, such as Harvard Professor (and former *New England Journal of Medicine* editor), Arnold S. Relman, MD (see chapter 1, *Historical Development*).[238]

From the perspective of many, the inevitable outcome of these efforts at placing additional restrictions on physician independence will be to 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. This begs the question whether physicians and their patients, who have benefited from independent physician ownership of ASTC enterprises, will now acquiesce to being "kept down on the farm" or whether they either can or will resist the forces arrayed against them.

Reform of the Insurance and Pharmaceutical Industries

Insurance Industry

In the past ten years, there have been more than 400 health insurer mergers, which have resulted in a highly consolidated market and negative consequences for consumers.[239] Part of the reason for this consolidation is that there have only been two cases in the past seven years in which the DOJ has required the restructuring of a merger agreement between two insurers.[240] The prevalence of these mergers without a strong enforcement of antitrust law has permitted a variety of anticompetitive behavior by major insurers, resulting in higher costs (whether from higher premiums, deductibles or co-pays), compromised patient care, and a record high level of uninsured Americans.[241]

In order to reverse the trend of insurer consolidation, 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, reform initiatives have suggested a repeal of the exemption.[242] 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.[243]

Reform efforts aimed at repealing this exemption are part of the current healthcare reform agenda,[244] but proponents of the exemption argue that states have done a good job to prevent anticompetitive behavior by insurers, and that there is no conclusive evidence that such repeal will have any positive impact on the insurance industry.[245] Legislators in support of the repeal were motivated by soaring insurance costs and an increasing number of uninsured Americans, however, they noted that the repeal signified the first step in a continuing evaluation of the antitrust system.[246] Beyond the repeal of the insurance company exemption, such legislation demonstrates the beginning of potential widespread impact of health reform on antitrust enforcement, particularly when a single-payor system is the end goal of many.

Pharmaceutical Industry

Related to the insurance industry is the constantly maturing PBM industry. This area of the healthcare industry has grown as consumer use of pharmaceutical drugs has grown and insurers have worked pharmacy benefits into their plans.[247] Forty to fifty PBMs exist around the country, and some insurers manage pharmacy benefits internally, however, only three major national PBMs are in operation, so careful attention to ensuring fair competition in this industry is important as more and more healthcare spending is devoted to pharmaceuticals.[248] 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.[249]

It should be noted, however, that recent reform efforts have addressed the possibility of removing the noninterference provision, discussed previously from the MMA, which would result in granting the secretary of HHS the ability to negotiate directly with pharmaceutical companies.[250] 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 time, starting with the implementation of Medicare in 1965 under a 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.[251] Beginning with the implementation of the PPS, whereby patients are classified into 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.[252] Even MedPAC's *Payment Basics* publications discuss Medicare reimbursement under the heading of "the products that Medicare buys."[253]

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.[254] 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.[255] The charge-per system places the focus on the amount of money a hospital will receive for a given diagnosis and will place the focus on reducing services to save money as well as incentivize hospitals to hire physicians who are not as expensive (that is, not as well qualified) in order that the hospital facility may retain as much of the payment as possible.[256]

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 chosen to be the only Medicare provider of DME in ten different metropolitan areas.[257] The competitive bidding program was implemented in 2008, but an eighteen-month moratorium was then placed on it under MIPPA in response to pressure from DME suppliers that claimed that the program would lower quality of care and reduce access.[258] Set to relaunch in 2010, 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.

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 increased population demands (that is, the baby boomers) regulations of the scope of mid-level providers have been lessening. This, along with a staining economy, causing physicians to expand the services they offer, is creating an overlap of services, which will likely continue to increase fueling the emergence of new competitors in the healthcare market. In addition, the rise in consumer driven healthcare will continue to change the way in which healthcare professional practice, as a business, is run, further removing the buffer between healthcare and pure commercialism. As the impact of competitive forces rises, in response to a changing system, government regulations will also adapt to the new healthcare environment.

Key Sources

Key Source	Description	Citation	Hyperlink
Medicare Physician Fee Schedule (PFS)	The Medicare PFS is how reimbursement is determined for physicians and nonphysicians by CMS for their services.	"Overview" Centers for Medicare and Medicaid Services, www.cms.hhs.gov/PhysicianFeeSched/ (accessed January 29, 2010).	www.cms.hhs.gov/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, www.physicanhospitals.org/organization_mission.php (accessed September 24, 2009).	www.physicianhospitals.org

Key Source	Description	Citation	Hyperlink
General Accounting 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, www.gao.gov/about/index.html (accessed January 29, 2010).	www.gao.gov
American Academy of Family Physicians (AAFP)	The AAFP attempts to affect "health care policy through interactions with government, the public, business and the health care industry," with a particular focus on equitable healthcare for all people.	"Mission and Strategic Plan" American Academy of Family Physicians, 2010, www.aafp.org/online/en/home/aboutus/theaafp/strategicplan.html (accessed January 29, 2010).	www.aafp.org
Graduate Medical Education National Advisory Committee (GMENAC)	Part E of Title VII of the Public Health Service Act, establishes the GMENAC, and "charges it with assessing physician workforce needs on a long term basis, recommending appropriate Federal and private sector efforts necessary to address these needs, and providing a forum to enable appropriate consideration of these needs."	"Charter" Graduate Medical Education National Advisory Committee, August 17, 2005, www.cogme.gov/charter.htm (accessed January 29, 2010).	www.cogme.gov
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 and Medicaid Services, U.S Department of Health and Human Services, www.cms.hhs.gov/Consortia/ (accessed January 29, 2010).	www.cms.hhs.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, www.medpac.gov/about.cfm (accessed January 29, 2010).	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" www.ftc.gov/ftc/about.shtm (accessed January 29, 2010).	www.ftc.gov

Associations

Type of Association	Professional Association	Description	Citation	Hyperlink	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 American Hospital Association," American Hospital Association, 2009, www.aha.org/aha/about/index.html (accessed January 28, 2010).	www.aha.org	American Hospital Association One North Franklin Chicago, IL 60606 Phone: 312-422-3000 Fax: n/a E-mail: n/a
National	American Medical Association	An association that "helps doctors help patients by uniting physicians nationwide to work on the most important professional and public health issues."	"Our Mission," American Medical Association, 2009, www.ama-assn.org//ama/pub/about-ama/our-mission.shtml (accessed January 28, 2010).	www.ama-assn.org/	American Medical Association 515 N. State Street Chicago, IL 60654 Phone: 800-621-8335 Fax: n/a E-mail: n/a
National	Ambulatory Surgery Center Association	Merger between the American Association of Ambulatory Surgery Centers and the Federated Ambulatory Surgery Association in 2008 resulted in this association.	"ASC Association" Ambulatory Surgery Center Association, 2009, http://ascassociation.org/about/association/ (accessed January 29, 201010).	http://ascassociation.org	Ambulatory Surgery Center Association 1012 Cameron St Alexandria, VA 22314 Phone: 703-836-8808 Fax: 703-549-0976 E-mail: ASC@ascassociation.org
National	American Health Insurance Plans	"The national association representing nearly 1,300 member companies providing health insurance coverage to more than 200 million Americans."	"About AHIP," American Health Insurance Plans, 2009, www.ahip.org/content/default.aspx?bc=31 (accessed January 28, 2010).	www.ahip.org	American Health Insurance Plans 601 Pennsylvania Avenue, NW South Building Suite 500 Washington, DC 20004 Phone: 202-778-3200 Fax: n/a E-mail: ahip@ahip.org
National	Radiological Society of North American (RSNA)	Founded in 1915, RSNA is a membership of medical imaging professionals committed to patient care through education and research. RSNA host the world's largest annual radiological meeting.	"About RSNA" Radiological Society of North America, 2010, www.rsna.org/About/whoswho/staff-departments.cfm (accessed January 20, 2010).	www.rsna.org	Radiological Society of North America, Inc. 820 Jorie Blvd. Oak Brook, IL 60523 Phone: 630-571-2670 / 800-381-6660 Fax: 630-571-7837 E-mail: n/a
National	American College of Radiology (ACR)	ACR's mission is to maximize the "value of radiology, radiation oncology, interventional radiology, nuclear medicine and medical physics by advancing the science of radiology, improving the quality of patient care, positively influencing the socio-economics of the practice of radiology, providing continuing education for radiology and allied health professions and conducting research for the future of radiology."	"About Us" American College of Radiology, www.acr.org/MainMenuCategories/about_us.aspx (accessed January 29, 2010).	www.acr.org	American College of Radiology 1891 Preston White Dr Reston, VA 20191 Phone: 703-648-8900 Fax: n/a E-mail: info@acr.org

Endnotes

1 "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.

2 "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. w347; "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).

3 "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.

4 "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).

5 "Do Health Care Costs Matter?" By William J. Baumol, The New Republic, November 22, 1993, p. 16.

6 "Do Health Care Costs Matter?" By William J. Baumol, The New Republic, November 22, 1993, p. 17.

7 "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.

8 "Do Health Care Costs Matter?" By William J. Baumol, The New Republic, November 22, 1993, p. 17.

9 "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.

10 "Dr. Chester A. Wilk et al, v. American Medical Association et al." 895 F.2d 352, 378 (7th Cir. 1990), p. [?].

11 "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. 34-35.

12 "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.

13 "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.

14 "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. 14.

15 "Redefining Competition in Health Care" By Michael E. Porter and Elizabeth Olmsted Teisberg, Harvard Business Review, June 2004, p. 3.

16 "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.

17 "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. 1521.

18 "Improving Health Care: A Dose of Competition" Report by the Federal Trade Commission and The Department of Justice, July 2004, p. 5.

19 "Improving Health Care: A Dose of Competition" Report by the Federal Trade Commission and The Department of Justice, July 2004, p. 20.

20 "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. 322-23.

21 "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.

22 "Defined Contribution: From Managed Care to Patient-Managed Care" By E. Haavi Morreim, Cato Journal, Vol. 22, No. 1 (Spring/Summer 2002), p. 112.

23 "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.

24 "Health Care Fraud and Abuse: Practical Perspectives" Edited by Linda A. Baumann, Washington, DC: American Bar Association, 2002, p. 48.

25 "Improving Health Care: A Dose of Competition" Report by the Federal Trade Commission and The Department of Justice, July 2004, p. 4-5.

26 "Improving Health Care: A Dose of Competition" Report by the Federal Trade Commission and The Department of Justice, July 2004, p. 5.

27 "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.

28 "Hospital-Physician Relations: Cooperation, Competition, or Separation?" By Robert A. Berenson, Paul B. Ginsburg, and Jessica H. May, (December 5, 2006), p. w31.

29 "Hospital-Physician Relations: Cooperation, Competition, or Separation?" By Robert A. Berenson, Paul B. Ginsburg, and Jessica H. May, (December 5, 2006), p. w34.

30 "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.

31 "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. 1513-1514.

32 "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.

33 "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. 1521.

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 (January/February 2006), p. 11.

35 *Ibid.*

36 *Ibid.*

37 "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. 19.

38 "Biomarket Trends: Pharmaceutical Industry Undergoing Transformation" By Steve Arlington and Anthony Farino, Genetic Engineering and Biotechnology News, Vol. 27, No. 15, (September 1, 2007), http://genengnews.com/gen-articles/biomarket-trends-b-pharmaceutical-industry-undergoing-b-b-b/2197/ (Accessed 05/18/10).; "Medicare Part B Imaging Services: Rapid Spending Growth and Shift to Physician Offices Indicate Need for CMS to Consider Additional Management Practices" Report to Congressional Requesters, GAO-08-452, Washington, D.C.: United States Government Accountability Office, June 2008, http://www.gao.gov/new.items/d08452.pdf (Accessed 05/03/10), p. [?].

39 "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. 19.

40 "Economic and Policy Analysis of Specialty Hospitals" By John E. Schneider et al., Health Economics Consulting Group, February 4, 2005, p. 14.

41 *Ibid.*

42 "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).

43 "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; "Fact Sheets: Final 2009 Policy, Payment Changes for Hospital Outpatient Departments and Ambulatory Surgery Centers" Centers for Medicare and Medicaid Services, October 30, 2008, http://www.cms.hhs.gov/apps/media/fact_sheets.asp (Accessed 9/24/09).

44 "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.

45 "Ambulatory Surgical Center Fee Schedule: Payment System Fact Sheet Series" The Centers for Medicare and Medicaid Services, Department of Health and Human Services, January 2009, http://www.cms.hhs.gov/MLNProducts/downloads/AmbSurgCtrFeepymtfctsht508.pdf (Accessed 01/13/09).

46 "Fact Sheets: Final 2009 Policy, Payment Changes for Hospital Outpatient Departments and Ambulatory Surgery Centers" Centers for Medicare and Medicaid Services, October 30, 2008, http://www.cms.hhs.gov/apps/media/fact_sheets.asp (Accessed 9/24/09).

47 "Medicare Program: Changes to the Hospital Outpatient Prospective Payment System and CY 2010 Payment Rates; Changes to the Ambulatory Surgery Center Payment System and CY 2010 Payment Rates" 42 CFR parts 410, 416, and 419 (2000), p. 60629, 60663.

48 "10 Interesting Facts and Statistics for ASCs" By S. Becker, Becker's ASC Review, January 2008, http://www.beckersasc.com/ambulatory-surgery-center/surgery-center-education/10-interesting-facts-and-statistics-for-ascs.html (Accessed 11/05/08).

49 "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).

50 "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.

51 "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).

52 "PHA Launches National Campaign to Protect Physician Ownership" SurgiStrategies, December 7, 2007, http://www.surgistrategies.com/hotnews/7ch7111647.html (Accessed 11/9/09).

53 "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).

54 *Ibid.*

55 "Limitations on Certain Physician Referrals" 42 U.S.C. 1395nn(d)(3), January 5, 2009, http://www.law.cornell.edu/uscode/html/uscode42/usc_sec_42_00001395--nn000-.html (Accessed 06/07/10).

56 "Specialty Hospitals: Information on National Market Share, Physician Ownership, and Patients Served" By the General Accounting Office, April 18, 2003, p. 3.

57 *Ibid.*

58 *Ibid.*

59 "Specialty Hospitals: Information on National Market Share, Physician Ownership, and Patients Served" By the General Accounting Office, April 18, 2003, p. 8.

60 "Specialty Hospitals: Geographic Location, Services Provided, and Financial Performance" By the General Accounting Office, October 22, 2003, p. 4.

61 "CMS Outlines Next Steps and Moratorium on New Specialty Hospitals Expires" Centers for Medicare and Medicaid Services, Press Release (June 9, 2005), http://www.cms.hhs.gov/apps/media/press/release.asp?Counter=1478 (Accessed 11/09/09).

62 "Medicare Prescription Drug, Modernization, and Improvement Act of 2003" §507(a)(1)(B).

63 "Advocacy and Representation" American Hospital Association, www.hospitalconnect.com/aha/advocacy-grassroots/advocacy/agenda/challenges.html (Accessed 02/28/05).

64 "Statement of the American Medical Association to the Subcommittee on Federal Financial Management, Government Information, and International Security of the Committee on Homeland Security and Governmental Affairs, United States Senate: Overview of the Competitive Effects of Specialty Hospitals" By William G. Plested, III, MD, May 24, 2005, p. 3, 11.

65 "Presentation to the Council on Health Care Economics and Policy on Specialty Hospitals, Ambulatory Surgery Center, and General Hospitals: Charting Wise Public Policy" By Michael D. Maves, American Medical Association, Sept. 10, 2004.

66 "Extend Moratorium on Specialty Hospitals Says Board" American Academy of Family Physicians, Feb. 4, 2005, www.aafp.org/x31982.xml (Accessed Feb. 28, 2005).

67 "Banning Physician Self-Referral is an Important Step Toward Health Reform" By Rich Umbdenstock and Chip Kahn, AHA News Now, http://www.ahanews.com/ahanews_app/jsp/display.jsp?dcrpath=AHANEWS/AHANewsArticle/data/AHA_News_090720_ Physician&domain=AHANEWS (Accessed 11/09/09).

68 "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. 6.

69 "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.

70 "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.

71 "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. 5.

72 Ibid.

73 "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.

74 "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.

75 "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.

76 *Ibid.*

77 *Ibid.*

78 *Ibid.*

79 *Ibid.*

80 *Ibid.*

81 *Ibid.*

82 *Ibid.*

83 *Ibid.*

84 "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.

85 "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. 6.

86 "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).

87 "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).

88 "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).

89 "Improving Health Care: A Dose of Competition" Report by the Federal Trade Commission and The Department of Justice, July 2004, p. 5.

90 *Ibid.*

91 *Ibid.*

92 *Ibid.*

93 *Ibid.*

94 *Ibid.*

95 "Improving Health Care: A Dose of Competition" Report by the Federal Trade Commission and The Department of Justice, July 2004, p. 11.

96 *Ibid.*

97 *Ibid.*

98 *Ibid.*

99 "Improving Health Care: A Dose of Competition" Report by the Federal Trade Commission and The Department of Justice, July 2004, p. 12.

100 "Improving Health Care: A Dose of Competition" Report by the Federal Trade Commission and The Department of Justice, July 2004, p. 12-13.

101 "Consolidations Should Bring Nationwide Contracts" By John Carroll, Managed Care Magazine, February 2006, http://www.managedcaremag.com/archives/0602/0602.mergers.html (Accessed 01/31/07).

102 "Competition in Health Insurance: A Comprehensive Study of U.S Markets, 2007 Update" American Medical Association, 2007, p. 2, 5.

103 "Competition in Health Insurance: A Comprehensive Study of U.S Markets, 2007 Update" American Medical Association, 2007, p. 5.

104 *Ibid.*

105 "Improving Health Care: A Dose of Competition" Report by the Federal Trade Commission and The Department of Justice, July 2004, p. 9.

106 *Ibid.*

107 *Ibid.*

108 *Ibid.*

109 *Ibid.*

110 "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.

111 "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.

112 "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.

113 "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.

114 "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.

115 *Ibid.*

116 "Is Health Insurance a Bad Idea? The Consumer-Driven Perspective" By Timothy Stoltzfus Jost, Connecticut Insurance Law Journal, Vol. 14 (Spring 2008), p. 380.

117 "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.

118 "Is Health Insurance a Bad Idea? The Consumer-Driven Perspective" By Timothy Stoltzfus Jost, Connecticut Insurance Law Journal, Vol. 14 (Spring 2008), p. 383.

119 "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.

120 "Competitive Strategy: Techniques for Analyzing Industries and Competitors" By Michael E. Porterm, The Free Press, 1980, p. 4.

121 *Ibid.*

122 "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).

123 *Ibid.*

124 *Ibid.*

125 "Limited Service—Niche Providers" American Hospital Association, 2005, http://www.hospitalconnect.com/aha/key_issues/niche/ (Accessed 02/27/05).

126 "Promises Under Pressure" By the American Hospital Association, www.hospitalconnect.com/aha/annual_meeting/content/03mtgpaper_Niche.pdf (Accessed February 27, 2005).

127 "Medicare Prescription Drug, Modernization, and Improvement Act of 2003" §507(a)(1)(B).

128 "Physician Services: Concierge Care Characteristics and Considerations for Medicare" By the United States Government Accountability Office, August 2005, p. 3.

129 "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.

130 *Ibid.*

131 *Ibid.*

132 *Ibid.*

133 *Ibid.*

134 *Ibid.*

135 "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; "Physician Services: Concierge Care Characteristics and Considerations for Medicare" By the United States Government Accountability Office, August 2005, p. 3.

136 *Ibid.*

137 "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).

138 "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.

139 "Improving Health Care: A Dose of Competition" Federal Trade Commission and Department of Justice, July 2004, p. 2.

140 "Improving Health Care: A Dose of Competition" Federal Trade Commission and the Department of Justice, White Paper, July 2004, p. 2, 5, 6.

141 "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..., (Accesed 09/11/08).

142 *Ibid.*

143 *Ibid.*

144 *Ibid.*

145 "Health Policy Reform: Competition and Controls" By J. Zwanziger, G. Melnick G, A. Bamezai, & R. Helms, ed., Washington, DC: AEI Press, 1993, p. 241-58.

146 "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.

147 "Specialty Versus Community Hospitals: What Role for the Law?" By Sujit Choudhry, Niteesh K. Choudhry, and Troyen A. Brennan, Health Affairs, Web Exclusive (August 9, 2005), http://content.healthaffairs.org/cgi/content/full/hlthaff.w5.361/DC1 (Accessed 5/21/10), p. w5-361.

148 "Certificate of Need Regulations and Use of Coronary Revascularization After Acute Myocardial Infarction" By Ioana Popescu, Mary S. Vaughan-Sarrazin, and Gary E. Rosenthal, Journal of the American Medical Association, Vol. 295, No. 18 (2006), p. 2146; "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).

149 "The Prevalence of Physician Self-Referral Arrangements After Stark II: Evidence From Advanced Diagnostic Imaging" By Jean Mitchell, PhD, Health Affairs, Vol. 26, No. 3 (April 17, 2007), http://content.healthaffairs.org/cgi/content/full/26/3/w415 (Accessed 05/21/10).

150 "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. 1.

151 "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.

152 *Ibid.*

153 "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.

154 "Innovation Abroad" Health Affairs, Vol. 27, No. 5, (September/October 2008), p. 1259.

155 "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.

156 "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.

157 *Ibid.*

158 *Ibid.*

159 *Ibid.*

160 *Ibid.*

161 "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; "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.

162 "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.; "Specialty Versus Community Hospitals: What Role for the Law?" By Sujit Choudhry, Niteesh K. Choudhry, and Troyen A. Brennan, Health Affairs, Web Exclusive (August 9, 2005), http://content.healthaffairs.org/cgi/content/full/hlthaff.w5.361/DC1 (Accessed 5/21/10), p. w5-361.

163 "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.

164 *Ibid.*

165 "A Bundle of Joy or Trouble? Hospitalists Debate Prospect of Bundled Fee System" By Stacey Butterfield, ACP Hospitalist, December 2009, http://www.acphospitalist.org/archives/2009/12/bundle.htm (Accessed 12/22/09).

166 *Ibid.*

167 *Ibid.*

168 "Statement of the American Hospital Association to the Senate Finance Committee" White Paper, April 21, 2009. p. 7.

169 "Statement of the American Medical Association to the Committee on Ways and Means Subcommittee on Health" U. S. House of Representatives, White Paper, September 11, 2008, p. 6.

170 "Independent Practice Associations (IPAs): A Primer for Physician Assistants" American Academy of Physician Assistants, http://www.aapa.org/advocacy-and-practice-resources/issue-briefs/498-independent-pract. (Accessed 12/22/09).

171 *Ibid.*

172 "Physician's Guide to Medicine—Antitrust" By the Missouri State Medical Association, 2009, http://www.msma.org/mx/hm.asp?id=Antitrust (Accessed 12/22/09).

173 *Ibid.*

174 "The Latest Forecast: Managed Care Collides with Physician Supply" By Steven A. Schroeder, American Medical Association, Journal of the American Medical Association, Vol. 272, No. 3 (July 20, 1994).

175 *Ibid.*

176 "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. 26-27.

177 "The Impending Disappearance of the General Surgeon" By Josef E. Fischer, American Medical Association, Journal of the American Medical Association, Vol. 298, No. 18 (November 14, 2007).

178 *Ibid.*

179 "Primary Care-The Best Job in Medicine?" By Beverly Woo, The New England Journal of Medicine, Vol. 355, No. 9 (August 31, 2006).

180 "Contributions of Primary Care to Health Systems and Health" By Barbara Starfield et al., The Milbank Quarterly, Vol. 83, No. 3 (2005).

181 *Ibid.*

182 "Hospitals Seen Seeking Closer Doc Partnerships" By Jennifer Lubell, Modern Healthcare, October 4, 2007, http://www.modernhealthcare.com/article/20071004/REG/310040025/1024&Template=printpicart (Accessed 05/18/10).

183 "New Twist in Employing Physicians" By Dan Beckham, Hospital and Health Networks, July 5, 2005, http://www.hhnmag.com/hhnmag_app/jsp/articledisplay.jsp?dcrpath=HHNMAG/PubsNewsArticle/data/050705HHN_Online_Beckham&domain=HHNMAG (Accessed 05/04/10).

184 "Financing the Future II Report 4: Joint Ventures with Physicians and Other Partners" Healthcare Financial Management Association, February 2006, p. 3.

185 "A Widening Rift in Access and Quality: Growing Evidence of Economic Disparities" By Robert E. Hurley et al., Health Affairs (December 6, 2005), http://content.healthaffairs.org/cgi/reprint/hlthaff.w5.566v1 (Accessed 04/28/10), p. W5-567.

186 "Changes in Hospital Competitive Strategy: A New Medical Arms Race" By Kelly J. Devers et al., Health Services Research, Vol. 38, No.1, Part II (February 2003), p. 460.

187 "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.

188 "Financing the Future II Report 4: Joint Ventures with Physicians and Other Partners" Healthcare Financial Management Association, February 2006, p. 4.

189 "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.

190 "The Perils and Payoffs of Hospital Joint Ventures: How We Built an ASC from Partnership and Perseverance" By Jay Klarsfeld, MD, Outpatient Surgery Magazine, January 2007, http://www.outpatientsurgery.net/guides/surgical-construction/2007/the-perils-and-payoffs-of-hospital-joint-ventures&pg=2 (Accessed 02/08/10).

191 "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.

192 *Ibid.*

193 "The Perils and Payoffs of Hospital Joint Ventures: How We Built an ASC from Partnership and Perseverance" By Jay Klarsfeld, MD, Outpatient Surgery Magazine, January 2007, http://www.outpatientsurgery.net/guides/surgical-construction/2007/the-perils-and-payoffs-of-hospital-joint-ventures&pg=2 (Accessed 02/08/10).

194 "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.

195 "The Perils and Payoffs of Hospital Joint Ventures: How We Built an ASC from Partnership and Perseverance" By Jay Klarsfeld, MD, Outpatient Surgery Magazine, January 2007, http://www.outpatientsurgery.net/guides/surgical-construction/2007/the-perils-and-payoffs-of-hospital-joint-ventures&pg=2 (Accessed 02/08/10). 18-19.

196 "Omeprazole as Adjuvant Therapy to Endoscopic Combination Injection Sclerotherapy for Treating Bleeding Peptic Ulcer" By Gul Javid et al., The American Journal of Medicine, Vol. 111, No. 4, (September 2001), p. 280-284; "Prilosec Helps Control Bleeding in Ulcer Patients" By Amanda Gardner, U.S. Department of Health and Human Services, April 18, 2007, http://www.healthfinder.gov/news/newsstory.asp?docid=603797 (Accessed 3/31/08).

197 "Medicare Update" American Academy of Nurse Practitioners, June 2007, http://nplocate.org/NR/rdonlyres/eicu2demfvlvh2e2vxaednvvnaeb4s5uurb64gqa72y2szwthizna4v3l5bopytbqz7lnr425gpdhhmgivm2xtdatpf/Fact+Sheet+Medicare+Update+6-14-07.pdf (Accessed 01/13/10).

198 "Primary Care Professionals: Recent Supply Trends, Projections, and Valuation of Services" By Bruce Steinwald, The United States Government Accountability Office (GAO-08-472T), p. 7-8.

199 "Self-Referral Issue Isolates Radiology in Multispecialty Forum" By Tracie L. Thompson, Auntminnie, October 7, 2004, www.auntminnie.com/index.asp?Sec=sup&Sub=imc&Pag=dis&ItemID=63177 (Accessed 2/18/05).

200 "Utilization of Diagnostic Medical Imaging: Comparison of Radiologist Referral Versus Same-Specialty Referral," By G. Scott Gazelle et al., Radiology, Vol. 245, No. 2 (November 2007), p. 517, 522.

201 *Ibid.*

202 "Medicare Improvements for Patients and Providers Act of 2008" Pub. L. 110-275, 122 Stat. 2494, July 15, 2008.

203 "ACR Pursues Designated Physician Imager Legislation" By James Brice, Diagnostic Imaging Online, January 10, 2005, http://www.diagnosticimaging.com/display/article/113619/1196742 (Accessed 02/18/05).; "Public Meeting" Medicare Payment Advisory Commission: Washington, D.C., December 9, 2004, p. 295-6.

204 "Medicare Improvements for Patients and Providers Act of 2008" Pub. L. 110-275, 122 Stat. 2494, July 15, 2008.Sec. 135(a).

205 "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).

206 "Improving Health Care: A Dose of Competition" Report by the Federal Trade Commission and The Department of Justice, July 2004, p. 8.

207 "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.

208 "McCarran-Ferguson Act" 15 U.S.C 1011, March 9, 1945.

209 "House Panel Approves Bill Curbing Insurers' Antitrust Exemption" By David M. Herszenhorn, New York Times, October 21, 2009.

210 "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.

211 "Improving Health Care: A Dose of Competition" Federal Trade Commission and Department of Justice, July 2004, p. 10.

212 "Medicare Prescription Drug, Improvement and Modernization Act of 2003" Pub. L. 108-173, Dec. 8, 2003, p. Sec. 1860D-11(i)(1).

213 "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.

214 "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. 2.

215 "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. 3.

216 "Improving Health Care: A Dose of Competition" Federal Trade Commission and the Department of Justice, White Paper, July 2004, p. 1-3.

217 "Improving Health Care: A Dose of Competition" Federal Trade Commission and the Department of Justice, White Paper, July 2004, p. 9; "Improving Health Care: A Dose of Competition" Report by the Federal Trade Commission and The Department of Justice, July 2004, p. 21-29.

218 "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.

219 "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. 186.

220 "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. 187.

221 "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. 12-13.

222 "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).

223 *Ibid.*

224 "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.

225 *Ibid.*

226 "Hospital Market Consolidation: Trends and Consequences" By William B. Vogt, PhD, National Institute for Health Care Management, November 2009.

227 "The Sherman Antitrust Act" Pub. L. No. 111-25, June 2, 2009.

228 "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. 6.

229 "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).

230 "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).

231 "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. 7.

232 "North Texas Specialty Physicians v FTC" Dkt. No. 9312, (July 18, 2005).

233 "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. 8.

234 *Ibid.*

235 *Ibid.*

236 "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. 9.

237 "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.

238 *Ibid.*

239 "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.

240 "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. [?].

241 "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.

242 "The McCarran-Ferguson Act" 15 U.S.C. § 1011 et seq. (2006).

243 "Senate Panel Hearing Airs Criticisms of Health, Malpractice Insurer Exemption" By Cecelia M. Assam, Bureau of National Affairs, Vol. 18, No. 41, October 22, 2009, p. 1397.

244 *Ibid.*

245 "House Panel Launches Hearings on Bill Limiting Insurers' Use of Antitrust Exemption" Bureau of National Affairs Health Law Reporter, Vol. 18, No. 40 (October 15, 2009), p. 1362; "Senate Panel Hearing Airs Criticisms of Health, Malpractice Insurer Exemption" By Cecelia M. Assam, Bureau of National Affairs, Vol. 18, No. 41, October 22, 2009, p. 1397.

246 "House Panel Launches Hearings on Bill Limiting Insurers' Use of Antitrust Exemption" Bureau of National Affairs Health Law Reporter, Vol. 18, No. 40 (October 15, 2009), p. [?].

247 "Improving Health Care: A Dose of Competition" Federal Trade Commission and the Department of Justice, White Paper, July 2004, p. 11, 15.

248 "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.

249 "Improving Health Care: A Dose of Competition" Federal Trade Commission and the Department of Justice, White Paper, July 2004, p. 11-16.

250 "Affordable Health Care for America Act" 111th Congress, October 29, 2009, http://docs.house.gov/rules/health/111_ahcaa.pdf (Accessed 11/10/09), p. 582.

251 "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.

252 *Ibid.*

253 "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.

254 "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.

255 "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).

256 "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.

257 "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).

258 *Ibid.*

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	Source Location
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.	"FCC Update on Rural Healthcare Pilot Program Initiative," by Federal Communications Commission, April 16, 2009, fcc.gov/Daily_Releases/Daily_Business/2009/db0416/DOC-290141A1.pdf. (Last Accessed July 14, 2009).
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. Also expected to address Joint Commission of Accreditation of Healthcare Organizations (JCAHO) and Centers for Medicare and Medicaid Services (CMS) credentialing issues.	"Medicare Telehealth Enhancement Act of 2009", 111th Congress, Bill H.R. 2068, introduced April 23, 2009; "Telemedicine Boosts Access to Needed Care" By Robert J. Waters, Roll Call, sponsored by Congress.org, June 8, 2009.
Licensed Independent Practitioners (LIPs)	JCAHO accreditation, according to JCAHO standards, suffice 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" Joint Commission Perspectives, Feb. 2003.
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.
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," by Geron: Visionary Therapeutics, January 23, 2009, www.geron.com/media/pressview.aspx?id=1148 (accessed July 1, 2009).
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, www.leaddiscovery.co.uk/registration/ (accessed July 1, 2009).
CMD tTechnology	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," Genetic Engineering and Biotechnology News, Vol. 29, No. 7, April 1, 2009.
Advanced Imaging Modalities	Magnetic resonance imaging, computerized tomography (CT), and nuclear medicine; these modalities are also the 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.
Multidetector Row CT (MDCT)	MDCT has raised the standard for image quality and accuracy in identifying differences in patient. 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, Diagnosticimaging.com, November 2005, available at www.diagnosticimaging.com/showArticle.jhtml?articleID=174402602 (accessed July 14, 2006).
"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.

Key Concept	Definition	Source Location
"Meaningful use"	Services of meaningful use will benefit from the recovery provisions (that is, test exchange methods), reporting of the percentages of patients older than age fifty screened for colorectal cancer, and the receipt of annual mammograms.	"Fed Advisors review 'meaningful use' recommendations for health IT," Greg Freiherr, DiagnosticImaging, June 16, 2009, www.diagnosticimaging.com/display/article/113619/1423016?CID=rss (accessed June 29, 2009).
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 the Gale Group, BusinessWire, (2007), (accessed June 29, 2009).
Stereotactic Rradiosurgery	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 June 29, 2009).
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).
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.
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.
Genedicine	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. 769–76.
Public Health Service Act	"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.	Legislation that has kept generic biopharmaceuticals from being marketed.
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 M.J. Mack, Surgical Endoscopy, Vol. 20 (2006), p. S488-S492; "Robot-Assisted Surgery," Mayo Clinic, 2009, www.mayoclinic.org/robotic-surgery/ (accessed April 6, 2009).
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, Int. J. Clin. Pract, February 2007, Vol. 61, No. 2, p. 309–14.
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, & J. Kenneth Salisbury, The American Journal of Surgery, Supplement to October 2004, 2S–15S.

Overview

Demographic shifts, the economic downturn, and changes in market-based technology collectively have contributed to the restructuring of the healthcare industry over the years. Currently, financially struggling healthcare and pharmaceutical industries face two problems: (1) the increasing incidence and prevalence of chronic disease in an aging population and (2) the introduction of new infectious diseases that are more aggressive than those of preceding generations.[1] Restructuring of the current healthcare industry, therefore, has become vital in order to contend with these pressures, and a successful transition is predominantly conditional upon insightful use of current technological instruments and innovative development of new advanced methodologies.

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. 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.[2]

Management Technology

Inpatient Versus Outpatient Care: A Bilateral Market

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 nearly doubled from 67 million in 1995 to 102 million in 2006. Simultaneously, the technology utilized in inpatient care has augmented the quality and efficiency of care for inpatient beneficiaries over the age of sixty-five, which has nearly doubled from 1970 to 2006.[3] 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 nearly doubled from 67 million in 1995 to 102 million in 2006.
>
> *"Health, United States, 2008 (with chartbook)," by the National Center for Disease Statistics, Centers for Disease Control and Prevention, U.S. Department of Health and Human Services, 2009.*

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." The 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 by way of an interface that includes evidence-based decision support, quality management, and outcomes reporting.[4] 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.[5]

Trends in EHR

Though paper health records have been used effectively in the past, drawbacks exist to administrative systems that continue to utilize nonelectronic documentation of patient information.[6] In addition to hindering the delivery of quality medical care, studies have indicated that paper records are costly, cumbersome, and easily misplaced, and they are difficult to use for meaningful decision analysis.[7] 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.[8]

The first EHRs were adopted in the 1960s, but many healthcare professional practices at the time did not view updates to their "anachronistic" medical record systems as a priority, despite the advent of technologies such as power files, audiotapes, microfilm, electronic data processes, and cathode ray tube real-time read-outs.[9] Many of today's EHRs are based on the work conducted in academic medical centers for use by major government clinical care organizations. The most notable of these include

- COSTAR (the Computer Stored Ambulatory Record), developed at Harvard Medical School and placed in the public domain in 1975;
- HELP (Health Evaluation through Logical Processing), developed at Latter-Day Saints Hospital at the University of Utah (brought to market by the 3M Corporation), which pioneered decision support features;
- TMR (The Medical Record), developed at Duke University Medical Center;
- THERESA, developed at Grady Memorial Hospital at Emory University, which encouraged direct physician data entry;
- CHCS (Composite Health Care System), used by the Department of Defense;
- DHCP (De-Centralized Hospital Computer Program), developed and used by the Department of Veterans' Affairs (VA); and
- Technical Data System(TDS), developed by Lockheed in the 1960s and 1970s.[10]

Early attempts to design and implement EHR technology encountered several difficulties, and although many improvements have been made, certain lingering problems in today's systems may explain why EHRs have not yet been widely implemented (See table 5-1 for status of EHR implementation as of 2009).

Although EHR implementation, is progressing at a relatively slow rate, it has continued to increase steadily since 2003. Notably, an estimated 43.9 percent of office-based physicians reported using an EHR system of some form in the first few months of 2009, although only 6.3 percent of systems were considered "fully functional."[11]

Table 5-1: Status of Electronic Health Record Implementation (2009)*

Stage of Implementation	Percentage
Not Yet Begun	5%
Developed a Plan	15%
Signed a Contract	2%
Begun to Install in One Facility	37%
Fully Operational in One Facility	24%
Fully Operational Across Whole Organization	17%
Unknown	1%

* "20th Annual 2009 HIMSS Leadership Survey" By HIMSS, Healthcare CIO Final Report, April 6, 2009, p. 24.

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, practices that implement EHR technology will benefit from a system of documenting patient vitals and test results, better supporting documentation in malpractice claims, improved reporting regarding patient practices, and improved communication between physicians.[12] Furthermore, results from a recent study published in *Health Affairs* suggests that implementation of EHRs could save more than $81 billion per year by preventing disease, reducing medical errors, and promoting efficiency within the healthcare system.[13]

Additionally, the implementation of an EHR system allows for computerized physician order entry (CPOE), which may reduce adverse drug events in inpatient and ambulatory settings.[14] 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.[15]

Practices that utilize EHR technology reduce their costs associated with utilizing and maintaining traditional paper medical records.[16] In addition to superior physician accessibility, EHRs allow physicians to enter key findings and progress notes at the point of care, minimizing duplicate documentation.[17] Additionally, problems with legibility are eliminated, reducing potential interpretation errors and saving time.[18]

Barriers to Implementation

Obstacles, such as cost and physician resistance to change, have delayed the widespread adoption of EHRs.[19] Some physicians admit that the cost of new technology is the greatest challenge for the conversion from paper health records to EHR.[20] However, research suggests that physicians who use EHRs with sophisticated Medicare coding support could see a revenue increase of up to 30 percent more than physicians who continue using paper records.[21] Some cardiology practices have already reported substantial EHR benefits, including lower Medicare rejection rates, fewer days in accounts receivable, the ability to increase their number of patients without an increase in staff, increases in revenue, and reductions in transcription and postage costs.[22] One multispecialty practice observed $2.5 million per year in EHR related savings.[23]

> Physicians who use EHRs with sophisticated Medicare coding support could see a revenue increase of up to 30 percent more than doctors who continue using paper records.

"The Benefits of Evidence Based Medicine in EHR Systems," by Tom Doerr, MD, EHR Scope, (Spring 2008).

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 percent of the cost for a new system.[24] Furthermore, it is estimated that the total cost per provider can be upward of $10,000; if the loss of productivity associated with initial implementation is accounted for, the cost of transitioning to an EHR system could be greater than $20,000.[25]

Regulatory and Reimbursement

Regulatory

As with all medical records, EHRs must align with current Health Insurance Portability and Accountability Act (HIPAA) regulations (see chapter 3, *Health Insurance Portability and Accountability Act of 1996* (*HIPAA*) for further discussion of these regulations). Due to ease of transfer and accessibility, practitioners and healthcare facilities that use EHR technology must be cautious about compliance.

In 2007, the Federal Trade Commission (FTC) issued a set of regulations known as the Red Flags Rules, requiring that certain entities develop and enforce written identity theft prevention and detection programs by August 1, 2009. These programs are targeted at all transferable personal files, including EHRs, and are discussed further in chapter 3, *Red Flags Rules*.

Reimbursement

In response to the slow transition to EHRs, the government has prioritized proactive legislation promoting universal access to electronic records. Congress recognized the impending healthcare crisis in its American Recovery and Reinvestment Act (ARRA), signed by President Barack Obama on February 17, 2009.[26] The ARRA allotted $19.2 billion to ensure that every patient has a complete, interoperable EHR by 2014. The net return of this investment will include long-term cost savings, improved outcomes, and increased ease of communication between physicians. In an effort to incentivize the implementation of EHR use, beginning in 2011, funding will increase reimbursement for Medicare and Medicaid providers (up to $65,000 per physician and $11 million per hospital) that use EHRs.[27] Conversely, in 2015, physicians who are not using EHRs will be penalized through reduced reimbursement.[28]

> The ARRA allotted $19.2 billion to ensure that each American has a complete, interoperable EHR by 2014.

"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).

Specific provisions of the ARRA, namely, Title IV of Division B and Title XIII of Division A, collectively are known as the Health Information Technology for Economic and Clinical Health Act (HITECH Act). These sections of the ARRA incentivize implementation of EHR and establish "meaningful use" criteria for EHR utilization by healthcare entities and providers.[29] For healthcare providers to qualify for HITECH incentives, they must demonstrate fulfillment of three requirements for "meaningful use" of EHRs:

> (1) Use of certified EHR technology in a meaningful manner (for example, electronic prescribing); (2) that 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) that, in using certified EHR technology, the provider submits . . . information on clinical quality measures and such other measures selected by the Secretary.[30]

In addition to the aforementioned criteria for "meaningful use," upheld by both Medicare and Medicaid, which currently link many EHR incentive programs, Medicaid also requires that healthcare providers receiving incentives under HITECH must indicate efforts to "adopt, implement, or upgrade certified EHR technology" wherever possible.[31] States also reserve the right to implement additional

requirements for "meaningful use" beyond the minimum standard upheld by Medicare, which will undergo additional changes as definitions for "certified EHR technology" and a "qualified EHR" are finalized.[32]

Electronic Prescribing: Computerized Physician Order Entry (CPOE)

Computerized physician order entry (CPOE) allows physicians and providers to electronically order laboratory, pharmacy, and radiology services.[33] Electronically entering orders minimizes error by eliminating the hassle and ambiguity associated with handwritten orders.[34] 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."[35]

More than 1 million serious medication errors occur every year in the United States.[36] One **adverse drug effect (ADE)** adds, on average, $2,000 to the cost of hospitalization, which is currently more than $7.5 billion per year nationwide.[37] An ADE is an injury caused by drugs, typically in the form of an allergic reaction or adverse physiological response to a certain combination of medications. Preventable ADEs are injuries that are caused by human error, such as prescribing or administering the wrong dose of a drug.[38] A 2008 study by the Leapfrog Group, a large consortium of healthcare purchasers, found that CPOE systems can reduce the frequency of ADEs by as much as 88 percent.[39]

> Only 8 percent of hospitals have fully implemented CPOE systems. In addition, CPOE hospitals tend to be larger, nonprofit, and teaching hospitals.
>
> *"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.*

Trends in CPOE

CPOE systems were first introduced in the late 1960s, but CPOE use was fairly sporadic until a 1999 study by the Institute of Medicine (IOM), "To Err Is Human," found that 44,000 deaths annually are attributable to medical errors and touted CPOE adoption as the solution to this newly recognized national crisis.[40]

> Between 2004 and 2005 the agency for healthcare research and quality awarded more than $166 million in funding for health IT, much of which focused on implementation and evaluation of CPOE.
>
> *"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 June 22, 2009), p. 2.*

CPOEs have received much public attention following 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.[41] Despite these initiatives, a 2009 study published in the *American Journal of Medical Quality* found that only 8 percent of hospitals have a fully implemented CPOE system. Additionally, these hospitals tended to be larger, nonprofit, teaching hospitals.[42] For a hospital to qualify as having a "fully implemented" system, 75 percent of all orders must go through its CPOE system, the system must alert physicians of possible errors, and it must require a physician response if an alert is overridden.[43]

In 2008, 472 U.S. hospitals had a CPOE system in place. Of those organizations using CPOE, 62 percent were described as having aggressive use (50 percent or more of orders are entered into CPOE system) (see table 5-2). Additionally, the following table 5-3 details the breakdown of CPOE usage measured by percentage of orders that are filled out through the hospital's CPOE system.[44]

Table 5-2: Number of Organizations using Computerized Physician Order Entry, 2008*

	Pilot (1–15%)	Moderate (16–50%)	Significant (51–85%)	Deep (86–100%)
Number	95	102	60	229
Percentage	20%	22%	13%	49%

* "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.

Table 5-3: Approximate Uses of Computerized Physician Order Entry (CPOE) in Inpatient and Ambulatory Settings, 2008*

	% of MD's Using CPOE		% of All Patient Orders MD's Enter		% of Medication Orders Electronic vs. Paper		% MD's Entering Notes Electronically	
Level of Use	Inpatient	Ambulatory	Inpatient	Ambulatory	Inpatient	Ambulatory	Inpatient	Ambulatory
Pilot	18	4	21	9	21	15	65	45
Moderate	22	12	19	25	16	8	9	11
Significant	10	12	22	20	19	8	5	4
Deep	46	70	38	48	44	65	19	35

* "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.

Other national organizations also have promoted the adoption of CPOE based on its potential to improve quality and reduce medical error. These include the Joint Commission on Accreditation of Healthcare Organizations (Joint Commission) and the President's Information Technology Advisory Committee.[45] Despite this initiative and support, hospital ownership and teaching status have historically been cited as important factors in whether a hospital is likely to implement a CPOE system (see table 5-4).[46]

Government hospitals have been the most likely to start implementing CPOE systems (including nonfederal community, city-, state-, and county-owned government hospitals) at three and seven times the rates of adoption by nonprofit and for-profit hospitals, respectively.[47] Larger government hospitals have been more prone to incorporating CPOE technologies, and teaching hospitals have been roughly three times as likely as nonteaching hospitals to adopt the technology.[48]

Studies indicate that institutions that adopt CPOE systems primarily are focused on the safe and proper delivery of clinical services.[49] 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

Table 5-4: Computerized Physician Order Entry (CPOE) Investment by Hospital Ownership*

	Ownership Type		
	Government	Non-for Profit	For-Profit
No CPOE System	24.1%	41.4%	54.1%
Early-Stage Adoption	12.7%	9.6%	6.8%
Middle-Stage Adoption	15.2%	12.1%	3.8%
Fully Implemented	10.1%	2.2%	0.0%

* "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 (Nov./Dec. 2005), p. 1657.

adoption of CPOE systems 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."[50] 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 systems has not spread widely enough among key physicians or hospital decision makers outside of teaching institutions."[51]

Cost-Benefit Analysis

Prudent prescription and medication use has a substantial impact on the total cost of healthcare.[52] Overall, the financial impact of reported CPOE use has had a positive effect on the net operating income of an institution.[53]

A 2008 survey by the Massachusetts Hospital CPOE Initiative calculated that Massachusetts saved $2.7 million per hospital annually with the adoption of CPOE technology.[54] The initiative found that the increased savings for Massachusetts hospitals essentially would generate sufficient return in approximately twenty-six months to cover the costs of installing and adapting CPOE software and protocols. In addition, the average annual benefits to Massachusetts payors amounts to approximately $900,000 per hospital. The initiative concluded that statewide adoption of CPOE systems would save, on average, $170 million a year, preventing 55,000 ADEs from occurring.[55]

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.[56] 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, those without.[57] In addition, studies of CPOE systems are constrained by the technology's comparative youth, continued evolution, emphasis on evaluation of potential rather than actual errors, and limited dissemination.[58]

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.[59] "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."[60] Additionally, changing the reimbursement environment to favor adoption of CPOE systems could offer a short-term solution to increasing investment in these systems.[61]

Between 2004 and 2005, the Agency for Healthcare Research and Quality (AHRQ) awarded more than $166 million in funding for health information technology (IT), much of which focused on implementation and evaluation of CPOE. 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 shrinking organizational budgets and competing IT projects, the task of funding CPOE implementation can be daunting for hospital administrators.[62] A 2008 survey of Massachusetts hospitals found that, on average, capital costs

associated with implementing a CPOE system was slightly more than $2 million and ongoing use and maintenance was just more than $425,000.[63]

> On average, one adverse drug effect adds $2,000 to the cost of hospitalization, which is more than $7.5 billion per year nationwide in hospital costs.
>
> *"Leapfrog Hospital Survey Results" The Leapfrog Group, 2008, p. 3.*

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.[64] 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. CDS systems provide pop-up warnings when a complication exists with an order. However, "**alert fatigue**" can occur when there is a combination of critical medical alerts and a high volume of marginally medically consequential alerts.[65] An overabundance of warnings may desensitize and even annoy practitioners.[66]

Quality of Care Improvements

A recently published study in the *American Journal of Medical Quality* found significant positive associations between specific objective quality indicators and CPOE implementation.[67] Hospitals with CPOE systems noted that errors related to legibility of paper orders were eliminated. Also, alerts regarding allergies, potential drug interactions, and dosing standards, improved patient safety, and "stat" orders were fulfilled quicker, because pharmacies were receiving the orders instantly.[68]

In addition to preventing ADEs, CPOE systems alert physicians of available generic options for any prescription drug, alert clinicians of redundant orders or laboratory test entries, and list the drug delivery methods suitable for any prescribed drug to prevent delivery errors (for example, intravenous administration of orally administered drugs). CPOE systems could be even more beneficial in long-term care facilities because residents are prescribed, on average, more than six concurrent drug therapies, which, exacerbated by problems associated with advanced age, can increase the risk of an ADE.[69] Table 5-5 shows expected minimal rates of improvement for preventable adverse occurrences with implementation of CPOE.

Barriers to Implementation

In addition to the costs associated with implementing a CPOE system (see *Cost-Benefit Analysis*), several other challenges should be considered: technical issues, costs, and clinician compliance.[70]

Technical Issues

It should be noted that there is no "one size fits all" CPOE system, so many hospitals may need to customize their systems, including the integration of current systems.[71] This process necessitates thorough project planning and execution, which may hinder production and cause unforeseen delays.

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.[72]

Table 5-5: Minimal Expected Rates of Improvement for Preventable Adverse Events with Computerized Physician Order Entry*

Preventable Event	Year 1	Year 2	Year 3
ADEs	15%	50%	70%
Expensive Drugs	20%	60%	80%
Renal Dosing	15%	60%	93%
I.V. to Oral	50%	75%	82%
Redundant Labs	50%	75%	85%

* "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, Feb. 2008, p.18.

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.[73] A 2005 study found that one CPOE system facilitated twenty-two types of medication error risks, generated by the fragmentation of data and failure to integrate the hospital's multiple computer and information systems and human-machine interface flaws reflecting machine shortcomings in light of generally accepted workplace practices and dynamics.[74] However, as systems become more advanced, some of these unforeseen problems are decreasing in frequency. In 2003, the average number of electronic patient entries being re-entered was 48 percent, whereas in 2008, this percent dropped to 21 percent.[75]

Physician Unwillingness

Another potential barrier to use of CPOE is provider reluctance. User satisfaction has been identified as an important predictor of the success of CPOE adoption and compliance.[76] Generally, younger interns and residents are more willing to use CPOE, although older, more experienced physicians tend to be less satisfied with CPOE.[77]

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 tests 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.[78]

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."[79] This law required all plans to be submitted by 2002, with the licensure changes taking affect January 1, 2005. A similar law in Massachusetts requires statewide implementation of CPOE systems by 2012.[80]

On a federal level, there have been several bills proposed in both the United States House of Representativesand the Senate regarding implementation of CPOE systems.[81] Although none of the bills specifically requiring CPOE implementation have 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.[82] In addition, the Centers for Medicare and Medicaid Services (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.[83]

Reimbursement

In the past, financial incentives to support investments in CPOE technology were lacking. One reason for this is that public payors paid the same reimbursement for unsafe care as they did for safe care.[84] To combat this, some private insurers are leading the charge to incentivize hospitals to incorporate CPOE.[85]

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 establishes incentives for 2009 through 2013, in which Medicare professionals who are successful e-prescribers will receive payments of 2 percent for 2009 and 2010, 1 percent for 2011 and 2012, and 0.5 percent for 2013. The goal of these incentives is to allow the Government Accountability Office (GAO) to submit a report on the implementation of the incentives for electronic prescribing to Congress by September 1, 2012.[86]

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."[87]

Outsourcing in healthcare has yielded higher efficiency levels and more cost-effective outcomes and also has provided increased physician and patient satisfaction.[88] Many health practices are utilizing foreign companies for medical billing in response to those companies' guarantees of dramatic savings compared to their American counterparts.[89]

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."[90] With lawmakers increasing penalties for noncompliance with privacy laws, it is likely that outsourcing services providers will begin to increase their compliance efforts. The HITECH Act, enacted as part of ARRA,[91] delineates a tiered system for determining the appropriate penalties for HIPAA privacy violations.[92] HITECH provisions significantly increase the penalties for violations of HIPAA, allowing for penalties up to $1.5 million.[93]

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.[94] **Telehealth** is 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.[95]

Utilizing communication equipment to link healthcare practitioners and patients in different locations increases cost efficiency; reduces transportation expenses, improves patient access to specialists and mental health providers, improves quality of care, and enhances communication among providers.[96]

Telemedicine services have been integrated successfully into approximately sixty different medical subspecialties.[97] The United States has approximately 200 telemedicine networks, involving close to 3,500 medical and healthcare institutions.[98] Some of the services offered through telemedicine are specialized and primary care consultations, imaging services, remote patient monitoring, remote medical education and consumer information, networked programs linking hospitals to rural clinics, point-to-point connection using private networks between hospitals and ambulatory care sites, primary or specialty care to home connections, home to monitoring centers, and Web-based e-health patient service sites. Today, nearly five hundred hospitals in the United States outsource some of their medical imaging services, often referred to as **teleradiology**.[99]

Telemedicine services have been successfully integrated into approximately sixty different medical subspecialties.

"What is Telemedicine and Telehealth?" American Telemedicine Association, info@americantelemed.org (accessed June 30, 09).

Trends in Telemedicine

The range of telemedicine technology is divided into two main application groups. **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).[100] **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.[101]

Some states, supported by Blue Cross Blue Shield (BCBS), have begun to implement virtual clinics using telehealth technologies. The virtual clinic is a pilot project, so far only fully adopted in Hawaii, in which for a flat fee, a patient can communicate with a physician using a webcam and an instant messaging program over the Internet for approximately ten minutes. Patrick Geraghty, the president of BCBS of Minnesota (one state beginning implementation), claims that these virtual clinics will change the current model of how physicians get paid and will save patients from expensive trips to the emergency room and clinic. Roy Schoenberg, M.D., the creator of the virtual clinic software, describes how the software connects patients to generalists, pediatricians, or other specialists who will have instant accesses to their patients' EHR provided by BCBS data. Currently, only in-state licensed physicians are allowed to participate in the program.[102]

Advances in robotics now allow telehealth to have a tangible component. Mercy 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.[103] Additionally, 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. NHC costs $50 to $70 per hour,

approximately half the cost of an in-house hospitalist.[104] Another pilot telehealth initiative, the RP-7 robot, at Eagle Hospital in Atlanta, Georgia, can maneuver through hospital floors through a telehealth link. Currently, ten hospitalists are participating in the pilot program.[105]

> 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. This 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.[106]

Cost-Benefit Analysis

The federal government has predicted that by 2020, there will be a shortage of approximately 24,000 physicians and nearly 1 million nurses.[107] For hospitals suffering from physician shortages, telemedicine facilitates hospitalist recruitment, providing more attractive work hours and the ability for a single practitioner to provide services to multiple hospitals at one time. In general, solving the physician shortage may help control "burnout" for hospitalists, leading to higher productivity and longevity of practitioners. In addition, telemedicine has enhanced access for hospitalists and their patients to medical specialists and better technology. Telemedicine also allows hospitals to expand their market service area by employing telemedicine technology at outlying medical clinics and offices.[108]

Telemedicine also allows hospitals to expand their market area by employing telemedicine technology at outlying medical clinics and offices.

"Night-Shift Solutions" By Lisa Ryan, The Hospitalist, April 2009, www.the-hospitalist.org/detains/article/183090/NightShift_Solutions.html (accessed June 20, 2009).

The VA is the largest provider of remote medical services, delivering an estimated 350,000 patient services remotely.[109] Through telemedicine, the VA has reduced the average length of stay at hospitals by 25 percent and has reduced hospitalization by 19 percent for patients using home health services.[110]

Through telemedicine, the VA has reduced the average number of days hospitalized by 25 percent and reduced hospitalization by 19 percent for patients using home health.

"New VA Study Shows Home Telehealth Makes Health Care More Effective" Government Health IT News, Jan. 7, 2009.

Many healthcare practitioners have obtained federal funds for investments in telemedicine technology through grants, contracts, and direct services. In 2003, the American Telemedicine Association (ATA) estimated that approximately $279 million was spent on federal grants and contracts in telemedicine.

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.[111] Further, the Medicare Telehealth Enhancement Act of 2009 (HR 2068) will provide $30 million in grants to health facilities to pay for telehealth equipment and expand telehealth support services.[112]

Finally, the Federal Communications Commission created the Rural Health Care Pilot Program to increase patient access to telemedicine and support the transfer of EHRs. Sixty-seven nationwide projects in forty-two states and 6,000 health facilities are eligible for the $417 million in grants under the program.[113]

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 use interstate telemedicine may have to be licensed in each of the states in which they treat patients, which can be time-consuming and expensive.[114]

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 a greater likelihood of lawsuit if a problem occurs.[115]

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.

Regulatory and Reimbursement

Regulatory

State

Physicians practicing medicine in any state must be approved by the licensure board of that state. As of 2006, twenty states have restrictive licensure laws regarding interstate telemedicine.[116]

These licensure laws require a practitioner to be fully licensed in each state in which he or she provides medical care in order to deliver telemedicine care across state lines, but it can be expensive and time consuming for a practitioner to maintain licenses in more than one state.[117]

However, licensure laws typically have several exceptions that allow interstate telemedicine without a license from both states, such as if

1. interstate telemedicine is infrequent,
2. a contractual relationship with compensation is not formed,
3. consultations are between two parishioners only (no patient involvement),
4. 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.[118]

Reciprocal or **limited licensure** provides an interstate license for use with telemedicine that practitioners can apply for through a simple application process and for reduced licensing fees. Reciprocal licenses work through a mutual exchange of privileges and permit one state to recognize the license a practitioner holds in another jurisdiction and subject practitioners to the rules from in the jurisdiction where the practitioner resides.[119] This license is solely for practicing telemedicine and may not be used

by practitioners to provide bedside care in another state. As of 2006, reciprocal licenses were only accepted in Alabama, California, and Oregon.[120] See table 5-6 for a summary of state participation in various types of interstate licensing practices. As an exception to this rule, an interstate license for nurses, first created in 2000, has been widely accepted and used through 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.[121]

Table 5-6: Summary of Telemedicine Interstate Licensure Types, 2006*

Type	No Action	Restrictive	Reciprocal	Nursing
Number of States	28	20	3	30

* "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, updated By TIE on Nov. 15, 2006, http://tie.telemed.org/articles/article.asp?path=article&article=interstateLicensure_gw_tie0 (Accessed 7/1/09).

Federal

Similar to any electronic transfer of patient medical information, telemedicine practitioners must comply with HIPAA regulations. Telehealth and telemedicine are also subject to Joint Commission standards.[122] Current Joint Commission standards focus on services provided by licensed independent practitioners (LIPs) who diagnose or treat patients by way of a telemedicine link.[123] Under the current standards, most recently revised in 2004, 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. Otherwise, the LIP must be credentialed at the site where the patient is located (the originating site).[124]

Telehealth and telemedicine are also subject to the JCAHO standards.

"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).

The same Joint Commission standards apply to practitioners who provide interpretive services (teleradiology and telepathology) and those who provide consultations.[125] These services are usually contracted out for and must therefore also meet the contracted service standard (LD.3.50).[126] 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.[127] 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.[128]

Reimbursement

State

In 2006, at least twenty-nine states had private insurers that were reimbursing for telemedicine services, with at least twenty-five states having passed legislation mandating some level of private payor reimbursement of telemedicine.[129] Some states, including Louisiana, California, Oklahoma, Texas, and Kentucky, have all-inclusive legislation prohibiting health insurers from denying coverage for services appropriately provided through telemedicine and subject to individual insurance contracts.[130]

A 2003 private payor survey conducted by the ATA found that 53 percent of telemedicine programs offer billable service and receive private payor reimbursement.[131] As of 2006, thirty-four states reimburse through Medicaid for telehealth services, and nineteen states have specific legislation that provides for Medicaid reimbursement.[132]

Federal

The Balanced Budget Act of 1997 limited the scope of Medicare telehealth coverage to consultation services. Section 223 of the Medicare, Medicaid and 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. 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 geographic areas included rural health areas with practitioner shortages and counties not classified as part of an established metropolitan statistical area.[133]

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. In addition, as of 2009, both the distant physician or practitioner and patient are required to be present at the telehealth "visit" and interacting in real-time communication.[134]

Clinical Technology

The Gateway: Genetics, Genomics, and Genome Technology

The landmark discoveries accompanying the advent of genome sequencing transformed the field of clinical medicine. In 2001, The Human Genome Project at the National Institute of Health completed the initial mapping of the human genome, a milestone that fueled interest in the field of genomics.[135] 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 93 percent of dollars spent on healthcare merger and acquisition activity in May 2009.[136]

In 2001, The Human Genome Project at the National Institute of Health completed the initial mapping of the human genome.

"The era of 'omics unlimited," by Raj P. Kandpal, Beatrice Saviola, and Jeffrey Felton, BioTechniques, Vol 46, April 2009 (special issue), p. 351–55.

Biotechnology and biopharmaceuticals are influential drivers in today's market, accounting for 93 percent of dollars spent on healthcare merger and acquisition activity in May 2009.

"Drug Deals Dominate M&A: Biotech and Pharma Outspend All Other Sectors," by the Healthcare M&A Monthly, Vol. 14, Issue 6, June 2009, p. 1.

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.[137] **The National Center for Human Genome Research Institute (NCHGRI)** is comprised of more than fifty researchers who are each dedicated to specific facets of genetic and genomic research and contribute accordingly to one of seven branches of the NCHGRI: Cancer Genetics, Genetic Disease Research, Genetics and Molecular Biology, Genome Technology, Inherited Disease Research, Medical Genetics, and Social and Behavioral Research.[138]

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 adapting their function to accommodate a certain type of tissue or organ under the proper conditions. The unique regenerative capacity of stem cells has the potential to change the way health problems, such as 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.[139] On January 23, 2009, the first human embryonic stem cell (hESC)-based therapy was approved for clinical trial; Geron Corporation announced clearance of their Investigational New Drug application for the clinical trial of *GRNOPC1* in patients with acute spinal cord injury. *GRNOPC1* manipulates the growth-stimulating properties of nerve cells to provide rehabilitation for acute spinal cord injuries.[140]

On January 23, 2009, the first human embryonic stem cell (hESC)-based therapy was approved for clinical trial.

"Geron receives FDA clearance to begin world's first human clinical trial of embryonic stem cell-based therapy," by Geron: Visionary Therapeutics, January 23, 2009, www.geron.com/media/pressview.aspx?id=1148 (accessed July 1, 2009).

Stem cell research is also used to investigate the causes of birth defects, enhance drug development by providing molecular insight, and expedite the drug approval process by facilitating preliminary drug testing. Additionally, understanding the differences between embryonic and nonembryonic stem cell proliferation may be the key to understanding—and treating—cancer.[141]

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).[142] 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.[143] Furthermore, molecular diagnostics represent the sector of the genomics market with the most promise.[144]

Diagnostic Technology

Diagnostic medicine is the 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 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."[145] Recent diagnostic advances support an attitude of prevention that, though inherently accepted, has not been practiced sufficiently in healthcare to date. In order to truly realign demand and delivery of healthcare services, future developments may need to be directed at a diagnostic market increasingly driven by prevention and early detection.

Molecular Diagnostics

Molecular diagnostics originally were used to screen for infections (for example, HIV, hepatitis, and tuberculosis) more accurately and effectively than traditional methods.[146] 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.[147] Similarly, advances in genetic engineering and enhancement, pharmacogenetics, and pharmacogenomics have lead to a fusion of molecular diagnostics and therapeutic measures for specialized screening and treatment plans; this 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.[148] The developments that materialized as a result of these molecular capabilities continue to affect the molecular, nonmolecular, and in vitro diagnostic markets.[149]

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.[150] 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.[151]

Trends in Molecular Diagnostics

The global market for molecular diagnostics encompasses more than 500 companies and, as of 2008, the United States controlled the majority of the market.[152] The area of greatest promise lies in developing companion diagnostics that incorporate therapeutic care.[153]

Regulatory and Reimbursement

In the past, molecular diagnostic innovations fell outside the stringent compliance requirements set by the Federal Drug Administration (FDA). In response to increased demand, regulations targeting in vitro diagnostic multivariate integrated assays (IVDMIA) and analyte-specific reagents (ASRs) were issued to increase FDA supervision of the field and elevate quality standards.[154] These draft guidelines, published

by the FDA's Office of In Vitro Diagnostic Device Evaluation and Safety in July 2007 and September 2007, for IVDMIA and ASR regulation, respectively, will serve as a challenge for developers, especially for companies entering the market for the first time.[155]

Despite that diagnostic testing influences 70 percent of all healthcare decisions made, diagnostics only comprises 2 percent of overall Medicare spending. In a healthcare system historically focused on the quality of acute care provided, reimbursement for services targeting prevention and chronic disease management have not been thoroughly assessed since the 1980s.[156]

> Despite the fact that diagnostic testing influences 70 percent of all healthcare decisions made, diagnostics only comprise 2 percent of Medicare spending.

"Medicare Needs to Get With the Times" The Burrill Report, Burrill and Company, 2009.

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."[157] 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.[158] 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 facilities under the Outpatient Prospective Payment System (OPPS).[159] See chapter 2, *Facility-Based Reimbursement Rates* for more detail regarding billing under OPPS. In June 2008, the GAO released a report affirming the findings that procured CMS's decision. Spending for imaging services more than doubled from 2000 to 2006, increasing to approximately $14 billion, with 80 percent of this growth explained by the increased quantities of complex imaging services.[160]

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.[161]

Of all the imaging services contributing to the $14 billion in imaging spending, the highest observed growth rates were attributable to advanced imaging modalities (MRI, CT, and nuclear medicine), with an average annual growth rate of 17 percent. These modalities are also the most expensive services.

Advanced imaging accounted for 54 percent of total imaging expenditures, with spending having more than doubled from $3 billion in 2000 to $7.6 billion in 2006.[162]

Advances in Magnetic Resonance Imaging

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.[163] fMRI is one of the most popular methods of brain imaging in today's market.[164] 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.[165]

As a result of these technological advances, an estimated 26.6 million MRI procedures were performed in 2006, representing an average annual growth rate of 3 percent, and a 10 percent total increase from the 24.2 million procedures conducted in 2003.[166] Spending on MRI services accounted for nearly half of the $4.6 billion increase in Medicare spending from 2000 to 2006.[167] The ease of use afforded by these technological expansions has resulted in increased outpatient procedures; in 2006, 84 percent of all MRI procedures were performed on an outpatient basis versus 16 percent on an inpatient basis.[168]

Advances in Computed Tomography

Computed tomography (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.[169] Since its creation in 1970, use of CT technology has grown rapidly, with a 600 percent increase in utilization between the mid-1980s and the mid-1990s.[170] As of 2000, approximately 46 million scans per year were taken in the United States.[171] Additionally, CT appears to expedite and improve initial triage of patients on an outpatient basis in the emergency room, allowing patients to either return home or be admitted for evaluation.[172] The number of visits for which diagnostic imaging services were ordered grew from 28.3 percent in 1996 (3.2 percent being CT) to 44.2 percent in 2006 (11.6 percent being CT).[173]

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, and thereby enhanced patient management and care.[174] 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.[175] Recent market research indicates that CT accounts for 13 percent of all diagnostic procedures in the United States, and that the 64-slice CT is the most popular CT technology in use.[176]

64-Slice CT is the most popular CT technology in use, as it made cardiac and cerebral CT imaging possible.

"Nuclear cardiology adopts hybrid and dynamic imaging" by David Berman, M.D., Diagnostic Imaging.com, 10/06, www.diagnosticimaging.com/display/article/113619/1193342 (accessed February 10, 2009).

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 sixty-four seconds faster than second generation 16-slice scanners.[177] A 64-slice CT scanner can complete a scan in as little as eight to twelve seconds, compared to a traditional CT scanner's time of twenty to thirty seconds.[178]

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 CT cardiac screening, CT colonography, CT lung screening, and CT whole body screening.[179]

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.[180] 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.[181]

"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.[182] 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.[183]

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."[184]

PET technology allows for substantially higher sensitivity than single-photon imaging technologies, such as SPECT.[185] However, due to the longer half-life of single-photon emitters, SPECT tracers last six hours; PET tracers have only a seventy-five second half-life. A longer half-life enables the use of a wider observational time window.[186] 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). Finally, the 1.6 million PET-CT procedures performed in 2007 cannot compete in quantity with the 15.9 million SPECT procedures performed during the same time period.[187] 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).[188]

PET technology allows for substantially higher sensitivity than single-photon imaging technologies like the SPECT.

"PET versus SPECT: strengths, limitations, and challenges," by Arman Rahmim and Habib Zaidi, Nuclear Medicine Communications, Vol. 29, (2008) p. 193–207.

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.[189] Recent market research indicates that nearly half of SPECT sales globally are in fact SPECT-CT sales.[190]

Despite these international trends, 75 percent of purchases in the United States are still SPECT. 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.[191] Additionally, the majority of SPECT procedures are performed in the field of cardiology, where SPECT-CT is only beneficial if it can generate sixty-four or more slices.[192] Often, the cost allocated to such technologies is beyond the budgeting capacity of many cardiology departments.[193] By contrast, PET-CT technology has been incorporated into many oncology practices, where budgets appropriately match the necessity of such technology.[194]

PET-CT technology has been most incorporated in oncology practices, in instances when budgets appropriately match the need.

"Great expectations and the saga of SPECT-CT," by Greg Freiherr, Diagnostic Imaging, June 25, 2009, www.diagnosticimaging.com/display/article/113619/1425226?CID=rss (accessed June 29, 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 ensuring a greater number of radiologists in the marketplace (average annual growth in the number of radiologists in the United States is 1.5 percent to 2 percent) and to increase in the number of images a radiologist must interpret (between 6 percent and 12 percent). Teleradiology allows for an increased reliance on remote reading of scans, which helps imaging providers by alleviating the off-hour burden that night reads can cause to radiology groups.[195]

Other advances in teleradiology technology have allowed for the connection of digital x-rays and other imaging modalities to **picture archives and communications systems (PACSs)**, which has greatly improved efficiency of imaging care by providing improved access to images with reduced delays Many of these systems are derived from infrastructures implemented in hospital radiology departments and have since expanded into a wide area of networks for healthcare systems and managed care organizations.[196]

NightHawk Radiology Services, founded in 1993, was the nation's first company providing night reads using teleradiology. By November 2006, NightHawk's market capital value was approximately $550 million,[197] and the company reported significant profits as recently as 2008. By 2009, however,

NightHawk's earnings moved from profit to loss, due in part to physician hesitation based on potential liability and lack of confidence in the telemedicine providers' competence.[198] Additionally, the extensive licensing and credentialing requirements of physicians who provide services by way of large teleradiology companies provide services across the country further complicates the practice of teleradiology.[199] Despite the negative effect of customer attrition in the first quarter of 2009, however, NightHawk and others maintain that business opportunities continue to grow.[200]

Companies providing day reads in subspecialty areas are beginning to show market expansion.[201] 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.[202]

Regulatory and Reimbursement

Specifically with regard to PET technology, federal regulations recently were updated to ensure compliance of drug production and manufacturing practices with federal regulations regarding safety and quality of radiologic tracers used in PET procedures. New regulations require all PET production facilities to comply with the updated requirements effective on December 12, 2011, and include 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.[203]

Therapeutic Technology

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.[204] The manufacturing of biopharmaceuticals, most specifically vaccines, monoclonal antibodies, recombinant proteins, and stem cells, relies heavily on the cell culture market.[205] 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: recombinant blood factors, recombinant thrombolytics and anticoagulants, recombinant hormones, recombinant growth factors, recombinant interferons and interleukins, recombinant vaccines, monoclonal antibody-based products, and miscellaneous recombinant products.[206]

Trends in Molecular Pharmacology

Advances in Proteomics

Therapeutic protein technology has seen developments of innumerable implications. Insulin, the first recombinant protein to be approved, remains the prototype for biopharmaceutical development. It was among the first biopharmaceuticals to undergo molecular engineering, a process which has since defined development and advancement in biopharmaceuticals.[207] Seven faster or time releasing engineered analogs for insulin have been approved, and with breakthroughs in drug delivery technology, Exubera inhalable recombinant insulin recently became the first biopharmaceutical to receive approval for

nonparenteral drug delivery (namely pulmonary but also oral, nasal, transmucosal, and transdermal delivery routes).[208] With the incidence of diabetes on the rise, it is probable that the demand and market for such products will continue to grow. [209]

Nucleic Acid-Based (RNAi) Therapeutics

Recent market reports predict RNAi therapeutics to generate sales of approximately $1 billion by 2015. These biopharmaceuticals show tremendous promise in countless areas, the most notable of which are Hepatitis C and cancer treatment.[210] 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 disease. (They) may turn out to be enormously beneficial in terms of drug discovery." [211] 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), *Genedicine*, reset the tone for nucleic acid-based RNAi drug development.[212] Approval of *Genedicine* 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.[213]

Regulatory and Reimbursement

As of 2006, 165 recombinant proteins, monoclonal antibodies, and nucleic acid-based drugs had been approved by the United States and Europe as treatments for cancer, diabetes, growth disturbance, hemophilia, and hepatitis. [214] As of 2007, the market size was estimated to be $75 billion, and spending is expected to continue to increase substantially through 2012.[215] Although biopharmaceuticals are nowhere near the peak of their development, they are already expensive, with some biologics costing approximately $100,000 per year. Furthermore, research by the American Association of Retired Persons (AARP) has shown that prices of these biopharmaceuticals are rising at a rate greater than both inflation and the prices of other prescription drugs.[216]

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.[217] 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.[218]

A 2008 AARP watchdog report suggests that the wholesale price of specialty drugs rose 8.7 percent during the course of 2007, while the average market price of those drugs rose 42.9 percent between December 2003 and December 2007. In contrast, nonspecialty branded drugs rose only 7.4 percent, and the price of generics fell 9.6 percent.[219] 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 their patients use cheaper alternatives before approving the use of an expensive biologic option.[220]

Supporting 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.[221] Based on the Congressional Budget Office's (CBO's) 2008 estimates, proposed legislation made possible by presidential budget provisions could save the federal government $6.6 billion in ten years and ensure biotech companies twelve years of market exclusivity for new drug development.[222]

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.[223] Radiation therapy uses high energy light beams or charged particles to stunt the proliferation of cancer cells, which are very susceptible to damage from radiation due to rapid proliferation and an inability to regenerate.[224] 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 and over the course of multiple sessions.[225] Radiation may be administered alone or simultaneously with chemotherapy either prior to, or in the absence of surgery. Approximately 50 to 60 percent of cancer patients are treated using radiation at some point during their disease.[226] The continuous development of increasingly sophisticated imaging technologies and procedures has resulted in earlier diagnoses and improved outcomes for patients through radiation therapies.[227]

Devices

Technology is the leading driver of radiation therapy's competitive market.[228] 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.[229] As radiation therapy has become one of the dominant methods of cancer treatment, demand is likely to increase as the population ages.[230]

Linear Accelerators

The **linear accelerator (LINAC)** is the device most commonly used in external beam radiation therapy treatments (see *Procedures*) for patients with cancer. [231] 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. A portion of these x-rays are collected and then shaped to form a beam that matches the patient's tumor. [232] The beam emanates from a gantry that rotates around the patient. During this process, the patient lies on a movable treatment couch.[233] 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 include multileaf collimators, they can be used in intensity modulated radiation therapy.[234] However, without the necessary modifications, LINAC systems simply are machines used for stereotactic radiosurgery.[235] A new linear accelerator can cost anywhere from $1.5 million to $3 million.[236]

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.[237] 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.[238]

Procedures

External beam radiation therapy (EBT) involves the administration of high-energy x-ray beams to kill cancer cells and treat tumors.[239] 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.[240] 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.[241] 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.[242] 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.[243]

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.[244] Alternately, 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.[245]

A 2004 survey of U.S. radiation oncologists indicated that 73 percent of respondents used IMRT, compared with 32 percent in 2002. Of those practitioners who had not used IMRT as of the 2002 survey release, 65 percent had begun using IMRT by 2004. Of all survey participants, 81 percent had used IMRT to enable the administration of high-dose radiation to their patients.[246] In recent years, market studies have shown that EBT has fallen short of IMRT, whose market growth may be attributed to higher dose capabilities with less damage.[247]

Stereotactic Radiosurgery

Stereotactic radiosurgery is a nonsurgical procedure involving the single, high-dose delivery of targeted gamma-ray or x-ray beams used to treat different parts of the body. It serves as an increasingly preferred alternative to invasive surgery for soft tissue tumors (for example, brain tumors).[248] 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. Linear accelerators, proton beams or heavy-charged particle beams, and gamma knives are all used to perform stereotactic procedures.[249]

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.[250] 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.[251] 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, and 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.[252]

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.[253] 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.[254]

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.[255] 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 postoperative hospital stays, lower hospital costs, and decrease patient morbidity and mortality.[256] Further, effective use of the da Vinci system reduces total operative time while minimizing blood loss.[257]

The da Vinci System revolutionized minimally invasive surgery by overcoming the limitations of both traditional surgical procedures and conventionally implemented noninvasive laparoscopic technology.

"Robotic Surgery," By Joan Trombetti, DotMed News, January 7, 2009, www.dotmed.com/news/story/7463 (accessed July 6, 2009).

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.[258]

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.[259]

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.[260] Further, the system requires a significant amount of space—something that many hospitals and facilities cannot spare.[261]

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 $6 billion in 2005; it is expected to reach $18 billion by 2015. Laparoscopic technology represents 25 percent of the market, mainly utilized in abdominal and pelvic procedures, which accounts for $600 million per year.[262]

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.[263] As of September 2008, 1,032 da Vinci units had been purchased internationally, 776 of which belong to facilities in the United States. In the third quarter of 2008 alone, ninety-one systems were sold, and Intuitive Surgical observed a 50 percent growth in its revenue to $236 million. 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.[264]

The CBO's 2007 report, *The Long-Term Outlook for Healthcare Spending*, predicts that the United States will see a rise in total healthcare spending from 16 percent of GDP as of March 2007 to 25 percent in 2025, 37 percent in 2050, and 49 percent in 2082.[265] These projections 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 out-dated and risky techniques with less invasive, yet more expensive, alternatives. This ongoing development of new technologies undoubtedly contributes to the role of the United States as the global leader in healthcare expenditures.[266]

According to the National Center of Health Statistics, a marked increase of inpatient elderly care has been seen in the past forty years, and the aging demographic does not suggest that this trend is slowing down in the near future. In 2006, 38 percent of the inpatient population was older than sixty-five, and 24 percent was older than seventy-five, as compared with 20 percent and 9 percent, respectively, in 1970.[267]

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.[268] 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. For example, researchers

have found a gradual annual increase in the number of operational robots in the United States (approximately 400), with 25 percent of all cardiac surgical programs having procured a robot and performing approximately 1,700 robotic or robotically assisted surgeries annually. However, only a handful of institutions are performing the majority of these surgeries. 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.[269]

A "tortuous learning curve" paired with economic barriers to use necessarily indicate that surgeons proficient in robotic surgical procedures are scarce; however, surgeons and other medical professionals agree that this is bound to change.[270] 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.[271] Upon approving the da Vinci robot for cardiac procedures, the FDA mandated training of all surgical teams and professionals intending to use the product.[272] 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.[273] As more institutions and surgical teams follow in their footsteps, a new tier of surgical competition will lead to different expectations in medical care.

Regulatory and Reimbursement

Although each insurance company differs in what procedures it reimburses, Medicare covers all laparoscopic and thorascopic procedures.[274] Currently, reimbursement for procedures that use robotic technologies is limited to the agreed-upon reimbursement for the baseline procedure.[275] 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.[276]

Home Health Technology

Home care patients represented approximately 2.5 percent of the U.S. population as of July 1, 2000.[277] In 2006, 2.9 million people reportedly used home health services, an increase from 2.6 and 2.8 million in 2003 and 2004, respectively.[278] 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 54 million (a 54 percent increase), accounting for 16 percent of the total population.[279] Approximately 69 percent of those receiving home care services are older than age sixty-five.[280] In addition, the growing baby boomer population will continue to inflate the number of candidates for home health care when they become eligible for Medicare beginning in 2011.[281]

Trends in Home Infusion Therapy

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.[282] By 2030, it is expected that approximately 20 percent of Americans will be older than the age of sixty-five, which will lead to an increase in the demand for home- and community-based services.[283] One of the most common services received at home is infusion therapy, with about 4,000 regional providers reported in 2005.[284]

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 (see chapter 2, *Facility-Based Reimbursement Rates* for further discussion of the PPS and DRG payment system). 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 percent in 1981 to 17.9 percent in 1985.[285]

The decrease of traditional inpatient utilization led to a virtual explosion of healthcare services in other areas, both on the hospital campus as well as 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.[286] This change in service delivery location significantly altered beneficiary access to care. As of 2008, approximately 99 percent of beneficiaries were located in an area for which at least one home health agency provided service, and 97 percent had access to services provided by two or more home health agencies.[287] Despite adequate patient access to home health services, the number of providers continues to grow, exceeding the growth rate in Medicare enrollees.[288] As of 2007, there existed more than 9,200 active home health agencies that participated in the Medicare payments program for home health care.[289]

The home infusion therapy market is comprised of approximately 3,000 to 4,000 national, regional, and local providers, with the majority operating primarily in either local or regional markets. Specifically, approximately one third are local or individually owned businesses, another third are hospital-based providers, and the remaining third are national providers.[290]

Regulatory and Reimbursement

Medicare remains the largest single payor of home healthcare services, paying for 37 percent of all home health expenditures in 2006, although private insurance represented a small portion of home health payments. "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.[291] In fact, total out-of-pocket spending declined from 14 percent in 2001[292] to 10 percent in 2006.[293] However, it is estimated that the rate of out-of-pocket expenditures will increase to 6 percent by 2017. This would bring parity to the ratio of out-of-pocket spending to private health insurance spending.[294]

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.[295] Due to regulatory actions in 2008, home health reimbursement was cut 2.5 percent, and an anticipated 12 percent cut in spending is projected through 2012.[296]

Industry stakeholders and proponents of home infusion therapy continue to work with CMS to improve coverage and payment policies.[297] Pharmacy experts claim that infusion therapy is a less risky market for reimbursement changes than other home healthcare services.[298] According to a 2008 "Market Watch: Home Infusion Therapy and Specialty Pharmacy Services" industry report published by The Braff Group, reimbursement for home infusion therapy is expected to remain relatively stable, despite the projected decreases in durable medical equipment and home health agency reimbursement.[299]

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.[300] Additionally, in 2006 and 2007, the House of Representatives unsuccessfully proposed HR 5791 and HR 2567.[301]

On January 15, 2009, Eliot Engel (D-NY) proposed The Medicare Home Infusion Therapy Coverage Act of 2009 (HR 574). The bill proposed that Part D coverage of home infusion services include equipment, supplies, and professional services.[302] Experts harbor mixed opinions on the fate of this bill based on the current administration's overburdened agenda, even though this economic justifications fare in favor of passing the bill, which was still in the House Ways and Means Committee as of March 2010.[303]

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. 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.

Key Sources

Key Source	Description	Citation	Hyperlink
"Electronic Health Records Overview"	Overview of EHR	"Electronic Health Records Overview" National Institute 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 a reasoning for CPOE implementation.	"To Err is Human: Building a Safer Health System" Institute of Medicine, Nov. 1999, p. 1.	n/a

(continued)

Key Source	Description	Citation	Hyperlink
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 health care 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/images/jan09cpoerport/cpoe_issue_paper.htm (accessed June 22, 2009), 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's 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 (Nov./Dec. 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, Feb. 2008.	n/a
Telemedicine Information Exchange	A good source for up to date news about telemedicine and telehealth.	http://tie.telemed.org	http://tie.telemed.org
"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. 769–76.	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.	n/a

Key Source	Description	Citation	Hyperlink
"Report to the Congress: Home Health Services"	MedPac report.	"Report to the Congress: Home Health Services", MedPac, March 2008, p. 171.	n/a
National Institutes of Health	A resource for stem cell research.	"Stem Cell Information: Stem Cell Basics," by the National Institutes of Health resource for stem cell research, April 28, 2009, http://stemcells.nih.gov/info/basics/ (accessed June 29, 2009).	http://stemcells.nih.gov

Associations

Type of Association	Professional Association	Description	Source	Hyperlink	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 November 25, 2009).	www.irsa.org	The International Radiosurgery Association 3002 N. 2nd Street Harrisburg, PA 17110 Phone: 717-260-9808
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, 2010, www.rsna.org/About/whoswho/staff-departments.cfm (accessed January 20, 2010).	www.rsna.org	Radiological Society of North America, Inc. 820 Jorie Blvd. Oak Brook, IL 60523 Phone: 630-571-2670 800-381-6660 Fax: 630-571-7837
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.	"About ATA" American Telemedicine Association, www.americantelemed.org/i4a/pages/index.cfm?pageID=3281 (accessed November 24, 2009).	www.americantelemed.org	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

Endnotes

1 Health, United States, 2008," By National Center for Disease Statistics, Centers for Disease Control and Prevention, U.S. Department of Health and Human Services, 2009, p. 3, 4.

2 Studies Show Electronic Medical Records Make Financial Sense," By Stacy Lawrence, Sept. 14, 2005, CIO Insight, (Aug. 2008), available at http://www.cioinsight.com/c/a/Health-Care/Studies-Show-Electronic-Medical-Records-Make-Financial-Sense/; "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 07/06/2009).

3 2006 National Hospital Discharge Survey," By Carol J. DeFrances et al., National Center for Health Statistics, Centers for Disease Control and Prevention, U.S. Department of Health and Human Services, National Health Statistics Reports, No. 5, June 30, 2008, p. 1.

4 Electronic Health Record" Health Information Management System Society, http://www.himss.org/ASP/topics_ehr.asp (Accessed 6/22/09).

5 *Ibid.*

6 *Ibid.*

7 *Ibid.*

8 *Ibid.*

9 Electronic Health Records Overview" National Institute of Health: National Center for Research Resources, April 2006, p. 2.

10 *Ibid.*

11 "Electronic Medical Record/Electronic Health Record Use by Office-based Physicians: United States, 2008 and Preliminary 2009", by Chun-Ju Hsiao et al., Centers for Disease Control and Prevention, National Center for Health Statistics, December 2009, p. 4.

12 "Benefits," By American Medical Association, 2008, http://www.ama-assn.org/ama/pub/category/16756.html. (Accessed 8/13/2008).

13 "Can Electronic Medical Record Systems Transform Healthcare? Potential Health Benefits, Savings, and Costs," By Richard Hillestad et al., Health Affairs, Vol. 24, No. 5, p. 1108-1110.

14 "Can Electronic Medical Record Systems Transform Health Care? Potential Health Benefits, Savings, and Costs," Health Affairs, Vol. 24 No. 5 (2005). p. 1103-1117.

15 "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.

16 "Better Technology...Better Patient Care Since 1994," ChartLogic Products, 2008, http://www.chartlogic.com/products.php.

17 "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.

18 "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.

19 *Ibid.*

20 "GEMMS Mid-Carolina Cardiology," Future Healthcare, 2006, http://www.futurehealthcareus.com/?mc=gemms-mid-carolina&page=card-viewarticle (Accessed 9/22/2009).

21 "The Benefits of Evidence Based Medicine in EHR Systems," By Tom Doerr, EHR Scope, Spring 2008.

22 "GEMMS Mid-Carolina Cardiology," Future Healthcare, 2006, http://www.futurehealthcareus.com/?mc=gemms-mid-carolina&page=card-viewarticle (Accessed 9/22/2009) (Cardiology practice, MMC, stated that since the implementation of an EMR system, their rejection rate for Medicare claims has been reduced to .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 8/13/2009) (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," By Clear Technologies, 2004, http://www.comparecrm.com/crm-vendors/c2crm/case-studies/csant.pdf (Accessed 8/13/2009)(stating that a cardiology practice in Texas has seen substantial improvements in Medicare & Medicaid reimbursements since implementation of EMR).

23 "Electronic Medical Record (EMR) Proves Profitable for Multispecialty Practice," By Jonathan S. Batchelor, Imaging Technology News, July/Aug. 2006, http://www.itnonline.net/node/28160/ (Accessed 8/13/2009) (stating that Affinity saved $3000 in chart costs for 417 patients in the first seven weeks, and ultimately allowed for staff reduction resulting in a salaries and benefits savings of $202,000. Further, EMR has allowed physicians to correctly code for each encounter, which has resulted in a net office charge revenue increase of 9.2 percent, or $2.5 million).

24 "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.

25 "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. 398-400.; "Productivity and Cost Implications of Implementing Electronic Medical Records Into a Ambulatory Surgical Subspecialty Clinical," By M. Patil, L. Puril and C. M. Gonzalez, Urology, Vol. 71, No. 2 (2008) p. 173.

26 "Healthcare and the American Recovery and Reinvestment Act," By Robert Steinbrook, The New England Journal of Medicine, Vol. 360 No. 11 (March 12, 2009), p. 1.

27 "Healthcare and the American Recovery and Reinvestment Act," By Robert Steinbrook, The New England Journal of Medicine, Vol. 360 No. 11 (March 12, 2009), p. 1, 3.

28 "Department of Health and Human Services," President Obama's 2010 Budget, The White House, p. 68, http://www.whitehouse.gov/omb/assets/fy2010_new_era/Department_of_Health_and_Human_Services1.pdf.

29 "Medicare and Medicaid Programs; Electronic Health Record Incentive Program; Proposed Rule", Federal Register, Vol. 75, No. 8 (January 13, 2010), p. 1846.

30 "Medicare and Medicaid Programs; Electronic Health Record Incentive Program; Proposed Rule", Federal Register, Vol. 75, No. 8 (January 13, 2010), p. 1850.

31 "Medicare and Medicaid Programs; Electronic Health Record Incentive Program; Proposed Rule", Federal Register, Vol. 75, No. 8 (January 13, 2010), p. 1851.

32 "Medicare and Medicaid Programs; Electronic Health Record Incentive Program; Proposed Rule", Federal Register, Vol. 75, No. 8 (January 13, 2010), p. 1848, 1851.

33 "Electronic Health Records Overview" By National Institute of Health: National Center for Research Resources, April 2006, p. 7.

34 "Welcome to CPOE.org" Oregon Health and Science University, http://www.ohsu.edu/academic/dmice/research/cpoe/index.php (Accessed 6/22/09).

35 "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.

36 "Fact Sheet: Computerized Physician Order Entry" By The Leapfrog Group, March 3, 2009; "To Err is Human: Building a Safer Health System" By Institute of Medicine, Nov. 1999, p. 1.

37 "Leapfrog Hospital Survey Results" By The Leapfrog Group, 2008, p. 3.

38 "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, Feb. 2008, p. 14.

39 "Leapfrog Hospital Survey Results" By The Leapfrog Group, 2008, p. 3.

40 "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" By Institute of Medicine, Nov. 1999, p. 1.

41 "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.

42 "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.

43 "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).

44 "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.

45 "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. 3; "Revolutionizing Health Care Through Information Technology" By President's Information Technology Advisory Committee, Report to the President, (June 2004) p. 10.

46 "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 (Nov./Dec. 2005), p. 1654.

47 "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 (Nov./Dec. 2005) p. 1656, 1659, 1660.

48 "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 (Nov./Dec. 2005) p. 1658.

49 "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 (Nov./Dec. 2005) p. 1660.

50 "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 (Nov./Dec. 2005) p. 201, 1661.

51 "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 (Nov./Dec. 2005) p. 1662.

52 "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, Feb. 2008, p. 15.

53 "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.

54 "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, Feb. 2008, p. 25.

55 "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, Feb. 2008, p. 8.

56 "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.

57 "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.

58 "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.

59 "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.

60 "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.

61 "Information Technology for Healthcare Quality Act" S.1223, Introduced (June 9, 1005); "The Future of Healthcare—Granting Access to Innovation in America Act" H.R.3607, Introduced (July 28, 2005).

62 "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).

63 "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, Feb. 2008, p. 37.

64 "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).

65 *Ibid.*

66 "CPOE: It Don't Come Easy" By Howard J. Anderson, Health Data Management, Vol. 17, No. 1 (Jan. 2009) p. 19.

67 "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.

68 "CPOE: It Don't Come Easy" By Howard J. Anderson, Health Data Management, Vol. 17, No. 1 (Jan. 2009) p. 20.

69 "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 (Jan. 3, 2006) p. 52.

70 "Principles for a Successful Computerized Physician Order Entry Implementation" By Joan S. Ash et al, American Medical Informatics Symposium Proceedings, 2003, p. 23.

71 "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).

72 *Ibid.*

73 "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.

74 "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.

75 "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.

76 "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.

77 "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, (July 2, 2008) p. 199.

78 "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 (Sept. / Oct. 2006) p. 552.

79 "Minimization of Medication-Related Errors" Health and Safety Code Section 1339.63, California Code, Sept. 2000.

80 "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.

81 "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" By Senate of the United States, S.890, April 23, 2009.

82 "Patient Safety and Quality Improvement Act of 2005" Public Law 109-41, 109th Congress, Sec 921(j)(1), July 29, 2005.

83 "Medicare and Medicaid Programs; Hospital Conditions of Participation: Quality Assessment and Performance Improvement" By Centers for Medicare and Medicaid Services, Department of Health and Human Services, Federal Register, Vol. 68, No. 16, Jan. 24, 2003, p. 3435.

84 "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.

85 "Massachusetts Hospitals Should Adopt CPOE Systems, Group Says" iHealth Beat, Feb. 15, 2008, http://www.ihealthbeat.org/Articles/2008/2/15/Massachusetts-Hospitals-Should-Adopt-CPOE-Systems-Groups-Say.aspx (Accessed 6/26/09).

86 "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. 12.

87 "Outsourcing of Healthcare Services: Issues & a Framework for Success," Ram Misra, et. al., Journal of Information Technology and Applications, Vol. 1, No. 2, p. 79-88 (Sept. 2006).

88 *Ibid.*

89 "Offshore Outsourcing: Current and Future Effects on American IT Industry," Laura L. Pfannenstein and Ray J. Tsai, Information Systems Management Journal, p. 79 (Fall 2004).

90 "Outsourcing of Healthcare Services: Issues & a Framework for Success," Ram Misra, et. al., Journal of Information Technology and Applications, Vol. 1, No. 2, p. 79-88 (Sept. 2006).

91 "HHS Strengthens HIPAA Enforcement," News Release, U.S. Department of Health and Human Services, Oct. 30, 2009, available at http://www.hhs.gov/news/press/2009pres/10/20091030a.html (accessed 11/20/09).

92 "HIPAA and the HITECH Act: Know the Level of Penalties," HIPAA Weekly Advisor, Mar. 16, 2009, available at http://www.hcpro.com/print/HIM-229707-866/HIPAA-and-the-HITECH-Act-Know-the-level-of-penalties.html (Accessed 11/20/09).

93 "HHS Strengthens HIPAA Enforcement," News Release, U.S. Department of Health and Human Services, Oct. 30, 2009, available at http://www.hhs.gov/news/press/2009pres/10/20091030a.html (Accessed 11/20/09).

94 "Telemedicine 101: A Brief History of Telemedicine" By Nancy Brown, Telemedicine Information Exchange, American Telemedicine Association, http://tie.telemed.org, May 30, 1995.

95 "Telemedicine Defined?" American Telemedicine Association, http:// www.@ americantelemed.org/i4a/pagees/index.cfm?pageid=3333 (Accessed 6/30/09).

96 "Chapter IV: Medicaid's Role in Reimbursement for Telehealth," Evolution & Summative Evaluation of the Alaska Federal Health Care Access Network Telemedicine Project, November 2004, http://www.alaska.edu/health/downloads/Telemed/08.Ch4.pdf (Accessed September 29, 2006), p. 119.

97 "What is Telemedicine and Telehealth?" American Telemedicine Association, info@ americantelemed.org (Accessed 6/30/09).

98 *Ibid.*

99 *Ibid.*

100 "Telemedicine 101: Telemedicine Coming of Age" By Nancy Brown, Telemedicine Information Exchange, American Telemedicine Association, http://tie.telemed.org, Jan. 13, 2005.

101 *Ibid.*

102 "State Telehealth News" Telemedicine Information Exchange, April 30, 2009, http://tie.telemed.org/funding/news.asp (Accessed 7/1/09), p. 2.

103 "State Telehealth News" Telemedicine Information Exchange, April 30, 2009, http://tie.telemed.org/funding/news.asp (Accessed 7/1/09), p. 5.

104 "Who are We?" Night Hospitalist Company, http://wwwnighthospitalist.com/nhc.php?pageID=1 (Accessed 7/2/09).

105 "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).

106 "What Works: Healing the Healthcare Staffing Shortage" PricewaterhouseCoopers' By Health Research Institute, 2007, p. 27.

107 "What Works: Healing the Healthcare Staffing Shortage" PricewaterhouseCoopers' By Health Research Institute, 2007, p. iii.

108 "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).

109 "Telemedicine Defined?" American Telemedicine Association, http://www.@ americantelemed.org/i4a/pagees /index.cfm?pageid=3333 (Accessed 6/30/09).

110 "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 9/24/2009).

111 "The American Recovery and Reinvestment Act of 2009: Summary of Key Health Information Technology Provisions" Healthcare Information and Management Systems Society, Feb. 18, 2009.

112 "New Legislation Would Increase Funding for Telemedicine," By Telemedicine Information Exchange, April 30, 2009, http://tie.telemed.org/labels/funding.html (Accessed 11/19/09).

113 "FCC Update on Rural Healthcare Pilot Program Initiative," By Federal Communications Commission, April 16, 2009, http://hraunfoss.fcc.gov/edocs_public/attachmatch/DOC-290141A1.pdf (Accessed 2/2/10).

114 "Interstate Licensure of Telemedicine Practitioners" By Glenn W. Wachter, Telemedicine Information Exchange, March 10,2000, updated By TIE on Nov. 15, 2006.

115 "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).

116 "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 Nov. 15, 2006, http://tie.telemed.org/articles/article.asp?path=article&article=interstateLicensure_gw_tie0 (Accessed 7/1/09).

117 *Ibid.*

118 *Ibid.*

119 *Ibid.*

120 *Ibid.*

121 "Nurse Licensure Compact" Nurse Licensure Compact Administration, National Council of State Boards of Nursing, https://www.ncsbn.org/nlc.htm (Accessed 7/2/09).

122 "JCAHO Published New Hospital Credentialing Standards for Telemedicine" Mondaq Business Briefing, Nov. 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, Feb. 2001, http://www.hrsa.gov/telehealth/pubs/hippa.htm (Accessed 11/19/09).

123 "Existing Requirements for Telemedicine Practitioners Explained" Joint Commission Perspectives, Feb. 2003.

124 "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 7/1/2009); "Existing Requirements for Telemedicine Practitioners Explained" Joint Commission Perspectives, Feb. 2003; "JCAHO Published New Hospital Credentialing Standards for Telemedicine" Mondaq Business Briefing, Nov. 5 2003, http://www.thefreelibrary.com/_/print/PrintArticle.aspx?id=109771648 (Accessed 7/1/09).

125 "Existing Requirements for Telemedicine Practitioners Explained" Joint Commission Perspectives, Feb. 2003.

126 "JCAHO Published New Hospital Credentialing Standards for Telemedicine" Mondaq Business Briefing, Nov. 5 2003, http://www.thefreelibrary.com/_/print/PrintArticle.aspx?id=109771648 (Accessed 7/1/09).

127 "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 7/1/2009).

128 "Medicare Telehealth Enhancement Act of 2009", 111th Congress, Bill H.R. 2068, introduced April 23, 2009; "Telemedicine Boosts Access to Needed Care" By Robert J. Waters, Roll Call, sponsored By Congress.org, June 8, 2009.

129 "The State of Reimbursement in the U.S." Telemedicine Information Exchange, Updated Nov. 15, 2006, http://www.tie.telemed.org/legal/state_data.asp?type=reimburse (Accessed 7/1/09).

130 *Ibid.*

131 "About Private Payer Survey" American Telemedicine Association, 2003, http://www.amdtelemedicine.com/private_payor/about_survey.html (Accessed 6/30/09).

132 "The State of Medicaid Reimbursement in the U.S." Telemedicine Information Exchange, Law and Policy, http://tie.telemed.org/legal/state_data.asp?type=medicaid (Accessed 7/1/09).

133 "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 and Medicaid Services, Pub 100-04, Nov. 14, 2008.

134 "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 and Medicaid Services, Pub 100-04, Nov. 14, 2008.

135 "The Era of 'Omics Ulimited," By Raj P. Kandpal, Beatrice Saviola, and Jeffrey Felton, BioTechniques, Vol.46 (April 2009) p. 351-355; "All About the Human Genome Project," By the National Human Genome Research Institute, November 7, 2008, http://www.genome.gov/10001772 (Accessed 06/29/2009).

136 "Drug Deals Dominate M&A: Biotech and Pharma Outspend All Other Sectors," By the Healthcare M&A Monthly, Vol. 14 Issue 6 (June 2009) p. 1.

137 "Issues in Genetics and Health," By the National Human Genome Research Institute, February 23, 2009, http://www.genome.gov/10001740 (Accessed 06/29/2009).

138 "Overview of the Division of Intramural Research," National Human Genome Research Institute, August 27, 2009, http://www.genome.gov/10001634 (Accessed 11/25/09).

139 "Stem Cell Information: Stem Cell Basics," By the National Institutes of Health Resource for Stem Cell Research, April 28, 2009, http://stemcells.nih.gov/info/basics/ (Accessed 06/29/2009).

140 "Geron Receives FDA Clearance to Begin World's First Human Clinical Trial of Embryonic Stem Cell-Based Therapy," By Geron, Visionary Therapeutics, January 23, 2009, http://www.geron.com/media/pressview.aspx?id=1148 (Accessed 07/01/2009).

141 "Stem Cell Information: Stem Cell Basics," By the National Institutes of Health Resource for Stem Cell Research, April 28, 2009, http://stemcells.nih.gov/info/basics/ (Accessed 06/29/2009).

142 "The Era of 'Omics Unlimited," By Raj P. Kandpal, Beatrice Saviola, and Jeffrey Felton, BioTechniques, Vol 46, April 2009, p. 351. "All About the Human Genome Project," By the National Human Genome Research Institute, November 7, 2008, http://www.genome.gov/10001772 (Accessed 06/29/2009).

143 "The Era of 'Omics Unlimited," By Raj P. Kandpal, Beatrice Saviola, and Jeffrey Felton, BioTechniques, Vol 46, April 2009, p. 351-355; "All About the Human Genome Project," By the National Human Genome Research Institute, November 7, 2008, http://www.genome.gov/10001772 (Accessed 06/29/2009).

144 "Proteomics—Technologies, Markets, and Companies," By LeadDiscovery, 1999, https://www.leaddiscovery.co.uk/registration/ (Accessed 07/01/2009).

145 "Biomarket Trends: Pharmaceutical Industry Undergoing Transformation," 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).

146 "The Molecular Diagnostics Industry Today," By Harry Glorikan, Drug Discovery & Development, Vol. 9, No. 9 (September 2007) p. 68.

147 "Proteomics—Technologies, Markets, and Companies," By LeadDiscovery, 1999, https://www.leaddiscovery.co.uk/registration/ (Accessed 07/01/2009).

148 *Ibid.*

149 "The Molecular Diagnostics Industry Today," By Harry Glorikan, Drug Discovery & Development, Vol. 9, No. 9 (September 2007) p. 68.

150 "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 07/06/2009).

151 *Ibid.*

152 "The Molecular Diagnostics Industry Today," By Harry Glorikan, Drug Discovery & Development, Vol. 9, No. 9, September 2007, p. 68; "Proteomics—Technologies, Markets, and Companies," By LeadDiscovery, 1999, https://www.leaddiscovery.co.uk/registration/ (Accessed 07/01/2009).

153 "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 07/06/2009).

154 "FDA Regulation of Molecular Diagnostics," By Ken Powell, Gehrson Lehrman Group, February 6, 2009, http://www.glgroup.com/NewsWatchPrefs/Print.aspx?pid=29010 (Accessed 07/06/2009).

155 *Ibid.*

156 "Medicare Needs to Get With the Times" The Burrill Report, Burrill and Company, 2009.

157 "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.

158 *Ibid.*

159 *Ibid.*

160 *Ibid.*

161 "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 06/29/2009).

162 "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.

163 "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 06/29/2009).

164 *Ibid.*

165 "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 06/29/2009).

166 "Latest IMV Market Report Shows Continued Demand for High Field MRI Systems," Gale Group, Business Wire (2007), http://www.imvinfo.com/user/documents/content_documents/nws_rad/MS_MRI_PressRelease.pdf (Accessed 06/29/2009).

167 "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.

168 "Running the Numbers," Medical Imaging, March 2007, http://www.imagingeconomics.com/issues/articles/MI_2007-03_04.asp, (Accessed 11/30/09).

169 "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.

170 "CT Scanning: Patterns of Use and Dose," F.A. Mettler, P.W. Weist, J.A. Locken, C.A. Kelsey, Journal of Radiological Protection Vol. 20, No. 4, (2000), p. 347-348.

171 "Nationwide Evaluation of X-Ray Trends: 2000 Computed Tomography," Conference of Radiation Control Program Directors, Inc. and the Food and Drug Administration, 04/06, http://www.crcpd.org/Pubs/NextTrifolds/NEXT2000CT_T.pdf (Accessed 06/22/09).

172 "CT Shines as Cardiac Triage Tool in the ER," By James Brice, Diagnosticimaging.com, November 2005, http://www.diagnosticimaging.com/showArticle.jhtml?articleID=174402997 (Accessed 7/14/2006).

173 "National Hospital Ambulatory Medical Care Survey: 1996 Emergency Department Summary," Linda F. McCaig and Barbara J. Stussman, Division of Health Care Statistics, National Health Statistics Reports, U.S. Department of Health and Human Services, Centers for Disease Control and Prevention, National Center for Health Statistics, No. 7, December 17, 1997; "National Hospital Ambulatory Medical Care Survey: 2006 Emergency Department Summary," By Stephen R. Pitts, Richard W. Niska, Jianmin Xu, and Catharine W. Burt, Division of Health Care Statistics, National Health Statistics Reports, U.S. Department of Health and Human Services, Centers for Disease Control and Prevention, National Center for Health Statistics, No. 7, August 6, 2008.

174 "Dynamic Volume: A Macroevolution?" By Jagat Narula, Radiology Today, Vol. 9, No. 23 (November 17, 2008) p. 10.

175 "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.

176 "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. 5; "Dynamic Volume: A Macroevolution?" By Jagat Narula, Radiology Today, Vol. 9, No. 23 (November 17, 2008) p. 10; "Cardiac CT: 64-Slice and Beyond," Clinical Advancements in Volumetric CT, Toshiba Medical Systems, February 2006.

177 "CT Flexes Muscle in Coronary Disease Detection," By James Brice, Diagnosticimaging.com, November 2005, http://www.diagnosticimaging.com/showArticle.jhtml?articleID=174402602 (Accessed 7/14/2006).

178 "State-of-the-art Cardiac CT Prompts Better, Quicker, Diagnosis and Shorter Hospital Stays," Cardiovascular Business, March/April. p. 22-2 ; "Cardiac CT for Calcium Scoring" By Radiological Society of North America, Oct. 1, 2008, http://www.radiologyinfo.org/en/info.cfm?PG=ct_calscoring (Accessed 4/30/09).

179 "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 (2005) p. 415-422.

180 "CT Beyond 64 Slices: 'Dynamic Volume CT' Promises to Streamline Workflow, Improve the Bottom Line," By Tony DeFrance, Cardiovascular Business, January/February 2009, [January 9, 2009], p. 24.

181 "Dynamic Volume CT: A Macroevolution?" By Jagat Narula, Radiology Today, Vol. 9, No. 23 (November 17, 2008) p. 10.

182 "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 2/10/2009).

183 "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).

184 "Nuclear Medicine Usage, Grows, Led By PET," IMV Medical Information Inc. Newsline, Vol. 47, No. 10 (2006) p. 13N.

185 "PET Versus SPECT: Strengths, Limitations, and Challenges," By Arman Rahmim and HabibZaidi, Nuclear Medicine Communications, Vol. 29 (2008) p. 193-207.

186 *Ibid.*

187 "SPECT vs. PET, Which is Best?" By Dave Fornell, October 2008, http://www.dicardiology.net/node/28668 (Accessed 02/10/2009).

188 "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).

189 "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).

190 "Great Expectations and the Saga of SPECT-CT," By Greg Freiherr, Diagnostic Imaging, June 25, 2009, http://www.diagnosticimaging.com/display/article/113619/1425226?CID=rss (Accessed 06/29/2009).

191 *Ibid.*

192 "PET versus SPECT: strengths, limitations, and challenges," By Arman Rahmim and HabibZaidi, Nuclear Medicine Communications, Vol. 29 (2008) p. 193.

193 "Great Expectations and the Saga of SPECT-CT," By Greg Freiherr, Diagnostic Imaging, June 25, 2009, http://www.diagnosticimaging.com/display/article/113619/1425226?CID=rss (Accessed on: 06/29/2009).

194 *Ibid.*

195 "Teleradiology: New players, high stakes create capital opportunity," By John C. Hayes, DiagnosticImaging, November 1m 2006, http://www.diagnosticimaging.com/display/article/113619/1193477 (Accessed 06/29/2009).

196 "DOTmed Industry Sector Report: PACS/RIS/HIS," By Barbara Kram, DOTmed Business News, March 2009, http://www.dotmed.com/news/story/8313/.

197 "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 06/29/2009).

198 "Night Hawk Swings Profit to Loss," DiagnosticImaging, May 1, 2009, http://www.diagnosticimaging.com/display/article/113619/1410494?verify=0 (Accessed 06/29/2009).

199 "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 06/29/2009).

200 "Night Hawk Swings Profit to Loss," DiagnosticImaging, May 1, 2009, http://www.diagnosticimaging.com/imaging-trends-advances/pacsweb/teleradiology/article/113619/1410494 (Accessed 06/29/2009).

201 "Teleradiology: New Players, High Stakes Create Capital Opportunity," By John C. Hayes, DiagnosticImaging, November 1m 2006, http://www.diagnosticimaging.com/display/article/113619/1193477 (Accessed 06/29/2009).

202 "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 10/1/2009).

203 "Current Good Manufacturing Practice for Positron Emission Tomography Drugs; Final Rule", Food and Drug Administration, HHS, 21 CFR Part 212, Federal Register, Vol. 74, No. 236 (December 10, 2009), p .65409, 65432-65435.

204 "Biologics," Dictionary.com, Dictionary.com, 2009, http://dictionary.reference.com/browse/biologic (Accessed 10/1/2009).

205 "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.

206 "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.

207 "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.

208 *Ibid.*

209 *Ibid.*

210 "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 06/29/2009).

211 *Ibid.*

212 "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.

213 *Ibid.*

214 "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.

215 "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 07/06/2009).

216 "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://www.aarp.org/research/ppi/ (Accessed 06/29/2009).

217 "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://www.aarp.org/research/ppi/ (Accessed 06/29/2009); "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 07/06/2009).

218 *Ibid.*

219 "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://www.aarp.org/research/ppi/ (Accessed 06/29/2009).

220 "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://www.aarp.org/research/ppi/ (Accessed 06/29/2009); "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 07/06/2009).

221 "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 06/29/2009); "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 07/06/2009).

222 "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 06/29/2009).

223 "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 06/26/2009).

224 "Radiotherapy Overview," By the International Radiosurgery Association, 2008, http://www.irsa.org/radiotherapy.html (Accessed 06/26/2009).

225 *Ibid.*

226 "Radiation Therapy," By the International Radiosurgery Association, 2008 http://www.irsa.org/radiotherapy.html (Accessed on: 06/26/2009); "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 06/26/2009).

227 "Radiotherapy Overview," By the International Radiosurgery Association, 2008, http://www.irsa.org/radiotherapy.html (Accessed 06/26/2009).

228 "DOTmed Industry Sector Report: Linear Accelerators and Simulators," By Barbara Kram, DOTmed News, November 19, 2008, http://www.dotmed.com/news/story/7013/ (Accessed 06/29/2009).

229 "IMV Reports Increased Use of Image-Guided Radiotherapy in Radiation Oncology," By Gale Group, BusinessWire, April 9, 2007, http://www.allbusiness.com/company-activities-management/sales-selling-sales/5380757-1.html (Accessed 06/29,2009).

230 "DOTmed Industry Sector Report: Linear Accelerators and Simulators," By Barbara Kram, DOTmed News, November 19, 2008, http://www.dotmed.com/news/story/7013/ (Accessed 06/29/2009).

231 *Ibid.*

232 "Linear Accelerator," By Radiological Society of North America, RadiologyInfo, June 10, 2009, http://www.radiologyinfo.org/content/therapy/linear_accelerator.htm, (Accessed 06/29/2009).

233 *Ibid.*

234 "DOTmed Industry Sector Report: Linear Accelerators and Simulators," By Barbara Kram, DOTmed News, November 19, 2008, http://www.dotmed.com/news/story/7013/ (Accessed 06/29/2009); "Linear Accelerator," By Radiological Society of North America, RadiologyInfo, June 10, 2009, http://www.radiologyinfo.org/content/therapy/linear_accelerator.htm, (Accessed 06/29/2009).

235 "DOTmed Industry Sector Report: Linear Accelerators and Simulators," By Barbara Kram, DOTmed News, November 19, 2008, http://www.dotmed.com/news/story/7013/ (Accessed 06/29/2009).

236 *Ibid.*

237 "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 06/26/2009).

238 "Gamma Knife Surgery," By the International RadioSurgery Association, irsa.org, June 10, 2009.

239 "External Beam Therapy (EBT)," By Radiological Society of North America, RadiologyInfo, June 10, 2009, http://www.radiologyinfo.org/en/info.cfm?PG=ebt (Accessed 06/26/2009).

240 *Ibid.*

241 "Proton Therapy," By Radiological Society of North America, RadiologyInfo, June 10, 2009, http://www.radiologyinfo.org/en/info.cfm?PG=protonthera (Accessed 06/26/2009).

242 *Ibid.*

243 *Ibid.*

244 "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 06/26/2009).

245 *Ibid.*

246 "Beaming and Booming: A Groundbreaking Advance for Radiation Oncology, IMRT Use is on the Rise" By Arno J. Mundt, et al., Advance News Magazines for Imaging and Oncology Administrators, Vol. 15 Issue 17 (July 1, 2005) p. 51.

247 *Ibid.*

248 "Stereotactic Radiosurgery," By Radiological Society of North America, RadiologyInfo, June 10, 2009, http://www.radiologyinfo.org/en/info.cfm?PG=stereotactic, (Accessed 06/29/2009).

249 *Ibid.*

250 "Minimally Invasive Surgery," Mayo Clinic, 2009, http://www.mayoclinic.org/minimally-invasive-surgery/ (Accessed 4/6/09).

251 "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.

252 "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 4/6/09).

253 "Minimally Invasive Surgery," Mayo Clinic, 2009, http://www.mayoclinic.org/minimally-invasive-surgery/ (Accessed 4/6/09).

254 "Robot-Assisted Surgery," Mayo Clinic, 2009, http://www.mayoclinic.org/robotic-surgery/ (Accessed 4/6/09).

255 "Robotic Surgery," By Joan Trombetti, DotMed News, January 7, 2009, http://www.dotmed.com/news/story/7463 (Accessed 07/06/2009); "Minimally Invasive and Robotic Surgery", By M.J. Mack, 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 4/6/09).

256 "Minimally Invasive and Robotic Surgery", By M.J. Mack, JAMA, Vol. 285 No.5 (2001) p. 568; "Robot-Assisted Surgery," Mayo Clinic, 2009, http://www.mayoclinic.org/robotic-surgery/ (Accessed 4/6/09).

257 "Robotics in Vascular Surgery," By Bernardo Martinez & Catherine Wiegand, The American Journal of Surgery, Vol. 188 (Supplement to October 2004) p. 58s.

258 "Endoscopic Coronary Artery Bypass Grafting with the Aid of Robotic Assisted Instruments", Didier Loulmet et al., The Journal of Thoracic and Cardiovascular Surgery, Vol. 118 (1999), p. 6.

259 "Robotic Surgery," By Joan Trombetti, DotMed News, January 7, 2009, http://www.dotmed.com/news/story/7463 (Accessed 07/06/2009).

260 "Recent Trends in Minimally Invasive Cardiac Surgery", By Alan P. Kypson, Cardiology, Vol. 107 (2007), p. 156.

261 "Robotic Technology in Surgery: Past, Present, and Future," By David B. Camarillo, Thomas M. Krummel, and J. Kenneth Salisbury, The American Journal of Surgery, Supplement to October 2004 , p. 2S-15S.

262 "Growing Trends Towards Minimally Invasive Surgery," By Sree Vidhya, November 21, 2008, http://www.frost.com/prod/servlet/market-insight-print.pag?docid=150117121 (Accessed 07/06/2009).

263 "Robotic Surgery," By Joan Trombetti, DotMed News, January 7, 2009, http://www.dotmed.com/news/story/7463 (Accessed 07/06/2009).

264 "CUREXO to Launch New Robotic Surgery Technology," By Diana Manos, Healthcare IT News, Feb. 23, 2009, http://www.healthcareitnews.com/news/curexo-launch-new-robotic-surgery-technology (Accessed 6/30/2009); "Robotic Surgery," By Joan Trombetti, DotMed News, January 7, 2009, http://www.dotmed.com/news/story/7463 (Accessed 07/06/2009).

265 "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 07/06/2009).

266 "Economics Issues in Medical Care" in "Cecil Medicine" edited By Goldman, L., Saunders, 2008, http://www.mdconsult.com.ezp.slu.edu/das/book/body/1301180599-5/826126389/1492/28.htm (Accessed April 4, 2008).

267 "2006 National Hospital Discharge Survey," By Carol J. DeFrances et al., National Center for Health Statistics, Centers for Disease Control and Prevention, U.S. Department of Health and Human Services, National Health Statistics Reports, No. 5, June 30, 2008.

268 "Economics Issues in Medical Care" in "Cecil Medicine" edited By Goldman, L., Saunders, 2008, http://www.mdconsult.com.ezp.slu.edu/das/book/body/1301180599-5/826126389/1492/28.htm (Accessed April 7, 2008).

269 "Robotic Cardiac Surgery: Time Told!", By Francis Robicsek, Journal of Thoracic Cardiovascular Surgery, Vol. 135 (2008), p. 243-246.

270 "Minimally Invasive Surgery: Continued Growth Opens New Doors," By Michelle Beaver, Surgistrategies, 2009, http://www.surgistrategies.com/articles/751feat3.html (Accessed April 7, 2008).

271 "Minimally Invasive Surgery: Continued Growth Opens New Doors," By Michelle Beaver, Surgistrategies, 2009, http://www.surgistrategies.com/articles/751feat3.html (Accessed April 7, 2008).

272 "Robotic Surgical Training in an Academic Institution," By W. Randolph Chitwood et al., Annals of Surgery, Vol. 234 No. 4 (Oct. 2001),p. 478.

273 "Building a Surgical Robotics Program" By Wiley Nifong and Randolph Chitwood, The American Journal of Surgery, Vol. 188, (2004), p. 16S.

274 "Medical Devices: National Coverage Provision" By Medicare, (2007), http://www.wpsic.com/medicare/part_b/policy/phys067.pdf (Accessed April 7, 2009).

275 "Note: The baseline procedure is denoted By HCPCS" Code S2900.

276 "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 April 7, 2009); "ASA: Robotic CABG Paint Cost-Effective Benefits for Patients" By Crystal Phend, 2008, MedPage Today, http://www.medpagetoday.com/Cardiology/CoronaryArteryDisease/9254 (Accessed April 7, 2009); "ASA: Robotic CABG Paint Cost-Effective Benefits for Patients" By Crystal Phend, 2008, MedPage Today, http://www.medpagetoday.com/Cardiology/CoronaryArteryDisease/9254 (Accessed April 7, 2009).

277 "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).

278 "MEDPAC Report to Congress: Home Health Services," Medicare Payment Policy, March 2008, p. 174.

279 "The Impact of the Aging Population on the Health Workforce in the United States: Summary of Key Findings," Bureau of Health Professions, 2006, p. 2, 4.

280 "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).

281 "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).

282 "Home Infusion Therapy" BlueCross BlueShield of Illinois, BlueCross BlueShield of Illinois, 2008 http://www.bcbsil.com/PDF/providermanual/home_infusion_therapy.pdf, (Accessed 10/2/2009).

283 "Older Americans 2004: Key Indicators of Well-Being," By Federal Interagency Forum on Aging-Related Statistics, http://www.agingstats.gov/chartbook2004/population.html (Accessed 07/21/2005).

284 "Option Care, Inc. Form 10K for Fiscal Year Ending December 31, 2005, Securities Exchange Commission, p. 8.

285 "Basic Statistics About Home Care" National Association for Home Care and Hospice, November 2001, www.nahc.org/Consumer/hcstats.html, (Accessed 6/5/03).

286 "Report to the Congress: Home Health Services", MedPac, March 2008, p. 171.

287 *Ibid.*

288 "Home Health Care Services Payment System", MedPac, October 2008, p. 1.

289 *Ibid.*

290 "Supply Chain/Logistics," By John Otrompke, Pharmaceutical Commerce, April 30, 2006, http://pharmaceuticalcommerce.com/frontEnd/main.php?idSeccion=297 (Accessed 11/19/09).

291 "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).

292 "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. 154.

293 "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).

294 *Ibid.*

295 "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.

296 Homecare and Hospice Facts and Stats," By Foundation for Hospice and Home Care, National Association for Hospice Care, 2008, http://www.nahc.org/facts/homecareStudy.html (Accessed 08/24/09).

297 "Apria Healthcare Group, Inc. Form 10K for Fiscal Year Ending December 31, 2005," Securities Exchange Commission, p. 9; "Option Care, Inc. Form 10K for Fiscal Year Ending December 31, 2005", Securities Exchange Commission, p. 9.

298 "Home Infusion Therapy and Specialty Pharmacy Services," Market Watch, The Braff Group, 2008, p. 2.

299 *Ibid.*

300 "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 05/05/2009); "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 05/05/2009).

301 "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 05/05/2009); "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 05/05/2009).

302 "H.R. 574 Medicare Home Infusion Therapy Consolidated Coverage Act of 2009," 111th Congress, January 15, 2009.

303 Economy Will Impact Pharma Changes; Follow-on Biologics May Become Reality," Specialty Pharmacy News, Vol. 6 No. 1, Atlantic Information Services (January 2009) p. 1-2; "H.R. 574: Medicare Home Infusion Therapy Coverage Act of 2009," www.govtracki.us, (Accessed 3/29/2010).

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

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. As this *Guide* goes to press, sweeping changes in federal healthcare policy have been 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 may not be 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 from the American Medical Association (AMA) and the American Hospital Association (AHA), the latter 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 and Ira Magaziner, ultimately failed to garner adequate support for passage of the Health Security Act of 1993.[2]

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—1912–1957

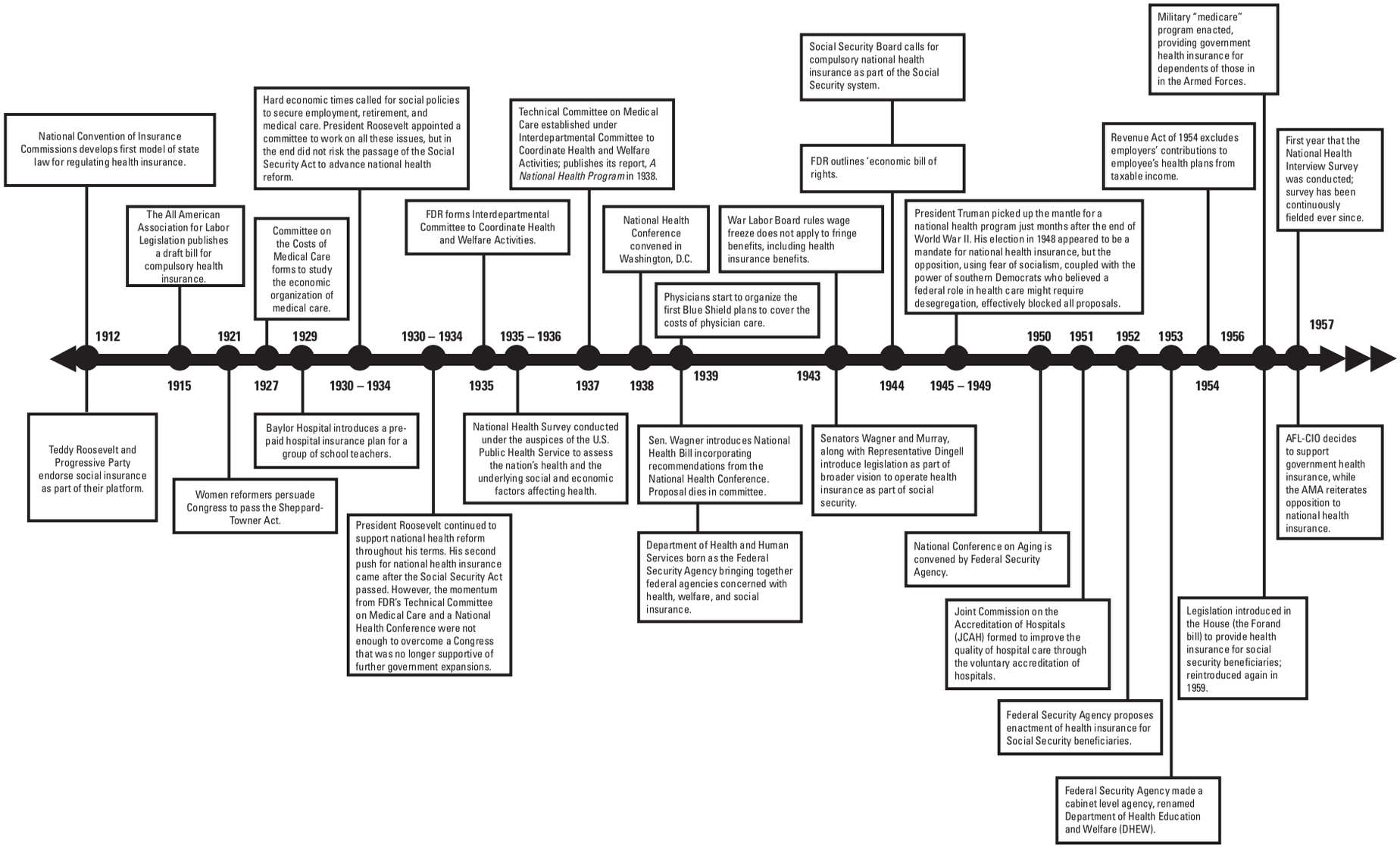
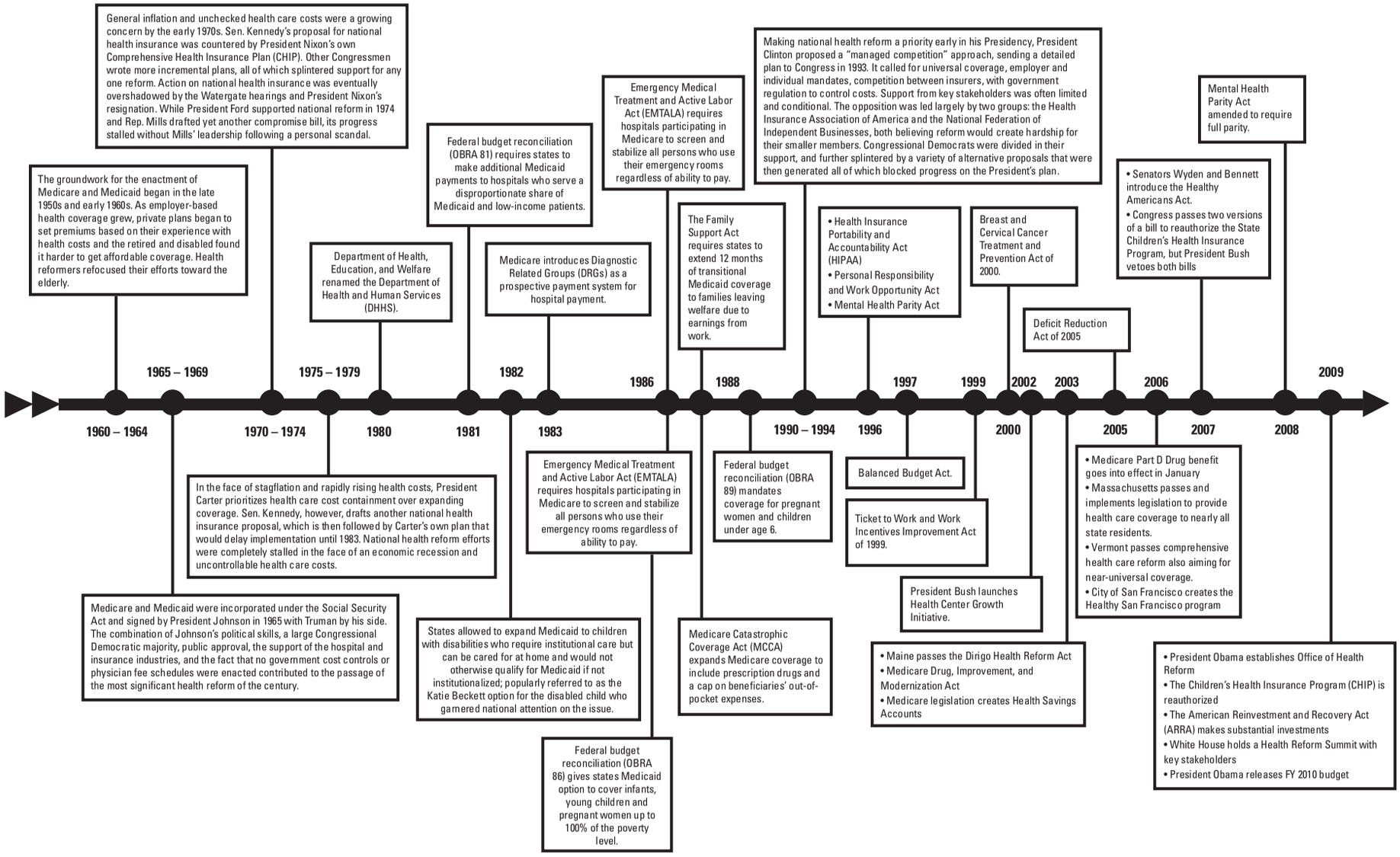


Figure 6-1: Healthcare Reform Historical Timeline—1960–2009



What Is Driving Healthcare Reform?

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. Based on the 2000 census, the population age sixty-five and older has been projected to grow from an estimated 39.4 million in 2010 to 53.2 million in 2010, an increase from 13.2 percent to 16.5 percent of the total population.[3] Additionally, the elderly population typically has a greater per capita use of healthcare services.[4]

The ethnicity of the U.S. patient population is also changing, with the 2000 census figures indicating an increasing degree of racial and ethnic diversity.[5] As the minority population increases, the demand for the services tailored to this population may also increase.[6] It is estimated that by 2020, physician patient-care hours devoted to minority patients will have increased to 40 percent from an estimated 31 percent in 2000.[7] 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 healthcare workers adequately trained to 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) also significantly drove healthcare reform efforts. In 2009, total national health expenditures (NHE) in the United States grew to $2.5 trillion, a 5.7 percent increase from 2008.[9] Concurrently, the nation's GDP shrank by 1.1 percent, and as a result, NHE increased from 16.2 percent to 17.3 percent of the GDP—the largest one-year increase in history.[10] NHEs are predicted to continue to rise substantially in the next few years. A March 2010 study in *Health Affairs* estimated that NHE would increase from $2,569.6 billion in 2010 (comprising 17.3 percent of the GDP in 2010) to $4,482.7 billion in 2019 (comprising 19.3 percent of the GDP).[11] A 2009 study published in *Health Affairs* found that the rise in medical prices most greatly contributes to the rise in expenditures for personal healthcare, which represents a large proportion of NHE.[12]

Despite a growing demand for healthcare services, the patient population continues to experience a financial strain to afford healthcare, with out-of-pocket spending for healthcare services rising faster than the typical household income from 2001–04.[13] From 2001–06, the number of Americans indicating high financial burdens due to healthcare spending increased by approximately 1 percent a year, rising from 16.4 percent to 19.1 percent from 2004–06 alone.[14]

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 antikickback statute (AKS), the False Claims Act (FCA), and the federal physician self-referral law (Stark law).[15]

The healthcare reform legislation incorporates the Sunshine Act by requiring extensive reporting and public disclosure of financial arrangements between certain provider customers and manufacturers of drugs, medical devices, medical supplies, and biologics.[16] This disclosure is intended to encourage voluntary avoidance of conflicts of interest that 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.[17]

In addition to the new transparency and disclosure requirements, the healthcare reform legislation also 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.[18]

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.[19] Secondly, the healthcare reform 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.[20]

The new legislation 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."[21] These changes have the potential to increase providers' FCA exposure by allowing for a greater number of whistleblowers to bring a claim.[22] Alternatively, the healthcare reform legislation 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, an initiative which will potentially provide considerable monetary relief for certain providers.[23]

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. This trend is driven by several factors, including the longer life expectancy of the aging baby boomer population, which typically utilizes a greater proportion of healthcare services than the nonelderly population.[24] Additionally, the number of practicing physicians in the United States is predicted to remain fairly stagnant during the next decade due to physician lifestyle changes, which have resulted in a reduction of the total number of work hours, and retirement of current physicians (approximately 99,000 of which were older than age sixty-five in 2008).[25] In its November 2008 report, the Association of American Medical Colleges (AAMC) indicated that solving the predicted physician shortage would not only depend on training more physicians but also on reconfiguring healthcare delivery and increasing efficiency.[26]

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 professionals with training-related scholarships and loans; (4) promoting training in the areas of preventive medicine and public health; (5) increasing the capacity for nurse education, the support for nurse training programs, and the number of loan repayment and retention grants; (6) creating a career ladder to nursing; and (7) establishing a Prevention and Public Health Fund for prevention, wellness, and public health activities.[27]

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.[28] The calculation of SGR relies upon four factors, according to the Centers for Medicare & Medicaid Services (CMS):

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 GDP per capita; and,
4. The estimated percentage change in expenditures due to changes in law or regulations."[29]

The purpose of instituting the SGR formula was two-fold: (1) to ensure patient access to physician services; and, (2) to predictably control federal spending on Medicare part B.[30] Since its enactment, actual Medicare expenditures remained below target expenditures through 2001. Thus, the updates to the physician fee schedule were close to the Medicare economic index (MEI), and for two consecutive years, 2000 and 2001, the actual physician fee schedule update was more than twice the MEI.[31] However, every year since 2002, actual expenditures have exceeded target expenditures, with a 65 percent increase in per-beneficiary expenditures on Medicare services between 1997 and 2005.[32] Because of actual expenditures exceeding target expenditures, the SGR formula dictated a reduction in the fee schedule.[33] 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.[34] Table 6-1 illustrates the proposed and actual physician fee schedule conversion factor (CF) updates for the years 1997 through 2010.

According to estimates by the CBO, under the current SGR mechanism, the cumulative gap between target and actual expenditures will continue to grow, perhaps increasing to a peak deficit of approximately 40 percent, until 2014, when it is predicted that actual spending will dip below target levels once again.[35]

Current Congressional Status Regarding the SGR: Fix or Repeal

The 2010 healthcare reform bill did not contain language to permanently repeal or change the SGR formula. However, on November 19, 2009, the U.S. House of Representatives passed a bill by a vote of 243 to 183, which would permanently repeal the SGR, replacing it with a framework that would update the Medicare physician payment schedule by GDP + 2 for evaluation and management services, and GDP + 1 for other services.[36] In anticipation of the Senate vote on this legislation, Congress temporarily postponed the 2010 cut, originally set to take effect on January 31, 2010. Upon reconvening on April 12, 2010, the Senate decided to temporarily fix the planned 21.3 percent Medicare physician fee cut by delaying implementation of the SGR formula until June 1, 2010.[37]

Table 6-1: Proposed and Actual Annual Updates to the Physician Fee Schedule Conversion Factor, 1997–2010*

Year	Formula Update	Conversion Factor Update
1997	2.0%	0.6%
1998	2.2%	2.3%
1999	2.3%	2.3%
2000	2.4%	5.5%
2001	2.1%	5.0%
2002	–4.8%	-4.8%
2003	–4.4%	1.7%
2004	–4.5%	1.5%
2005	–3.3%	1.5%
2006	–4.4%	0.2%
2007	–5.0%	0.0%
2008	–10.1%	0.5%
2009	–15.1%	1.1%
2010	–21.3%	2.2%

* "Estimated Sustainable Growth Rate and Conversion Factor, for Medicare Payments to Physicians in 2010" Centers for Medicare & Medicaid Services, November 2009, p. 7.

On May 20, 2010, text of the "American Jobs and Closing Tax Loopholes Act of 2010" was introduced by Congress. On May 28, 2010, the House of Representatives chose to separate the text regarding the postponement of the Medicare physician payment cut from the remainder of the bill text and subsequently approved the physician payment legislation by a vote of 245 to 171. While this bill would not repeal the SGR, it would delay the scheduled June 1, 2010 cut to physician payment rates under Medicare until 2012, providing a 2.2% increase to rates from June 1 to December 31, 2010, and a 1% increase for 2011, with the rate for 2012 to be, once again, determined depending on a targeted growth rate.[38]

To avoid disruption in the delivery of health care services to beneficiaries and payment of claims for physicians, on May 27, 2010, CMS directed its contractors to hold claims for services paid under the MPFS for the first 10 business days of June (i.e., through June 14, 2010).[39] This hold only applied to MPFS claims with dates of service of June 1, 2010, and later. With the expectation of Congressional action in the near future, CMS extended this hold and directed its contractors to continue to hold June 1, 2010 and later claims through Thursday, June 17, 2010, with the plan to lift the hold on Friday, June 18, 2010.[40]

Yet, with an agreement not yet reached, and the expiration of CMS's hold rapidly approaching, on Wednesday, June 16, 2010, the proposed nineteen month fee fix was reduced to seven months in an attempt to gain the 60 percent supermajority needed to pass the legislation. However, even after shaving off twelve months, the "test vote" on the measure failed to pass, with every Republican and twelve Democrats voting against the bill, in a 52-45 vote.[41] Forced to restart the process, Democrats gave doctors

even shorter relief from the impending one-fifth Medicare cuts in their payments, by giving doctors only a 6 month reprieve in the looming cuts, and only increasing the physician reimbursement rate by 2.2% through November 30, 2010.[42]

Late Thursday night, June 17, 2010, the Senate reached a deal and passed a short-term six month physician pay cut, blocking the 21 percent reimbursement cut scheduled to go into effect on June 18, 2010, after making the physician fee fix a separate provision from the larger H.R. 4213.[43] This update came after failing earlier Thursday to pass the entire H.R. 4213, which not only would have provided the physician payment relief, but also included provisions to extend tax and jobless benefits.[44] With Senate approval, the newly crafted compromise bill returned to the House, but the House was unable to consider the measure before Monday, as they had already broken for the weekend.[45] The House was expected to pass the bill quickly, since in May, they approved a more expansive version of the bill that stayed the physician fee cuts until 2012. However, because House Democrats were seeking to pass a longer-term fix for the payment, they did not approve the bill until Thursday June 25, 2010, forced to concede to the $6.5 billion, six-month stand-alone physician fix as a compromise.[46]

The House's passage and enactment of the Senate's bill reversed the 21.3 percent cut to Medicare physician payments that had been in effect since the previous Friday, affecting all claims submitted and processed after June 1, 2010, and it provided the expected 2.2 percent increase for claims dated from June 1, 2010 to November 30, 2010.[47] On Friday, June 26, 2010, President Obama signed into law The Preservation of Access to Care for Medicare Beneficiaries and Pension Relief Act. Once the bill became law, CMS directed its contractors to begin processing the physician and provider claims at the new increased rate.[48]

President Obama has pushed for an extension of the payment freeze until the end of the year,[49] while others, including the American Medical Association, have pushed for a permanent repeal. The Congressional Budget Office has estimated, however, that permanently fixing the Sustainable Growth Rate formula, will cost $276 billion over the next decade, which is a thirty three percent increase from the initial estimation of $207 billion.[50] This projected cost of a permanent repeal has been a major issue for Congress, which has in turn resulted in Congress choosing to postpone the date and shorten the length of the cut.

Meanwhile, during the debate about fixing the Sustainable Growth Rate, the uncertainty about the SGR's future has significant present day implications. With forty-five million Americans counting on Medicare, physicians face substantial difficulty maintaining viable practices in an environment with such extreme financial uncertainty. Increasing numbers of doctors are simply choosing to cease accepting Medicare patients altogether,[51] and the uncertainty from one month to the next ultimately threatens patients' access to care by undermining the ability of physicians to plan for the future.

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.

The reduction in reimbursement levels for physicians may have had more widespread effects than adversely affecting physician revenue and income levels. An article 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).[52] 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.[53] This trend has also become a concern to health workforce analysts, who predict an impending physician shortage.[54]

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.

As revenue streams available to physicians are limited by these changes, 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.), 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 during the next several years.[55] Providers with older revenue cycle management systems could possibly upgrade these systems to improve patient satisfaction and convenience and also to more efficiently manage their revenue cycle.[56] Patient satisfaction, convenience, and increased efficiency may result from a patient's ability to pre-register, schedule, and pay for his or her services through the provider's website, among other things.[57] Furthermore, providers will likely benefit from new systems that improve efficiency by easily checking payors' rules to ensure that the services to be performed are covered, automatically creating bills from patients' electronic medical records, bypassing clearinghouses and submitting claims directly to payors, enabling providers to receive electronic funds transferred directly from payors to the provider's bank, and allowing providers to integrate their financial and clinical data.[58] Nonetheless, the 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.[59] Recently, legislators have advanced several proposals to reduce Medicare costs. The proposals employ various methods of bundling payments to hospitals and physicians for services provided during the course of a patient's treatment plan. The Senate Finance Committee's "Proposals to Improve Patient Care and Reduce Health Care Costs," demonstrated this trend in a plan to use the bundling of payments for inpatient and post-discharge care.[60]

Proponents of bundled payments argue that the move toward bundled payments could provide higher coordination between providers and more efficient levels of care.[61] Critics, on the other hand, articulate concern about the level of savings and patient care improvement that blanket bundling of payments actually will 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.[62] 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.[63] Similarly, in a letter to the Senate Finance Committee, the AHA stated that the Obama 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 healthcare delivery and payment system.[64] Finally, the AAMC, which supports the concept of care coordination provided through bundling, criticized Medicare's Acute Care Episode Demonstration program for not ensuring that payments are made directly to all parties (that is, physicians) who provide the services.[65]

Although no actual bundling policy has been implemented, recent actions by both the Senate and CMS have demonstrated that such initiatives are on the healthcare horizon and may soon become a part of the healthcare reimbursement environment. For example, the 2010 healthcare reform legislation includes a provision for the creation of a new demonstration project to pay bundled payments for episodes of care that include hospitalization (effective January 1, 2012, through December 31, 2016).

The changing patient population demographic, rising levels of healthcare expenditures, growing concern about fraud and abuse, continuing controversy about physician reimbursement, growth in NHE, and the SGR formula for determining the annual conversion factor are all significant drivers of the efforts that have propelled healthcare reform initiatives under the Obama administration.

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. However, with the election of a Republican senator in Massachusetts and waning public approval of the healthcare initiative driven by rising unemployment rates, a declining economy, and an increase in the federal deficit, problems arose for those expecting a speedy legislative reform process.[66] However, after 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, and the Health Care and Education Reconciliation Act of 2010, HR 4872, were enacted on March 23, 2010, and March 25, 2010, respectively.

Summary of Key Provisions

The passage of HR 3590 and HR 4872 will result in significant changes to the country's healthcare landscape. Table 6-2 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.

Table 6-2: Chart of Key Provisions

Company	Provision	Effective Date
Insurance Industry		
	Insurance market rules	September 23, 2010
	Grandfathered plans—eliminate pre-existing condition exclusions for children	September 23, 2010
	Grandfathered plans—eliminate pre-existing condition exclusions for adults	July 6, 1905
	National high-risk pool	Dissolved after 2014
	Health insurance exchanges for individual states	January 1, 2014
	National Association of Insurance Commissioners must establish uniform definitions and standard methodologies	December 31, 2010
	Consumer-operated and oriented plan (CO-OP)	2013
Individuals and Employers		
	All individuals required to obtain health insurance coverage	2014
	Employers with more than fifty employees that do not offer coverage	2014
	Employers with fewer than fifty employees	2014
	Employers that offer coverage to their employees	2014
	Employers with more than 200 employees	2014
Medicare		
	Reduce the gap between generic and brand-name drugs	2020
	Restrictions on revenue spending for Medicare Advantage plans	2014
Medicaid		
	Increase payments for primary care services	2013 and 2014
Public Health	Workforce training and expansion is supported, as well as support for prevention and wellness initiatives	[2010]
Tax Provisions		
	Provides a refundable credit for coverage under a qualified health plan	January 1, 2014
	Provides a sliding-scale tax credit to small employees	2010
	Excise tax on individuals	2013
	Excise tax on businesses	

Table 6-2: Chart of Key Provisions (continued)

Company	Provision	Effective Date
Prevention and Wellness		
	Coordination of federal prevention, wellness, and public health activities	2014
	Create Prevention and Public Health fund	2014
	Create task forces on preventive services and community preventive services	2014
Fraud and Abuse	Streamlined Medicare prepayment medical review limitations and additional funds for programs focusing on reducing healthcare fraud	[2010]
Funding Mechanisms	Impose tax on high-cost insurance	[?] 2013
Hiring Incentives to Restore Employment Act		
	Exemption from payment of employer's share of Social Security employment taxes	March 18, 2010, to January 1, 2011
	Tax breaks for private-sector businesses that hire unemployed workers in 2010	February 3, 2010, to January 1, 2011

The various entities and sectors of the healthcare industry that are affected by provisions included in the 2010 healthcare reform legislation include:[67]

1. **Insurance industry.** The 2010 healthcare reform legislation subjects the insurance industry to increasing restrictions regarding expanding coverage requirements.
2. **Individual states.** All states are required to establish an American Health Benefit Exchange by January 1, 2014, 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.
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 percent of individual income, and those whose individual (or household) income was below the tax filing thresholds.[68]
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. Chapter 7 of *Professional Practices* discusses the legislation in detail as it pertains to the extensive provisions for both small and large employers.
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 in 2014 on revenue spending for Medicare Advantage plans; update disproportionate share payments (DSH); address the impact of physician ownership; and control the diagnostic imaging utilization rate.

6. **Medicaid.** Reform initiatives related to Medicaid will be 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 with and increase Medicaid payment rates for primary care physicians.
7. **Public health.** The 2010 healthcare reform legislation also supports public health workforce training and expansion, as well as support for prevention and wellness initiatives.[69] Additionally, the initial 2010 healthcare reform legislation 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.[70]
8. **Tax provisions.** The 2010 healthcare legislation 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.

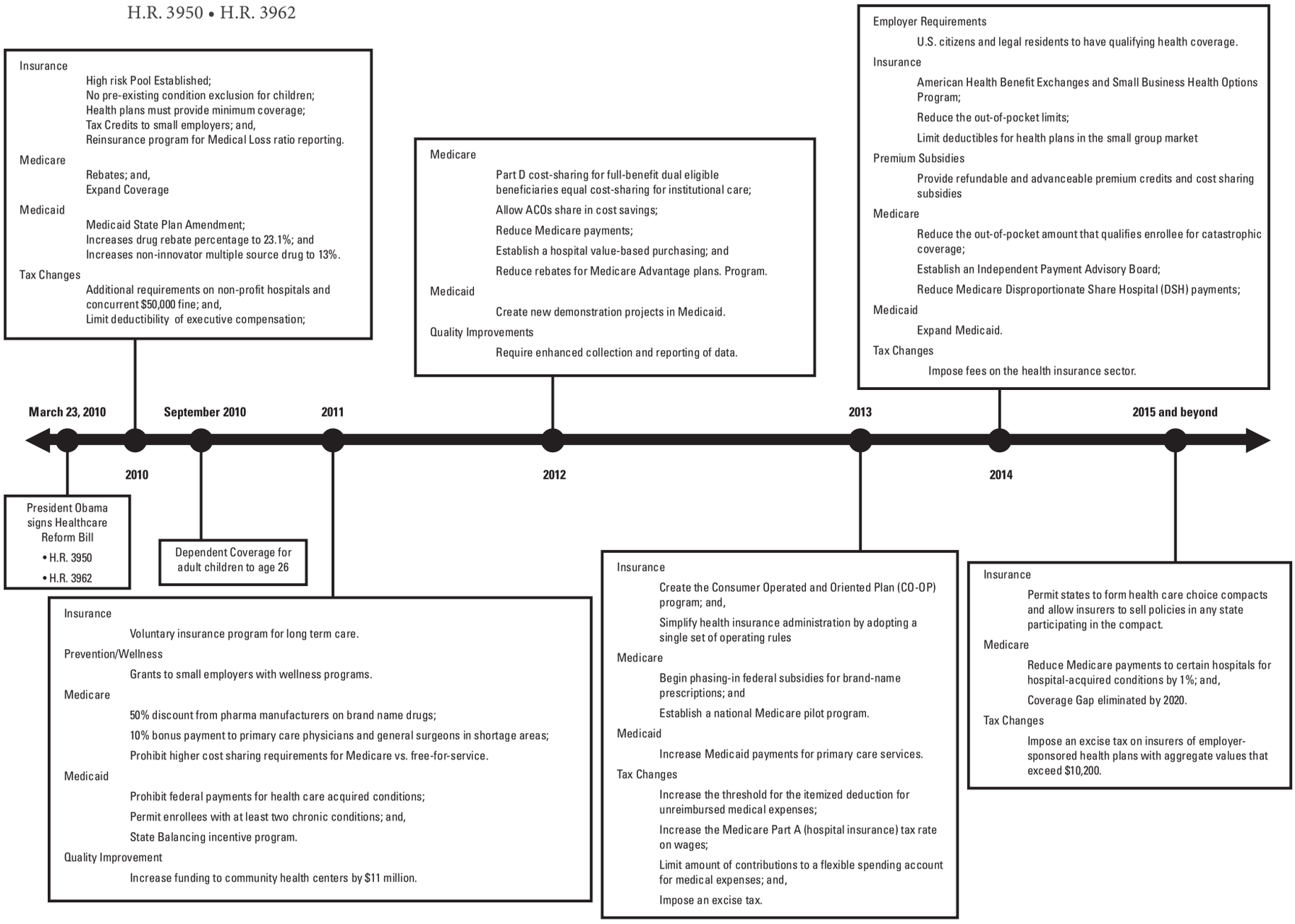
Timeline for Implementation of HR 3590 and HR 4872

Figure 6-2 provides an overview of the implementation timeline related to certain key healthcare reform initiatives.

Obstacles to the Implementation of Healthcare Reform

After passage of the 2010 healthcare reform legislation, there remains heated opposition from the Republican Party regarding the content and implementation of the bill's provisions. This may be in part due to differing perceptions with regard to quality and access to care. An April 2010 study in *Health Affairs* found that respondents who identified themselves as being affiliated with the Republican Party, male, of senior status, and wealthy were more likely than their counterparts to believe that uninsured individuals have little or no difficulty in obtaining healthcare.[71] The fundamentally different views expressed by the Democratic Party, which supports government intervention, and the Republican Party, which supports increased market competition to control spending in a capitalist market, regarding how to best contain healthcare costs also suggest a division in opinion regarding the proposed reform initiatives.[72]

Figure 6-2: A Brief Primer on Healthcare Reform —2010 U.S. Healthcare Reform Timeline
H.R. 3950 • H.R. 3962



The success of the implementation timeline will depend largely on the continued political and fiscal support for the measures proposed in HR 3590, 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.[73] 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.[74] 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 HR 3590 and HR 4872 may be countered, similar to when the Medicare Catastrophic Coverage Act of 1988 was repealed slightly more than a year after its passage.[75] The result of the November 2010 midterm elections may play a large role in determining whether the current reform initiatives will maintain the majority of political support required to successfully implement the provisions of HR 3590 and HR 4872.[76]

Several of the attorneys general running for political office or up for re-election in the near future are challenging the reform bill.[77] State attorneys general filed lawsuits in federal court, within minutes of President Obama's signing of the healthcare reform legislation into law. Each lawsuit claims that the healthcare reform legislation violates the United States Constitution. One lawsuit, led by Florida Attorney General Bill McCollum, and joined by twelve other state attorneys general, claims that the reform legislation exceeds Congress's power to regulate commerce, violates the 10th Amendment protection of state sovereignty, and imposes an unconstitutional direct tax.[78] The other suit, filed by Virginia Attorney General Kenneth T. Cuccinelli, states that Virginia is in a unique situation, as it is the only state to pass a law that creates a conflict of interest between the state law and the federal law by "protecting its citizens from a government-imposed mandate to buy health insurance."[79]

In addition to political obstacles to the enactment of healthcare reform, some consider physicians a potential barrier to some reform initiatives, namely, cost-containment measures.[80] Some 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 reform efforts focused on reducing spending in high-cost regions (for example, limiting unnecessary visits, procedures, etc.) would greatly assist in cost-containment initiatives.[81]

Proposed Supplemental Reform Initiatives

Despite the monumental passage of HR 3590 and HR 4872, 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 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.

Paying for Healthcare Reform

Reforming healthcare in America may cost the government an estimated $820 billion or more over ten years,[82] which may be funded in a variety of ways including (1) cutting fraud and abuse within existing government health programs, (2) removing large subsidies to insurance companies, (3) increasing healthcare delivery efficiency through streamlining paper work and coordinating care, and (4) obtaining various tax revenues from individuals and companies.[83] The CBO projects the legislation will save $511 billion in medical spending and produce a net reduction in the federal budget deficit by $143 billion during 2010-19 as a result of changes in direct spending and raising revenues.[84]

Significant changes to Medicare alone are projected to result in net savings of $575 billion from 2010–19.[85] Overpayments to Medicare-managed plans identified through increased pressures on fraud and abuse through audits are projected to save more than $204 billion from 2010–19.[86] Additionally, Medicare payments to providers will be adjusted for improvements in quality and productivity. These adjustments will apply to payments made to inpatient hospitals, long-term care facilities, inpatient rehabilitation facilities, psychiatric hospitals, and outpatient hospitals. The CBO projects these payment adjustments will save $160 billion from 2010–19.[87] Under the new healthcare reform, the CBO projects Medicare spending growth to be slowed from anticipated increases of 6.8 percent annually to 5.2 percent, which will extend the stability of the Medicare trust fund through 2026 and save an estimated $397 billion from 2010–19.[88]

CMS also estimates substantial savings in Medicare costs that can be attributed to (1) reducing Part A and Part B payment levels and adjusting future market backset payment updates for productivity improvements ($233 billion), (2) abolishing the Medicare improvement fund ($27 billion), (3) decreasing DSH payments ($50 billion), (4) reducing Medicare Advantage payment benchmarks and permanently extending the ability to adjust for coding intensity ($145 billion), (5) freezing the income thresholds for the Part B income-related premium for nine years ($8 billion), (6) implementing an independent payment advisory board to maintain strict Medicare expenditure growth rate targets ($24 billion), and (7) increasing the hospital insurance payroll tax rate by 0.9 percent for individuals with incomes above $200,000 and families with incomes above $250,000 ($63 billion).[89]

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 2014–19; (2) new annual fees paid by pharmaceutical manufacturers, estimated to raise $27 billion from 2013–19; (3) a 2.9 percent excise tax on medical device manufacturers, estimated to raise $20 billion from 2013–19; and (4) an excise tax on high-cost insurance plans, estimated to raise $32 billion from 2018–19.[90]

Healthcare Reform Impact on the Future of U.S. Healthcare Delivery

The CBO has estimated that the enactment of HR 3590 would reduce federal budget deficits by $118 billion from 2010–19.[91] Combined with the passage HR 4872, the federal deficit was estimated to be reduced by $143 billion.[92] In addition to the budgetary benefits of bill passage, the CBO estimates that the number of people (nonelderly) who are uninsured will be reduced by approximately 32 million, and the percentage of nonelderly residents with insurance coverage will increase from 83 to 94 percent by 2019.[93]

Impact on Individuals

The 2010 healthcare reform legislation requires U.S. citizens and legal residents to maintain minimum amounts of health insurance coverage. 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. To assist U.S. citizens in paying for this coverage, the initial 2010 healthcare reform 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. 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.[94]

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. 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.[95]

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. Effective later during the second half of 2010, a temporary national high-risk pool will be 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 will be dissolved after January 1, 2014, when all insurers and group health plans will be prohibited from excluding persons with pre-existing conditions.[96] Additionally, health plans beginning on January 1, 2011, must report the proportion of premium dollars spent on clinical services and quality improvement and other costs, and provide rebates to consumers based for any cost less than 85 percent for large group plans and 80 percent for individual and small group plans. In addition, starting in 2010, a process for reviewing increases in health plan premiums will be established, which will require insurance companies to justify increases.[97]

Also effective September 23, 2010, insurance plans will be required to provide dependent coverage for children up to age twenty-six for all individual and group policies.[98] Eligible children up to twenty-six years of age who do not qualify for other coverage must be covered under their parents' employer's plan.[99]

Healthcare reforms related to Medicaid are significant, with such expanded coverage provisions effective beginning in 2010 as (1) creation of a state option to cover childless adults through a Medicaid State Plan Amendment; (2) creation of 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; (3) creation of a new option for states to provide Children's Health Insurance Program (CHIP) coverage for children of state employees eligible for health benefits, under certain conditions; (4) an increase in the drug rebate percentage for brand name drugs up to 23.1 percent (except the rebate for clotting factors and drugs approved exclusively for pediatric use increases to 17.1 percent); (5) an increase in the drug rebate percentage for noninnovator, multiple-source drugs up to 13 percent of the average manufacturer price; (6) extension of the drug rebate to Medicaid managed care plans; (7) provision of additional funding for the

Medicaid and CHIP Payment and Access Commission to include assessments of adult services (including those persons who are dually eligible for Medicare and Medicaid); and (8) issuance of regulations by the secretary of HHS that establish a process for public notice and comment for section 1115 waivers in Medicaid and CHIP.[100]

Additional Medicaid reform initiatives will be effective in 2011, including the (1) prohibition of federal payments to states for Medicaid services related to healthcare acquired conditions; (2) creation of a new Medicaid state plan option to permit enrollees with at least two chronic conditions, one condition and a risk of developing another, or at least one serious and persistent mental health condition, to designate a provider as a health home (and provide states taking accepting the option with 90 percent Federal Medical Assistance Percentage for two years for health home related services such as care management, care coordination, and health promotion); (3) creation of the State Balancing Incentive Program in Medicaid to provide enhanced federal matching payments to increase noninstitutionally based long term care services; and (4) establishment of the Community First Choice Option in Medicaid to provide community-based attendant support services to certain people with disabilities.[101]

Such Medicaid reform initiatives for 2010 include the creation of new demonstration projects to pay bundled payments for episodes of care that include hospitalization (effective January 1, 2012, through December 31, 2016), as well as to make global capitated payments to safety net hospital systems (effective for the fiscal years 2010 through 2012). Providers of pediatric services will be allowed to organize as accountable care organizations (ACOs) to share in cost-savings (effective January 1, 2010, through December 31, 2016). Additional provisions include expanded Medicaid payments to institutions of mental disease for adult enrollees who require stabilization of an emergency condition (effective October 1, 2011, through December 31, 2015).[102]

Effective 2013, there will be increased Medicaid payments for primary care services provided by primary care physicians for 2013 and 2014, with 100 percent federal funding.[103] Significantly, in 2014, Medicaid coverage will be expanded to all non-Medicare-eligible individuals under sixty-five-years of age (that is, children, pregnant women, parents, and adults without depending children) with incomes up to 133 percent of the federal poverty level based on a modified adjusted gross income and will provide for enhanced federal matching funds for new eligible enrollees. Additionally, effective 2014, there will be a reduction in states' Medicaid DSH allotments and an increase in spending caps for territories.[104]

Specifically as related to Medicaid and CHIP, healthcare reform provisions require states to maintain current income eligibility levels for children in Medicaid and CHIP until 2010 and to extend funding levels for CHIP through 2015, with the CHIP benefit package and cost-sharing rules to continue under current laws. Beginning in 2015, states will be given the option to receive a 23 percent increase in the CHIP match rate up to a cap of 100 percent. Additionally, children who are eligible for CHIP but who are unable to enroll in the program due to enrollment caps will be eligible for tax credits.[105]

Impact on Small and Mid-Sized Employers

The impact of the 2010 healthcare reform legislation is not limited to individuals. By January 1, 2014, states are required to establish an American Health Benefit exchange. 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.[106] 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.

Effective for tax years beginning in 2010 or later, an "eligible small employer" that purchases health insurance for its employees receives a tax credit for amounts spent for health insurance coverage for employees.[107] 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.[108]

Beginning in 2010 and up to 2013, small employers providing healthcare coverage for employees are eligible to receive a tax credit up to 35 percent of the employer's contribution toward its employees' health insurance premiums, if the employer contributes at least 50 percent of the total premium cost of 50 percent of the benchmark premium.[109] In 2014, the applicable tax credit percentage will increase to 50 percent. Employers with ten or fewer employees and average wages of less than $20,000 will receive 100 percent of the credit. 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.

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 "qualified coverage" to their employees. Qualified coverage is minimum essential coverage that includes government-sponsored coverage, employer-sponsored coverage, grandfathered health plans, and plans offered in the individual market. A qualified health plan (1) provides the essential health benefits package, (2) limits annual cost-sharing to the high-deductible health plan limit, (3) limits the annual deductible for small group market plans to $2,000 for individual and $4,000 for adults, (4) and does not require cost-sharing for preventive services or immunization.[110] Qualified coverage also includes the availability of catastrophic coverage for individuals under the age of thirty.

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.[111] The employer penalties assessed include a $2,000 penalty for each of its full time employees, with the first thirty employees not counted toward the penalty calculation. 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.[112]

The 2010 healthcare reform legislation also requires employers that offer coverage to provide a free choice voucher to employees with incomes less than 400 percent of the federal poverty level whose share of the premium is greater than 8 percent but is less than 9.8 percent of their income and who chose to enroll in a plan in the health insurance exchange. This amount of the voucher will equal what the employer would have paid to provide coverage to the employee under the employer's plan. Additionally, employers with more than 200 employees that offer group health plans are required to automatically enroll employees into employer-sponsored health insurance plans.[113] Employers must provide employees

with notice of automatic enrollment and give the employees the ability to opt out of coverage.[114] No effective date has been established by the secretary of Labor, who is required to issue regulations implementing this requirement. Further, through December 31, 2013, the initial legislation provides for a temporary reinsurance program for employers providing healthcare coverage to retirees over age fifty-five but who are not yet Medicare eligible. This government-funded reinsurance program reimburses employers for 80 percent of claims with amounts between $15,000 and $90,000. The funding for this program is $5 billion for the entire period, with HHS required to establish the program by June 21, 2010.[115] Effective 2013, the healthcare reform legislation eliminates the deduction for the employer subsidy for employers that provide prescription drug coverage to employees eligible for Medicare Part D.[116]

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 new legislation's enactment. 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.[117] Collectively bargained agreements are grandfathered until the date on which the last of the collective bargaining agreements relating to the grandfathered coverage terminates.[118] Grandfathered plans are generally able to avoid many of the new legislation's requirements, but they are still subject to the following key provisions: pre-existing conditions, dependent coverage, elimination of coverage rescissions, coverage limits, and, in 2014, excessive waiting periods.[119]

Effective in 2018, a 40 percent excise tax on high-cost plans will be assessed to plans costing more than $10,200 for individual coverage or more than $27,500 for family coverage.[120] The tax percentage will be adjusted for age, gender, and high-risk professions. Also, beginning in 2011, the healthcare legislation requires employers to report the value of employee health benefits on W-2 forms. Beginning on or after September 23, 2010, employers with self-funded health plans or health insurers from which they obtain employer sponsored health insurance must make the following changes to benefits. Adult children up to age twenty-six are able to receive coverage from a parent's plan, regardless of student status, marital status, and whether or not they are supported by or living with the parent.

Additionally, the plan may not impose annual maximum benefit limits for "essential benefits," except those that may be permitted by regulations at a later date. The plans cannot prohibit or limit coverage for pre-existing conditions for children under age nineteen. Plans that are self-funded must give covered individuals the right to seek external independent medical review of certain claims, for example, claims that are denied based upon medical necessity. Plans cannot require prior authorization or increased cost sharing for emergency services, even if those services are provided out-of-network. The plans are prohibited from discriminating in favor of highly compensated employees. Employers also are allowed to increase incentives for wellness program investments from 20 percent to 30 percent of the cost of the insurance premium.[121] By 2014, an employer may not impose a waiting period greater than ninety days for the employee to satisfy before getting health coverage.

Impact on Professional Practice Providers

Professional practice providers, in this era of healthcare reform, will be affected both directly and indirectly by many aspects of the reform bill and reconciliation act. These include, among others, changes and restrictions related to reimbursement, fraud and abuse regulations, and technological and compliance

requirements. In addition, professional practices will face changes in the competitive marketplace due to proposed restrictions on other healthcare providers, for example, by the restrictions for expansion and growth of the specialty hospital market. 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.[122] 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.

In addition to the 2010 healthcare reform legislation's affect on individuals and employers, the recent reform efforts also will have major implications for healthcare providers. For example, 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 2011 through 2016.[123] 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 2011–16.[124] Medicare also will increase payment for psychotherapy services by 5 percent[125] and extend Medicare incentive payments of 1 percent in 2011 and 0.5 percent from 2012–14 for voluntary participation in Medicare's Physician Quality Reporting Initiative (PQRI).[126] Beginning in 2015, 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.

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.[127]

Although there appears to be an increase in reimbursement for some physician services, other physician providers will face a decrease in reimbursement. Beginning July 1, 2010, Medicare reimbursement for the technical component of diagnostic imaging services will be reduced by 50 percent (currently set at 25 percent) for subsequent procedures on consecutive body parts.[128] 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.[129]

Conclusion

Some feel that the passage of HR 3590 and HR 4872 is one of the most important fundamental changes to federal healthcare policy, on a similar scale to the implementation of the Medicare and Medicaid programs.[130] 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.[131] However, the successful implementation and potential

impact of the new provisions detailed in this legislation depends largely on the 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 recently passed reform legislation, the public and political fight regarding the U.S. healthcare delivery system reform is 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.

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" or 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.[132]

As discussed in this *Guide*, recent efforts at regulatory and reimbursement reform and the increasing change and complexity of healthcare reimbursement, regulatory, competitive, and technological pillars of healthcare indicate that the current healthcare environment is one of the most dramatic and challenging times in U.S. history for healthcare professional practices.[133] 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 that, "Marcus Welby 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.

Chapter 2, *Reimbursement Environment*, provides an overview of current and future trends in healthcare reimbursement. With the recent 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 payment plans, and consumer driven health plans), and the new rules related to overall insurance industry practices.

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.

Endnotes

1 "Harry S. Truman Versus the Medical Lobby: The Genesis of Medicare" By Monte M. Poen, Columbia, MO: University of Missouri Publisher, 1979, p. 1.

2 "Timeline: History of Health Reform in the U.S.", Kaiser Family Foundation, 2010, http://healthreform.kff.org/flash/health_reform-print.html (Accessed 4/2/2010).

3 "Changing Demographics: Implications for Physicians, Nurses, and Other Health Workers", Health Resources and Services Administration, 2003, p. 7.

4 "Changing Demographics: Implications for Physicians, Nurses, and Other Health Workers", Health Resources and Services Administration, 2003, p. 7-8.

5 "Changing Demographics: Implications for Physicians, Nurses, and Other Health Workers", Health Resources and Services Administration, 2003, p. 38.

6 "Changing Demographics: Implications for Physicians, Nurses, and Other Health Workers", Health Resources and Services Administration, 2003, p. 37.

7 *Ibid.*

8 "Changing Demographics: Implications for Physicians, Nurses, and Other Health Workers", Health Resources and Services Administration, 2003, p. 37-38.

9 "Health Spending Projections Through 2019: The Recession's Impact Continues" By Christopher J. Truffer, et al, Health Affairs, Vol. 29, No. 3 (March 2010), p. 522.

10 "National Health Expenditure Projections 2009-2019," Centers for Medicare and Medicaid Studies, 2009, http://www.cms.hhs.gov/NationalHealthExpendData/downloads/proj2009.pdf (Accessed February 17, 2010).

11 "Health Spending Projections Through 2019: The Recession's Impact Continues" By Christopher J. Truffer, et al, Health Affairs, Vol. 29, No. 3 (March 2010), p. 523.

12 "Health Spending Projections Through 2018: Recession Effects Add Uncertainty to the Outlook" By Andrea Sisko et al., Health Affairs, Vol. 28, No. 2 (February 24, 2009), p. w351.

13 "The Growing Financial Burden of Health Care: National and State Trends, 2001-2006" By Peter J. Cunningham, Health Affairs, Vol. 29, No. 5 (May 2010), p. 1-2.

14 "The Growing Financial Burden of Health Care: National and State Trends, 2001-2006" By Peter J. Cunningham, Health Affairs, Vol. 29, No. 5 (May 2010), p. 2.

15 "Health Care Reform: Substantial Fraud and Abuse and Program Integrity Measures Enacted" McDermott Will & Emery, April 12, 2010, p. 2.

16 *Ibid.*

17 *Ibid.*

18 "Health Care Reform: Substantial Fraud and Abuse and Program Integrity Measures Enacted" McDermott Will & Emery, April 12, 2010, p. 3.

19 *Ibid.*

20 *Ibid.*

21 *Ibid.*

22 *Ibid.*

23 *Ibid.*

24 "The Complexities of Physician Supply and Demand: Projections Through 2025: Executive Summary" Center for Workforce Studies of the Association of American Medical Colleges, http://www.aamc.org/workforce (Accessed 5/6/2010).

25 "The Anticipated Physician Shortage: Meeting the Nation's Need for Physician Services" By Gregory C. Kane, et al., American Journal of Medicine, Vol. 122, No. 12 (December 2009), p. 1159.

26 "The Complexities of Physician Supply and Demand: Projections Through 2025: Executive Summary" Center for Workforce Studies of the Association of American Medical Colleges, http://www.aamc.org/workforce (Accessed 5/6/2010).

27 "Summary of New Health Reform Law" Kaiser Family Foundation, April 21, 2010, http://www.kff.org/healthreform/upload/8061.pdf (Accessed 5/6/2010).

28 "Estimated Sustainable Growth Rate and Conversion Factor, for Medicare Payments to Physicians in 2010", by Centers for Medicare & Medicaid Services, November 2009, p. 1.

29 *Ibid.*

30 "Medicare's Physician Payment Rates and the Sustainable Growth Rate", Statement of Donald B. Marron before the Subcommittee on Health, Committee on Energy and Commerce, and U.S. House of Representatives, Congressional Budget Office, July 25, 2006, p. 3-4.

31 "Medicare Physician Payment Updates and the Sustainable Growth Rate (SGR) System," By Jim Hahn, Congressional Research Service Report for Congress, November 6, 2009, p. 3.

32 "Medicare's Physician Payment Rates and the Sustainable Growth Rate", Statement of Donald B. Marron before the Subcommittee on Health, Committee on Energy and Commerce, and U.S. House of Representatives, Congressional Budget Office, July 25, 2006, p. 3-4.

33 "Medicare Physician Payment Updates and the Sustainable Growth Rate (SGR) System," By Jim Hahn, Congressional Research Service Report for Congress, November 6, 2009, p.3.

34 "Medicare's Physician Payment Rates and the Sustainable Growth Rate", Statement of Donald B. Marron before the Subcommittee on Health, Committee on Energy and Commerce, and U.S. House of Representatives, Congressional Budget Office, July 25, 2006, p. 9-10.

35 "Medicare's Physician Payment Rates and the Sustainable Growth Rate", Statement of Donald B. Marron before the Subcommittee on Health, Committee on Energy and Commerce, and U.S. House of Representatives, Congressional Budget Office, July 25, 2006, p. 4-5.

36 "House Passes H.R. 3961—Legislation to Permanently Repeal the SGR", American Medical Association, Health System Reform Bulletin, November 19, 2009, http://www.ama-assn.org/ama/pub/health-system-reform/resources/bulletin/november-2009/19nov2009.shtml (Accessed 5/18/10).

37 "Senate Passes Temporary Physician Fee Fix, Will Delay Rate SGR Cuts Until June," Becker's Hospital Review, http://www.hospitalreviewmagazine.com/news-and-analysis/business-and-financial/senate-passes-temporary-physician-fee-fix-will-delay-rate-sgr-cuts-until-june.html, Accessed May 5, 2010.

38 "House Takes First Step to Block 21.3 Percent Medicare Cut", Medical Group Management Association, Washington Connexion, May 28, 2010.

39 "Fee Cut to Go Into Effect, but CMS Holding Off Claims Processing," by Leigh Page, Becker's ASC Review, June 1, 2010. http://www.beckersasc.com/news-analysis-asc/business-financial-benchmarking/fee-cut-goes-into-effect-but-cms-holding-off-claims-processing.html. (Accessed 06/15/2010).

40 *Ibid.*

41 "Unemployment Bill Dealt Senate Defeat," Associated Press, June 16, 2010, http://www.google.com/hostednews/ap/article/ALeqM5gBPaHA8wyvhZsKWPW8Ux-p30QpfqgD9GCEQR05 (Accessed 6/16/2010).

42 "Modern Physician Alert: Senate Crafts Six-Month Doc-Pay Fix," Modern Physician, June 16, 2010, http://www.modernhealthcare.com/apps/pbcs.dll/article?AID=/20100616/MODERNPHYSICIAN/306169941# (Accessed 6/16/2010).

43 "Senate Reaches Deal, Passes Short-Term "Doc Fix"" Kaiser Health News, June 18 2010, http://www.kaiserhealthnews.org/Daily-Reports/2010/June/18/Doc-Fix-Passes.aspx (Accessed 6/18/2010).

44 *Ibid.*

45 *Ibid.*

46 "House Approves Stand-Alone 'Doc Fix" GOP Blocks 'Extenders' Bill," California Healthline, June 25, 2010, http://www.californiahealthline.org/articles/2010/6/25/house-approves-standalone-doc-fix-gop-blocks-extenders-bill.aspx (Accessed 6/28/2010).

47 "Senate reaches Medicare physician payment deal, House scheduled to vote next week", Medical Group Management Association, Washington Connexion, May 28, 2010.

48 "Obama signs doc pay 'fix,' but bigger cuts could face physicians next year," McKnight's Long-Term Care News & Assisted Living, June 28, 2010 http://www.

mcknights.com/obama-signs-doc-pay-fix-but-bigger-cuts-could-face-physicians-next-year/article/173318/, (Accessed 6/25/2010).

49 "Yet Another SGR Reprieve" By Matthew DoBias, Modern Healthcare, April 19, 2010, http://www.modernhealthcare.com/apps/pbcs.dll/article?AID=/20100419/MAGAZINE/100419952 (Accessed 5/19/2010).

50 "CBO Estimate of Changes in Net Federal Outlays from Alternative Proposals for Changing Physician Payment Rates in Medicare" Congressional Budget Office, http://www.cbo.gov/budget/factsheets/2010b/SGR-menu.pdf (Accessed 5/18/2010).

51 "Texas Doctors Opting Out of Medicare at an Alarming Rate" By Todd Ackerman, Houston Chronicle, May 17, 2010, http://www.chron.com/disp/story.mpl/metropolitan/7009807.html (Accessed 5/19/2010).

52 "Trends in the Work Hours of Physicians in the United States" By Douglas O. Staiger, David I. Auerbach, Peter I. Buerhaus, Journal of the American Medical Association, Vol. 303, No. 8 (February 24, 2010), p. 750.

53 "Trends in the Work Hours of Physicians in the United States" By Douglas O. Staiger, David I. Auerbach, Peter I. Buerhaus, Journal of the American Medical Association, Vol. 303, No. 8 (February 24, 2010), p. 751.

54 "Trends in the Work Hours of Physicians in the United States" By Douglas O. Staiger, David I. Auerbach, Peter I. Buerhaus, Journal of the American Medical Association, Vol. 303, No. 8 (February 24, 2010), p. 752.

55 "The Next Generation of Revenue Cycle Management Index" In "Essentials of the U. S. Hospital IT Market, Fourth Edition" By HIMSS Analytics, 2009, http://www.himssanalytics.org/docs/4thEditionEssentialsNGRCMfinal.pdf (5/17/ 2010); "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).

56 "The Next Generation of Revenue Cycle Management Index" In "Essentials of the U. S. Hospital IT Market, Fourth Edition" By HIMSS Analytics, 2009, http://www.himssanalytics.org/docs/4thEditionEssentialsNGRCMfinal.pdf (5/17/ 2010).

57 "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).

58 *Ibid.*

59 "The Managed Health Care Handbook," By Peter R. Kongstvedt, Third Edition, Aspen Publishers, Inc., 1996, p. 187.

60 "President Obama's Budget Request Includes $828B for HHS" Kaiser Family Foundation, May 8, 2009. http://www.kaisernetwork.org/daily_reports/print_report.cfm?DR_ID=58379&dr_cat=3 (Accessed 5/14/09).

61 "Analysis of Bundled Payment" RAND Compare, 2010 http://www.randcompare.org/analysis/mechanism/bundled_payment (Accessed 5/18/10).

62 "Reforming Medicare's Physician Payment System," Statement of the American Medical Association presented by Nancy H. Neilson to the Committee on Ways and Means Subcommittee on Health, U. S. House of Representatives." p. 6. Sept. 11, 2008.

63 "Statement of the American Medical Association to the Committee on Ways and Means Subcommittee on Health, U. S. House of Representatives." Sept. 11, 2008, p. 6.

64 "Statement of the American Hospital Association to the Senate Finance Committee" Roundtable on Health Care Delivery, April 21, 2009, p. 7.

65 "Transforming the Health Care Delivery System: Proposals to Improve Patient Care and Reduce Health Care Costs" Comments of the American Association of Medical Colleges to the Senate Finance Committee, May 16, 2009, http://www.aamc.org/advocacy/library/teachhosp/corres/2009/051609.pdf (Accessed 5/17/10).

66 "The Democrats' Last Ditch - Reconciliation or Bust" By John K. Iglehart, New England Journal of Medicine, March 3, 2010, www.nejm.org, p. e39(1)-e39(2) (Accessed 5/17/2010).

67 "Congress Passes Reconciliation Bill Amending Reform Law", CCH, CCH Briefing: Special Report, March 25, 2010, p. 1-5.

68 "Summary of New Health Reform Law" Kaiser Family Foundation, April 21, 2010, http://www.kff.org/healthreform/upload/8061.pdf (Accessed 4/14/2010).

69 "Key Provisions of Comprehensive Health Care Reform Legislation" Sonnenschein Nath & Rosenthal, LLP, March 30, 2010, p. 13.

70 "Patient Protection and Affordable Care Act" H.R. 3590, 111th Congress, March 23, 2010, Accessed at http://thomas.loc.gov/cgi-bin/query/F?c111:7:./temp/~c111G8zJzJ:e0: (Accessed 4/28/2010).

71 "A Partisan Divide on the Uninsured" By Tara Sussman Oakman et al., Health Affairs, Vol. 29, No. 4 (April 2010), p. 3.

72 "The Democrats' Last Ditch—Reconciliation or Bust" By John K. Iglehart, New England Journal of Medicine, March 3, 2010, http://www.nejm.org, p. e39(1)-e39(2) (Accessed 5/17/2010).

73 "The War Isn't Over" By Henry J. Aaron, and Robert D. Reischauer, New England Journal of Medicine, March 24, 2010, http://www,nejm.org, p. 1-2 (Accessed 5/17/2010).

74 "Pulling it Together: Implementation is Forever" by Drew Aultman, Kaiser Family Foundation, April 6, 2010, http://www.kff.org/pullingittogether/040610_altman.cfm (Accessed 5/17/2010).

75 "Implementation and the Legacy of Health Care Reform" By Christopher C. Jennings, New England Journal of Medicine, March 31, 2010, http://www,nejm.org, p. e51(3), (Accessed 5/5/2010); "The War Isn't Over" By Henry J. Aaron, and Robert D. Reischauer, New England Journal of Medicine, March 24, 2010, http://www.nejm.org, p. 2 (Accessed 5/5/2010).

76 "The War Isn't Over" By Henry J. Aaron, and Robert D. Reischauer, New England Journal of Medicine, March 24, 2010, http://www.nejm.org, p. 2 (Accessed 5/5/2010).

77 "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).

78 *Ibid.*

79 "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).

80 "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.

81 "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.

82 "The Congressional Budget Office Cost Estimate of H.R. 4872, Reconciliation Act of 2010", March 20, 2010, http://www.cbo.gov/doc.cfm?index=11379.

83 "Frequently Asked Questions about Health Insurance Reform," Health Insurance Reality Check, The White House, http://www.whitehouse.gov/realitycheck/faq#c1[6/16/2010 11:10:05 AM].

84 "The Congressional Budget Office Cost Estimate of H.R. 4872, Reconciliation Act of 2010", March 20, 2010, http://www.cbo.gov/doc.cfm?index=11379.

85 "Estimated Financial Effects of the 'Patient Protection and Affordable Care Act,' as Amended, Centers for Medicare and Medicaid Studies, Office of the Actuary, April 22, 2010.

86 "The Congressional Budget Office Cost Estimate of H.R. 4872, Reconciliation Act of 2010", March 20, 2010, http://www.cbo.gov/doc.cfm?index=11379

87 *Ibid.*

88 *Ibid.*

89 "Estimated Financial Effects of the 'Patient Protection and Affordable Care Act,' as Amended, Centers for Medicare and Medicaid Studies, Office of the Actuary, April 22, 2010.

90 "What Will Happen Under Health Reform- and What's Next?" The Commonwealth Fund, April 30, 2010. http://www.commonwealthfund.org/Content/Publications/Other/2010/What-Will-Happen-Under-Health-Reform-and-Whats-Next.aspx

91 "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.

92 *Ibid.*

93 "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. 9.

94 "Tax Provisions of in the Health Care Act," Journal of Accountancy, March 22, 2010, http://www.journalofaccountancy.com/Web/20102724.htm (Accessed April 10, 2010).

95 *Ibid.*

96 "Patient Protection and Affordable Care Act" H.R. 3590, 111th Congress, March 23, 2010, Accessed at http://thomas.loc.gov/cgi-bin/query/F?c111:7:./temp/~c111G8zJzI:e0: (Accessed 4/28/2010).

97 "Summary of New Health Reform Law" Kaiser Family Foundation, April 21, 2010, http://www.kff.org/healthreform/upload/8061.pdf (Accessed 5/6/2010).

98 *Ibid.*

99 "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).

100 "Health Reform Implementation Timeline," Kaiser Family Foundation, March 31, 2010, http://www.kff.org/healthreform/upload/8060.pdf, (Accessed 4/19/2010).

101 *Ibid.*

102 *Ibid.*

103 *Ibid.*

104 *Ibid.*

105 "Summary of New Health Reform Law" Kaiser Family Foundation, April 21, 2010, http://www.kff.org/healthreform/upload/8061.pdf (Accessed 5/6/2010).

106 "Key Provisions of Comprehensive Health Care Reform Legislation" Sonnenschein Nath & Rosenthal, LLP, March 30, 2010, p. 3.

107 "Health Care Reform Legislation: Provisions Affecting Employer-Sponsored Group Health Plans," Sonnenschein Nath & Rosenthal, LLP, April 14, 2010, p. 3.

108 *Ibid.*

109 "Summary of New Health Reform Law" Kaiser Family Foundation, April 21, 2010, http://www.kff.org/healthreform/upload/8061.pdf (Accessed 4/14/2010).

110 "Key Provisions of Comprehensive Health Care Reform Legislation," Sonnenschein Nath & Rosenthal, LLP, March 30, 2010, p. 4.

111 "Tax Provisions of in the Health Care Act," Journal of Accountancy, March 22, 2010, http://www.journalofaccountancy.com/Web/20102724.htm (Accessed April 10, 2010).

112 "Patient Protection and Affordable Care Act" H.R. 3590, 111th Congress, March 23, 2010, Accessed at http://thomas.loc.gov/cgi-bin/query/F?c111:7:./temp/~c111G8zJzI:e0: (Accessed 4/28/2010).

113 "Summary of New Health Reform Law" Kaiser Family Foundation, April 21, 2010, http://www.kff.org/healthreform/upload/8061.pdf (Accessed 4/14/2010).

114 *Ibid.*

115 "Federal Health Care Reform: Impacts on Employers," Anthem, April 7, 2010, http://preferredinscenter.com/learn/Anthem-Employer-HealthcareAct-Full.pdf, (Accessed 4/14/2010).

116 "Summary of New Health Reform Law" Kaiser Family Foundation, April 21, 2010, http://www.kff.org/healthreform/upload/8061.pdf (Accessed 4/14/2010).

117 "'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).

118 "Federal Health Care Reform: Impacts on Employers," Anthem, April 7, 2010, http://preferredinscenter.com/learn/Anthem-Employer-HealthcareAct-Full.pdf, (Accessed 4/14/2010).

119 "'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).

120 "Tax Provisions of in the Health Care Act," Journal of Accountancy, March 22, 2010, http://www.journalofaccountancy.com/Web/20102724.htm (Accessed April 10, 2010).

121 "Federal Health Care Reform: Impacts on Employers," Anthem, April 7, 2010, http://preferredinscenter.com/learn/Anthem-Employer-HealthcareAct-Full.pdf, (Accessed 4/14/2010).

122 "Patient Protection and Affordable Care Act" H.R. 3590, 111th Congress, March 23, 2010, Accessed at http://thomas.loc.gov/cgi-bin/query/F?c111:7:./temp/~c111G8zJzI:e0: (Accessed 4/28/2010).

123 "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).

124 *Ibid.*

125 *Ibid.*

126 *Ibid.*

127 "Provider Participation in ACOs May Hinge on HHS Regulations" By Robert Belfort, BNA Health Law Reporter, Vol. 19, No. 546 (April 15, 2010).

128 "The Patient Protection and Affordable Care Act Summary Implementation Timeline" Medical Group Management Association, (April 1, 2010), p. 1-8.

129 *Ibid.*

130 "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); "Restructuring, Consolidation in Health Care Make Reform Top Health Law Issue for 2010" By Susan Carhart, Mary Anne, Pazanowski, and Peyton M. Sturges, BNA Health Law Reporter, Vol. 19 No.5 (January 7, 2010), p. 2.

131 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; "Will Health Reform Slow Cost Growth" By John Sheils, The Lewin Group, March 26, 2010.

132 "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, Basic Books Inc. 1982, p. ix.

133 "Plunkett's Health Care Industry Trends and Statistics 2008 (Summary)," By Jack W. Plunkett, Plunkett Research Ltd., 2007, p. 44.

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.