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FEDERAL HEALTH CARE REGULATION

DON W. KING
Senior Scholar, Mercatus Center

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ABOUT DON W. KING, MD, JD, AUTHOR

DON W. KING is a senior scholar with the Mercatus Center at George Mason University. He is an Emeritus Professor at the Medical College of Georgia (MCG). While at MCG, he was Director of the Adult Epilepsy Program, maintaining a large clinical practice and publishing widely on topics related to epilepsy. His present research interests include health care regulation and policy. Dr. King received a B.A. from Baylor University and an M.D. from the University of Texas Medical Branch. He recently completed a J.D. at the George Mason University School of Law.

ABOUT SUSAN E. DUDLEY, SERIES CO-EDITOR (WITH FREDERIC SAUTET)

SUSAN E. DUDLEY is the Director of the Mercatus Center at George Mason University's Regulatory Studies Program and adjunct professor at the George Mason University School of Law. She has written on a variety of topics related to regulatory policy and applied finance. Before joining the Mercatus Center, she was Vice-President and Director of Environmental Analysis at Economist Incorporated, a consulting firm in Washington, DC, and has worked at several government agencies, including the Environmental Protection Agency, the Office of Management and Budget, and the Commodity Futures Trading Commission. Susan holds an MS from the Sloan School of Management at MIT and a BS (*summa cum laude*) in resource economics from the University of Massachusetts.

For more information about the Mercatus Center's Regulatory Studies Program visit us online at <http://www.mercatus.org/regulatorystudies> or contact Susan Dudley, Director of the Regulatory Studies Program, at (703) 993-4930 or sdudley@gmu.edu.

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FEDERAL HEALTH CARE REGULATION

DON W. KING

PREFACE

In his 1998 testimony before the National Bipartisan Commission on the Future of Medicare, Dr. Robert Waller, President and Chief Executive Officer of the Mayo Clinic, discussed the complexity of Medicare regulations:

My colleagues in the business office say there are 132,720 pages with which they must deal in terms of the regulatory environment....

This complexity has a negative effect on patient care.... It steals time from patient care, and it steals time from scholarly activities....¹

While Dr. Waller's testimony dealt primarily with physician billing, detailed federal regulations govern all aspects of health care. In addition, the number and complexity of regulations continue to grow.

Regulations have worthy goals and often have significant benefits. For example, a billing regulation may decrease the number of billing errors or decrease the number of excess payments that occur. However, regulations also have costs. As noted by Dr. Waller, the time and effort required to comply with regulations is time that could be spent on patient care, the discovery of new knowledge, or the development of innovative services.

The Regulatory Studies Program of the Mercatus Center at George Mason University conducts studies of the impact of regulations on society. This primer provides an overview of the major statutes and regulations that govern U.S. health care. It is designed to serve as an introduction to health care regulation for

¹ Statement of Robert Waller, M.D., President and Chief Executive Officer, The Mayo Clinic, to the National Bipartisan Commission on the Future of Medicare (Aug. 10, 1998) at <http://thomas.loc.gov/medicare/transcript81098.html>.

health care professionals, policymakers, academics, and lay people. This primer is not a compliance manual, and nothing it contains should be construed as legal advice.

As noted, there are thousands of pages of administrative regulations that govern U.S. health care. We have tried to include those regulations that we believe have the most influence on the care that patients receive. The primer undoubtedly contains errors of commission and omission. It will be posted on the Mercatus Center website. We would appreciate your corrections, comments, criticisms, and recommendations so that we may provide a more accurate and complete picture of the regulations that govern U.S. health care.

The primer has four components. **Chapter 1** provides an introduction to the concept of regulation, the types of regulation, and their application to health care.

Chapters 2-5 describe federal statutes and regulations that govern health care financing. Chapter 2 describes the effects of the U.S. Tax Code on health care. Chapter 3 describes Medicare, its payment structure, and its effects on both patients and health care providers. Chapter 4 provides a brief description of two statutes, the Health Maintenance Organization (HMO) Act and the Employee Retirement Income Security Act (ERISA). Each influences the structure of health care insurance and health care delivery. Chapter 5 describes the Consolidated Omnibus Budget Reconciliation Act (COBRA) and the Health Insurance Portability and Accountability Act (HIPAA), two statutes by which Congress attempted to increase health insurance coverage.

Chapters 6-9 describe federal statutes and regulations that directly affect health care professionals. Chapter 6 describes the Food and Drug Administration (FDA) and the regulation of pharmaceutical and medical device manufacturers. Chapter 7 describes federal regulation of hospitals and other health care facilities. Chapter 8 describes the federal government's efforts to eliminate fraud and abuse related to Medicare billing and payment. Chapter 9 describes recently implemented regulations designed to assure the security and privacy of health information.

Chapters 2-9 each contain an introduction that reviews the major legislation authorizing the regulations discussed in that chapter. Next is a general description of the statutory provisions and administrative regulations. The last portion of each chapter includes a brief analysis of the major effects the regulations have had on the regulated parties, a review of the benefits and costs, and a discussion of how the regulations have helped to shape U.S. health care.

Chapter 10 provides alternatives to the current federal regulatory structure. Appendix A is a table of the primary statutes governing U.S. health care, and Appendix B is a table of the principal administrative regulations governing U.S. health care.

CHAPTER 1: INTRODUCTION TO HEALTH CARE REGULATION

In 2004, health care expenditures represented 16.0 percent of U.S. gross domestic product (GDP).¹ These expenditures paid for the services and products of millions of professionals and organizations, including: (1) physicians and other professionals, (2) hospitals and other facilities, (3) health insurers and health plans, and (4) pharmaceutical and medical device manufacturers.

This primer provides an overview of federal regulations that govern U.S. health care. Most federal regulations are directed at physicians and other professionals who provide services. However, the regulations that most influence health care are tax code regulations that apply directly to individuals and employers. In addition, those regulations that apply to professionals have a major influence on the health care that individuals receive.

A. METHODS OF REGULATING HEALTH CARE

When used in conjunction with economic activity, the term “regulation” usually refers to enforcement of rules by an administrative agency of government. The regulation’s goal may be to prevent injury, lower prices, or make a product or

service more accessible. There are other methods to promote these goals, and, in a sense, these other methods are also a form of regulation. In this primer, we consider four categories of health care regulation: (1) competition within a marketplace or “market regulation,” (2) tort law, (3) criminal law, and (4) regulation by administrative agencies. These four types of regulation are inter-related, and together they provide the institutional framework within which patients, physicians, and other health care participants interact.

A1. Market Regulation

Within a marketplace, individuals who produce safe and effective goods at a price customers are willing to pay will have many customers. Conversely, producers whose goods are unsafe, ineffective, or over-priced, will fail. To thrive, the latter must adjust their activity to a higher standard. They must improve their goods, decrease their prices, or both.

In a marketplace, the consumer is the regulator, purchasing those goods that are both safe and effective while avoiding those that are not. Market regulation takes advantage of producers’ knowledge of the most effective way to produce high quality goods and of their voluntary actions

¹ Centers for Medicare and Medicaid Services, Table 1, *National Health Expenditures Aggregate and Per Capita Amounts, Percent Distribution, and Average Annual Percent Growth by Source of Funds: Selected Calendar Years 1960-2004*, NHE Web Tables, Historical, National Health Expenditure Data, at <http://www2.cms.hhs.gov/NationalHealthExpendData/downloads/tables.pdf>.

to improve those goods. Market regulation also takes advantage of consumers' knowledge of their needs and of their voluntary actions to purchase goods that best meet those needs.

Producer competition enhances market regulation. In a marketplace, producers compete to better serve their customers. Competition provides consumers with options, and when consumers have options, they are more likely to find goods that meet their needs at a price they can afford.

Widely disseminated information also enhances market regulation. When consumers have information concerning product safety, effectiveness, and price, they can choose goods they desire and avoid unsafe, ineffective, or expensive products. Word-of-mouth, newspapers, television, and the Internet provide information to consumers. Advertising is also a useful method for disseminating information.² In addition, some organizations exist primarily to disseminate information about products to potential buyers. Consumer's Union, the publisher of *Consumer Reports*, is probably the best known of these organizations.³

Certifying or accrediting bodies also provide

information and thus enhance market regulation. Accrediting organizations evaluate products or services and certify whether the product meets certain standards. These bodies encourage producers to provide high quality products and inform consumers whether a product meets their standards. In general, these organizations are flexible, readily adapting to new procedures and technology. The most widely known accrediting body for consumer product safety is Underwriters Laboratory, Inc.⁴

Although not as numerous as with consumer products, an increasing number of organizations evaluate health care quality. For example, Health Grades, Inc. is an independent, for-profit organization that rates hospitals and nursing homes.⁵ It provides information to the public for a small price. The National Committee for Quality Assurance (NCQA), a nonprofit organization, provides information related to health plan quality.⁶ At this time, however, there is little public information concerning health care prices, and the information that is available is often confusing.⁷

Health care accrediting bodies also enhance market regulation. The most widely known is the Joint Commission on Accreditation of Health

² See George J. Stigler, *The Economics of Information*, 69 J. Pol. Econ. 213 (Jun., 1961); J. Howard Beales, III, *Economic Analysis and the Regulation of Pharmaceutical Advertising*, 24 Seton Hall L. Rev. 1370 (1993-1994).

³ <<http://www.consumersunion.org>>

⁴ <<http://www.ul.com>>

⁵ <<http://www.healthgrades.com>>

⁶ <<http://www.ncqa.org>>

⁷ See Federal Trade Commission/Department of Justice, *Executive Summary*, IMPROVING HEALTH CARE: A DOSE OF COMPETITION (July 23, 2004) at <<http://www.ftc.gov/reports/healthcare/040723healthcarerpt.pdf>>.

Care Organizations (JCAHO).⁸ JCAHO audits hospitals, evaluating their facilities and procedures. If the hospital meets standards, JCAHO will award accreditation. The NCQA provides similar accreditation for health plans.⁹

Professional organizations that certify medical specialists also serve an accrediting function. Each physician who completes the required training and passes an examination becomes certified to practice in a specialty. A physician may provide care without becoming certified. However, board certification becomes public information, and this information is available to patients when choosing a physician and to physicians when making referrals.

A2. Tort Law

Tort law is another form of economic and professional regulation. Tort law's stated objectives include: (1) deterring injuries, (2) compensating victims, and (3) providing justice. From an economic perspective, tort law's primary goal is to deter all injuries except those that are less costly than the precautions necessary to prevent them. Although the purpose of tort law is prevention, courts impose liability after an injury has occurred. Economic theory suggests that award-

ing damages to a victim after an injury has occurred provides an incentive for a potential injurer to use precautions prior to the injury, thus preventing the injury from occurring.

Americans frequently use tort law in an attempt to regulate health care providers. Since tort law is primarily state law, this primer does not discuss most tort law. It does discuss a number of federal laws that grant individuals and organizations a right to bring lawsuits under certain circumstances.¹⁰

A3. Criminal Law

Criminal law also represents a form of regulation. Legislatures establish rules to deter actions that cause harm to others, and courts impose penalties if one violates those rules. In general, criminal laws require criminal intent on the part of the wrongdoer, and criminal law deals with more egregious forms of behavior than tort law. Because society considers criminal behavior a harm to the public, the state prosecutes the alleged wrongdoer. Penalties include fines and imprisonment.

Numerous criminal laws apply to health care providers. Most are state laws and thus are not the

⁸ <<http://www.jcaho.org>>

⁹ See <<http://www.ncqa.org>>, supra note 6.

¹⁰ See Chapters 4, 7, and 8.

subject of this primer. In addition to generally applicable criminal laws, Congress has created a number of “health care offenses” that apply specifically to health care providers. This primer discusses federal criminal laws that most affect U.S. physicians.¹¹

A4. Regulation by Administrative Agencies

Similar to tort and criminal law, the purpose of many administrative regulations is to decrease the probability that an injury or harm will occur. For example, the goal of a regulation requiring a new drug to be safe is to decrease the risk that a patient taking a drug will be harmed. Unlike the situation with tort law, an agency may impose a penalty before harm occurs. Violation of a regulation may result in a fine, an injunction against further activity, or a criminal penalty. Market regulation and tort law take advantage of an individual’s knowledge of how best to prevent harm. Administrative regulation takes advantage of an agency’s knowledge of harm prevention.

Administrative regulation differs from market regulation in that administrative regulations apply uniformly to many regulated entities. However, regulations that may be appropriate for one entity may be inappropriate for others. Unlike the case with market regulation, it is difficult to build flexibility into an administrative

regulation. There are numerous administrative regulations that govern health care. This primer focuses on those regulations enforced by federal administrative agencies.

B. REGULATION BY ADMINISTRATIVE AGENCIES

B1. Rationale for Regulation

The public interest theory of regulation suggests that administrative regulations are necessary because of “market failure,” i.e. for one or more reasons, a free market does not provide the appropriate quantity, quality, price, or safety of goods or services. Proponents of the public interest theory maintain that administrative regulations are necessary to correct the following types of market failure: (1) externalities, (2) monopolies, (3) public goods, and (4) information asymmetries.

Another argument in support of regulation is that a competitive marketplace may not provide equitable outcomes. For example, unregulated health care markets may exclude low income individuals or persons who have a genetic or medical condition that renders health insurance or health care very expensive. This primer discusses a number of regulations that attempt to ensure market participation for certain individuals.¹²

¹¹ See Chapter 8.

¹² See Chapters 3, 5, and 7.

Students of regulation have observed that regulations are sometimes unrelated to market failures or equity concerns. The economic theory of regulation suggests that regulations occur for two primary reasons: (1) well organized advocacy groups, often groups representing the regulated industry, exert pressure for regulations, and (2) legislators enact regulations because of their interest in remaining in office.¹³ Opponents of administrative regulation argue that administrative regulations also may fail, i.e. in many instances, an administrative regulation may be less satisfactory and more costly than imperfect market regulation.

B2. Statutes and Agency Regulations

Statutes passed by legislative bodies contain provisions that require regulated entities to behave in certain ways. Also, statutes may authorize agencies to issue regulations. As a result, administrative agencies enforce regulations contained in statutes as well as regulations issued by the agencies themselves. In addition to issuing binding regulations, agencies may issue nonbinding documents that in effect regulate the behavior of the governed entity. For example, the Food and Drug Administration (FDA) commonly issues “guidance documents” to inform pharmaceutical companies how it views certain practices. This primer discusses statutes as well as both binding and nonbinding regulations issued by the agencies themselves.

B3. Federal vs. State Regulation

In the United States, both federal and state governments exert regulatory authority. Prior to the twentieth century, there was minimal federal regulation of the private sector and no significant federal regulation of health care. This changed dramatically in the twentieth century. Today, federal regulation has a much greater influence on health care than state regulation. In some instances, federal regulation preempts state regulation, effectively eliminating a state’s ability to regulate the activity. In others, federal and state regulations coexist. When federal and state regulations coexist, federal regulation usually becomes the “floor” of regulation, i.e. a state may enact more stringent rules on the regulated entity, but not less stringent rules.

With respect to health care, states issue professional licenses, handle disciplinary actions, and to varying degrees, regulate hospitals and health insurance. This primer focuses principally on federal regulation. However, it briefly discusses state health insurance regulation and state regulation of health care facilities.¹⁴

B4. Benefits and Costs of Administrative Regulation

Administrative regulations often have benefits. For example, a safety regulation may result in

¹³ See George J. Stigler, *The Theory of Economic Regulation*, 2 Bell J. Econ. and Mgmt. Sci. 3 (Spring, 1971); Sam Peltzman, *Toward a More General Theory of Regulation*, 19 J. L. Econ. 211 (Aug., 1976).

¹⁴ See Chapters 4, 5, and 7.

fewer injuries than would occur if the activity were unregulated. Similarly, an environmental regulation may improve environmental quality. To estimate the monetary benefit of a regulation to prevent injuries, one can multiply the estimated cost of an injury by the difference between the number of injuries without the regulation and the number with the regulation. One can make similar estimates concerning environmental and other regulations.

In addition to benefits, there are at least three types of economic or opportunity costs associated with administrative regulations: (1) the cost to the taxpayers to support the regulatory agency; (2) the cost to the regulated entity to comply with the regulation; and (3) the indirect costs. Indirect costs include the cost of the consequences or changes in behavior that result from the regulation, i.e. the difference between the value of the economic activity that would have occurred without the regulation and the value of the economic activity that occurs because of the regulation.

The first type of cost is relatively easy to measure. The cost of the regulatory agency includes the cost to conduct research and analysis, to issue regulations, to monitor the regulated entity's behavior, and to bring enforcement actions. One can estimate this cost using the budget of the agency that enforces the regulation.

Compliance costs for the regulated entity include: (1) research necessary to understand the

regulation, (2) training of personnel to comply with the regulation (3) equipment needed for compliance, e.g. information systems, (4) monitoring of the organization's compliance activities, (5) record keeping and reporting to the agency, and (6) defense against enforcement actions if necessary. Compliance costs are more difficult to measure than an agency's costs, but one can estimate them in a number of ways. These include: (1) a step-by-step analysis of the measures taken by regulated entities to comply, (2) a survey of regulated entities to determine their estimates of compliance costs, or (3) an inference of costs by analogy to compliance costs in another industry.

The indirect or invisible costs of a regulation are the costs of the behavior change or consequences that result from the regulation. These are especially difficult to measure. Regulations alter the incentives one faces when choosing between alternative courses of action. For example, a regulation may decrease the incentive to develop a product or service, or a regulation may prohibit one from providing a service in the most efficient way. Since the prohibited activity did not occur, its precise value remains unknown. Thus, although indirect costs are very real, they may be difficult to measure.

Even though indirect costs are difficult to measure, one must fully consider them, especially when dealing with regulations that affect safety or health. As an illustration, the FDA is responsible for determining which drugs U.S. physicians may use to treat patients. Assume there is a

potentially life-saving drug that has serious side effects, and there is no life-saving alternative. In this situation, disapproving the drug has the benefit of eliminating the morbidity and mortality that would occur from use of the drug. On the other hand, disapproving the drug has the cost of the excess morbidity and mortality in patients who would have survived or improved if the new drug had been available.

As noted above, the primary goal of many health care regulations is to provide services to individuals who otherwise might not have access to them. These regulations often result in a transfer of wealth from individuals who do not benefit from the regulation to those who do. For example, an insurance mandate may transfer wealth from a policyholder who does not benefit from the mandate to one who does. This is because a mandate may increase the price for those who do not need the mandated services. In these situations, a gain to one person is a cost to another.

In general, wealth transfers are not an economic cost and do not result in a decrease in total social wealth. On the other hand, it is important to consider how these transfers affect different groups of people. In addition, even when a regu-

lation is primarily a wealth transfer, there are economic costs. These include the cost of the government agency implementing the transfer, compliance costs for transferor and transferee, indirect costs secondary to the consequences for both transferor and transferee, and often lobbying or “rent-seeking” costs for and against the regulation by the transferee and transferor respectively.

Until recently, there were very few studies of the benefits and costs of health care regulation. In 2004, Conover published the most comprehensive analysis of these benefits and costs.¹⁵ This primer includes estimates from his analysis.¹⁶

C. MEASURING THE VALUE OF HEALTH CARE REGULATIONS

Researchers define high quality health care in various ways, e.g. the extent to which physicians or other professionals use evidence-based guidelines, make the correct diagnosis, select the appropriate treatment, or avoid errors.¹⁷ In general, excellent quality refers to care that is most likely to produce the best health outcome.

There are few studies measuring the effect of health care regulations on measures of quality.

¹⁵ See Christopher J. Conover, *Health Care Regulation: A \$169 Billion Hidden Tax*, Policy Analysis No. 527, Cato Institute (Oct. 4, 2004).

¹⁶ See Chapters 4 – 9.

¹⁷ See Federal Trade Commission/Department of Justice, *Overview/Background*, IMPROVING HEALTH CARE: A DOSE OF COMPETITION, Chapter 1 (July 23, 2004).

However, in other settings, individual choice and producer competition result in high quality services and low prices. Thus, more patient choice and more competition might be expected to improve health outcomes. Regulations that prevent physicians, hospitals, insurers, or manufacturers from providing services in the most efficient manner may have negative effects on health outcomes.

The most common marker for health care access is the presence or absence of health insurance. Lack of health insurance has been shown to correlate with poor health outcomes.¹⁸ Thus, one goal of many health care regulations is to increase the prevalence of health insurance. Since high prices may result in less access to health insurance and health care, a lower price for the same service may be associated with better outcomes.

In this primer, we consider the effects of health care regulations on a number of measures. These include the prevalence of health insurance, the

extent of patient choice, the possibility for competition and innovation, and prices.

D. SUMMARY

There are at least four types of regulation: (1) market regulation; (2) tort law; (3) criminal law; and (4) regulation by administrative agencies. Market regulation is enhanced by competition among producers, by wide dissemination of information concerning quality and price, and by accrediting organizations that certify that certain standards are met.

Both federal and state governments enforce administrative regulations. Administrative agencies enforce statutes passed by the legislative branch and regulations issued by the agencies themselves. Regulation by administrative agencies has benefits and costs. This primer focuses on administrative regulations enforced by federal administrative agencies.

ADDITIONAL READING

1. John Blundell and Colin Robinson, *REGULATION WITHOUT THE STATE...THE DEBATE CONTINUES* (London, The Institute of Economic Affairs 2000).
2. Christopher J. Conover, *Health Care Regulation: A \$169 Billion Hidden Tax*, Policy Analysis No. 527, Cato Institute (Oct. 4, 2004).
3. Susan E. Dudley, *PRIMER ON REGULATION*, Mercatus Center at George Mason University (Nov., 2005). David D. Friedman, *LAW'S ORDER* (Princeton, Princeton University Press 2000).
4. George J. Stigler, *The Theory of Economic Regulation*, 2 Bell J. Econ. M'gmt Sci. 3 (Spring, 1971).
5. Sam Peltzman, *Toward a More General Theory of Regulation*, 19 J. L. Econ. 211 (Aug., 1976).

¹⁸ See J. Hadley, *Sicker and Poorer – The Consequences of Being Uninsured*, 60 Med. Care Res. Rev. 3 (2003).

CHAPTER 2: REGULATION OF HEALTH CARE FINANCING THROUGH THE TAX CODE¹

Prior to 1930, private health insurance was limited primarily to direct service plans provided by employers in certain industries.² During the 1930s, health insurance became more common and took two additional forms, Blue Cross service benefit plans and commercial indemnity plans. Blue Cross plans were nonprofit hospitalization plans established primarily by hospitals.³ An individual paid an annual fee to the plan, and when the individual required hospitalization, the plan paid the hospital directly for the services provided. Commercial, for-profit plans differed from Blue Cross plans.⁴ A patient with commercial insurance paid the hospital directly, and the insurance company reimbursed or indemnified the patient for costs. Blue Shield plans developed later and covered physician services. Blue Shield plans combined features of service benefit plans and indemnity plans.⁵

During World War II, the U.S. imposed wage controls on American businesses.⁶ Precluded from

increasing monetary wages, businesses increased fringe benefits, which often included health insurance. In 1943, the Internal Revenue Service (IRS) ruled that employees could exclude the value of employer-paid health insurance premiums from their taxable income.⁷ In 1954, Congress excluded by statute the value of employer-purchased health insurance from an individual's gross income.⁸

Because employer-provided health insurance was not taxable to the employee, an employee effectively purchased employer-provided insurance with before-tax dollars. In contrast, individually purchased health insurance required after-tax dollars. The difference in tax treatment between employer-provided insurance and individually purchased insurance is still present. In 2006, individually purchased insurance and out-of-pocket expenses are tax deductible only if the individual itemizes deductions and only for expenses that exceed seven and one half percent of adjusted

¹ See Appendix A for related statutes; see Appendix B for related regulations.

² See Paul Starr, *The Triumph of Accommodation*, in *THE SOCIAL TRANSFORMATION OF AMERICAN MEDICINE* 290, 291-295 (1982).

³ *Id.* at 295-310.

⁴ *Id.*

⁵ *Id.*

⁶ See Clark C. Havighurst, *American Health Care and the Law*, in *THE PRIVATIZATION OF HEALTH CARE REFORM 1* (M. Greg Bloche, ed. 2003); Joint Economic Committee, *How the Tax Exclusion Shaped Today's Private Health Insurance Market* (Dec. 17, 2003) at <<http://jec.senate.gov/files/HealthTaxExclusion.pdf>>.

⁷ See Joint Economic Committee, *supra* note 6.

⁸ *Id.*

gross income.⁹ Disparate tax treatment between employer-provided insurance and individually purchased insurance is a major reason most working Americans obtain health insurance through their employer.

During the 1990s, a number of reformers proposed that individuals be allowed to establish tax free medical savings accounts (MSAs).¹⁰ MSAs are accounts to which a person may deposit before-tax funds, and then withdraw these funds tax free to pay for health care expenses.

As a part of the Health Insurance Portability and Accountability Act (HIPAA) of 1996, Congress passed a five year MSA demonstration project, limited to 750,000 persons.¹¹ When the project was reauthorized in 2000, Congress renamed these accounts “Archer MSAs” in recognition of Congressman Archer, the primary sponsor. In 2003, Congress passed the Medicare Prescription Drug Improvement and Modernization Act (MMA). Title XII of MMA amended the tax code, allowing all Americans who meet certain criteria to establish tax free health care accounts.¹² These accounts, called Health

Savings Accounts (HSAs), are structurally similar to the previously authorized MSAs.

A. PROVISIONS OF TAX CODE AFFECTING HEALTH CARE

A1. Exclusion of Employer-Provided Health Insurance and HSA Contributions

The Internal Revenue Code states, “except as otherwise provided . . . gross income of an employee does not include employer-provided coverage under an accident or health plan.”¹³ The code provides for similar exclusions from income for an employer’s contribution to an Archer MSA or to an HSA.¹⁴

A2. Deductibility of Individual Medical Expenses

The Internal Revenue Code allows an individual to deduct “expenses paid . . . for medical care . . . to the extent that such expenses exceed more than seven and one half percent of adjusted gross income.”¹⁵

A3. Health Savings Accounts

An HSA is a trust established within a bank or other financial institution to pay for qualified

⁹ 26 U.S.C. § 213(a).

¹⁰ See John C. Goodman and Gerald L. Musgrave, *Controlling Health Care Costs with Medical Savings Accounts*, Study No. 168, National Center for Policy Analysis (Jan., 1992).

¹¹ Pub. L. No. 104-91.

¹² Pub. L. No. 108-73.

¹³ 26 U.S.C. § 106(a).

¹⁴ 26 U.S.C. § 106(b); 26 U.S.C. § 106(d).

¹⁵ 26 U.S.C. § 213(a).

medical expenses.¹⁶ The Internal Revenue Code allows an individual to deduct contributions made “by or on behalf of” the individual to an HSA.¹⁷ Since this deduction is “above the line,” HSA contributions are effectively excluded from gross income.¹⁸ The code limits HSAs to individuals who are ineligible for Medicare, who maintain a high deductible health plan (HDHP), and who have no health plan other than an HDHP.¹⁹ For 2006, an HDHP is defined as a health plan that has an annual deductible not less than \$1,050 for an individual or not less than \$2,100 for a family.²⁰ In addition, to qualify as an HDHP, the HDHP must limit the policyholder’s annual out-of-pocket expenses. For 2006, the maximum out-of-pocket expense is \$5,250 for an individual or \$10,500 for a family.²¹

An HSA owner may not use HSA funds to purchase an HDHP or another type of health insurance.²² However, one may use HSA funds to pay for long term care insurance. If an HSA owner withdraws funds for a reason other than qualified medical expenses, the owner must pay a ten percent penalty plus income tax on the amount withdrawn.²³ The owner may invest funds main-

tained in the HSA account, and the proceeds remain tax free. An HSA owner may retain funds within the HSA from year to year to pay for medical expenses in subsequent years. For 2006, the maximum annual contribution is \$2,700 for an individual HSA or \$5,450 for a family HSA.²⁴

B. EFFECTS OF DISPARATE TAX TREATMENT BETWEEN EMPLOYER-PROVIDED HEALTH INSURANCE AND OTHER HEALTH CARE EXPENSES

When the tax code allows individuals to exclude from income one type of expense, but not another, individuals have a strong incentive to meet their needs using the type of expense that is excludable. Since employer-provided insurance is excludable and individually purchased insurance is not, the tax code encourages individuals to obtain health insurance through their employer. Since out-of-pocket expenses are not excludable, except for persons who recently have established HSAs, there is a strong incentive for individuals to choose comprehensive plans that cover even minor expenses.

¹⁶ 26 U.S.C. § 223(d).

¹⁷ 26 U.S.C. § 223(a).

¹⁸ Unlike a below-the-line itemized deduction, an “above the line” deduction is in effect an exclusion from gross income. Throughout this primer, we will use the terms exclusion or excludable when referring to an HSA.

¹⁹ 26 U.S.C. § 223(b), (c).

²⁰ Internal Revenue Service, *Rev. Proc. 2005-70*, Internal Revenue Bulletin: 2005-47 (Nov. 21, 2005), at <http://www.irs.gov/irb/2005-47_IRB/ar13.html>.

²¹ *Id.*

²² 26 U.S.C. 223(d).

²³ 26 U.S.C. 223(f).

²⁴ Internal Revenue Service, *supra* note 20.

Employer-sponsored group insurance offers many advantages.²⁵ Large employers provide an effective means for pooling risk. In addition, employers can gather information concerning insurance products, bargain for discounts, save on administrative costs, and bargain for improvements in health care quality. Disadvantages include decreased portability and fewer choices for employees. Also, limiting tax-excludability to employer-provided insurance results in higher prices and decreased access for those without employer-provided insurance.

B1. Effects on Prices

Tax advantaged, employer-purchased health insurance increases the demand for health care services in a number of ways. Preferred tax treatment renders health care expenses “less costly” for an individual in comparison to the same individual’s other expenses. This increases the individual’s demand for health care services. Second, the tax advantage for insurance, but not for out-of-pocket expenses, provides an incentive for employees to choose expensive, comprehensive plans with “first-dollar” coverage, i.e. the health plan pays for minor services, including office visits. This also increases the demand for health care services. Finally, because the individual does not pay directly for health insurance, the cost is “hidden” from the individual. Each of these factors increases the demand for health care services, and

the increased demand results in increased prices for both health care and health insurance.

B2. Effects on Access

The tax-preference for employer-sponsored insurance initially increased the percentage of working Americans with health insurance. Also, because employer-provided insurance is less costly for an individual than individually purchased insurance, the disparate tax treatment has increased the percentage of insured individuals who obtain insurance through their employer.

Since individual health insurance is not tax deductible, except for expenses greater than seven and one half percent of adjusted gross income, health insurance is “more costly” for an individual who pays with after-tax dollars. Because employer-provided insurance has made both health insurance and health care more expensive than they otherwise would be, health insurance and health care are less available to those without employer-provided insurance. As a result, few people purchase individual insurance, and a large number of individuals remain uninsured. Based on the 2004 Current Population Survey, in 2004, 59.8 percent of Americans had employment-based insurance, 9.3 percent had direct-purchase insurance, 27.2 percent had government-provided insurance, and 15.6 percent had no insurance.²⁶

²⁵ See David A. Hyman and Mark Hall, *Two Cheers for Employment-Based Health Insurance*, 2 Yale J. Health Policy L. Ethics 23 (2001).

²⁶ Carmen De Navas-Walt, Bernadette D. Proctor, Cheryl Hill Lee, *Income, Poverty, and Health Insurance Coverage in the United States: 2004*, Current Population Reports, P60-229 (Aug., 2005). The sum of the percentages is greater than 100 because some people have more than one type of insurance.

B3. Effects on Individual Choice, Competition, and Innovation

When an individual obtains health insurance through an employer, the individual must choose one of the options the employer makes available. Employers may have different preferences than their employees, and employees of the same firm may have different preferences than their fellow employees.²⁷ To control costs, employers and health plans must use measures that also may decrease an individual's options for care. In contrast, individually purchased insurance and direct payment for services allow an individual a broader range of options.

Disparate tax treatment has resulted in less competition in the individual health insurance market. Because one pays for individually purchased insurance with after-tax dollars, there is little demand for individual health insurance. As a result, insurers have little incentive to develop flexible, inexpensive products for individuals who are responsible for their own health care.

C. EFFECTS OF HEALTH SAVINGS ACCOUNTS

As with employer-provided insurance, allowing HSA owners to exclude HSA deposits from taxable income provides an incentive for individuals to pay

a portion of their health care using HSAs. Because contributions to HSAs are limited and individuals cannot use HSAs to purchase an HDHP policy, the tax benefit for HSA owners is less than for employees with employer-provided insurance.

According to a recent report from the trade organization, America's Health Insurance Plans (AHIP), more than three million Americans had chosen HSAs as of January, 2006, two years after tax-excludable HSAs were allowed.²⁸ The rapid acceptance thus far suggests that HSAs will be a popular option for many Americans.

C1. Effects on Prices

Because HSAs allow individuals to take advantage of tax free health care for a portion of their expenses, there may be some overall increase in demand for health care services, and this could result in increased prices. However, since most Americans under 65 years of age already have tax-excludable health insurance, this effect should be small. It is possible that the decreased demand resulting from individual control over health spending will more than offset the increased demand resulting from increased tax free health care.

Because individuals who own HSAs pay directly for their care up to the annual deductible, HSA owners are likely to be more cost-conscious than

²⁷ See David A. Hyman and Mark Hall, *supra* note 25.

²⁸ America's Health Insurance Plans, *HSAs Triple in 10 Months*, Press Release (Jan. 16, 2006) at <<http://www.ahip.org/content/pressrelease.aspx?docid=14641>>.

those who maintain first-dollar coverage. In one study, there was a direct relationship between the percentage of expenses paid by a third party and an individual's total outpatient expenses.²⁹ To the extent that people choose HSAs to finance their health care, there will likely be a cumulative decrease in demand for health care services. This may result in decreased prices.

HSAs should also result in fewer administrative and claims costs than are necessary with employer-provided insurance. When a health plan pays a physician for a minor patient visit, the physician must document each service, must generate a claim for each service, and must send each claim to the payer. The payer must determine that the service was covered and that it was "necessary" for the patient's condition. The payer usually sends an explanation of benefits to the individual, and often both the payer and the patient pay a portion of the fee.

Unlike patients who have insurance for minor services, individuals with HSAs pay for many services directly, often at the time of service. Even with HSAs, it is necessary for a physician to document the service provided and to send information to the HDHP insurer, so that expenses can

be applied against the deductible. Nevertheless, the administrative costs associated with HSAs and HDHPs may be significantly less than with comprehensive coverage. A 1992 study estimated that the combined use of MSAs and health care debit cards may save up to \$33 billion per year in administrative costs.³⁰ To the extent direct payment for services decreases information flow to third party payers, there also will be an enhancement of patient privacy.³¹

C2. Effects on Access

Because HSAs provide tax free coverage for at least a portion of health care expenses, some previously uninsured individuals establish HSAs. Of those persons who initially established HSAs with an HDHP insurer that tracked prior coverage, 37 percent were uninsured prior to establishing the HSA.³² To the extent that uninsured individuals establish HSAs, there will be an increase in the number of Americans with health insurance.

One additional advantage of HSAs is they are portable. Employees with HSAs own their HSAs. Thus, HSA owners do not lose insurance coverage or need to change physicians when they change jobs. The increased portability of HSAs should also increase the number of insured Americans.³³

²⁹ See Willard G. Manning, et al., *Health Insurance and the Demand for Medical Care: Evidence from a Randomized Experiment*, 77 Am. Econ. Rev. 251, 259 (1987).

³⁰ See John C. Goodman and Gerald L. Musgrave, *supra* note 10.

³¹ For more a more complete discussion of health information privacy, see Chapter 9.

³² America's Health Insurance Plans, Center for Policy Research, *Number of HSA Plans Exceeded one Million in March 2005* (May 4, 2005) at <<http://www.ahip.org/content/fileviewer.aspx?docid=9771&linkid=83197>>.

³³ For a more complete discussion of insurance portability, see Chapter 5.

C3. Effects on Patient Choice

HSAs offer individuals additional choices. For most Americans, an employer or government entity pays a large portion of health care expenses. For those with employer-provided insurance, the employee must choose one of the options made available by the employer. Because the payer has large expenses, it must make efforts to control these expenses. The efforts to control costs may restrict a patient's choice of physician, diagnostic test, or treatment.

Unlike individuals with employer and government-provided insurance, individuals who maintain HSAs are able to control and pay for their own health care expenses up to the deductible amount. Instead of a third party, an HSA owner is responsible for cost control. In consultation with a physician or other trusted person, an HSA owner may choose the desired physician, diagnostic testing, or treatment. Also, removing the third party from the decision-making process for minor services may lead to a more effective patient-physician relationship.

As noted above, HSAs offer individual control over health care expenditures up to the deductible amount. However, if the HSA owner

has expenses that exceed the deductible, the HDHP will pay the expenses in a manner similar to other insurers. As a result, an HDHP insurer may use cost control measures similar to those of managed care organizations (MCOs).³⁴ Also, some HSA owners may choose to have the HDHP insurer assist in cost control measures even when using HSA funds.³⁵

C4. Effects on Competition

Since HSAs allow patients to control more of their health care expenditures, physicians, hospitals, and insurers may compete more actively for individual patients. At present, there is competition among health plans to provide insurance for large employer groups and competition among physicians and hospitals to serve as providers for health plans. There is also competition to better serve individual patients, but it has been insufficient to maintain stable prices.

A comparison between cosmetic surgery and other health care services illustrates the effect direct patient payment may have on competition and price. Traditional health plans do not usually cover cosmetic surgery. Thus, individuals pay directly for most cosmetic procedures. One investigator found that between 1992 and 2001, prices

³⁴ For a more complete discussion of managed care and MCOs, see Chapter 4.

³⁵ See Mark A. Hall and Clark C. Havighurst, *Reviving Managed Care with Health Savings Accounts*, 24 *Health Affairs* 1490 (2005).

for cosmetic procedures increased less than 20 percent, while the price of standard health services increased almost 50 percent.³⁶ During this time, the increase in prices for cosmetic procedures was less than the inflation rate, and cosmetic procedures became more widely available. Competition among surgeons is one likely explanation for the wide availability and relative stability of prices for cosmetic surgery. Competition among physicians, hospitals, and insurers to provide non-cosmetic medical services and health insurance may result in greater availability of medical services, better insurance products, and lower prices.

D. SUMMARY

The Internal Revenue Code effectively excludes employer-provided health insurance from an individual's income for income tax purposes. It does

not exclude individually purchased insurance or out-of-pocket expenses. As a result, most working Americans obtain health insurance through their employer, and health plans tend to be comprehensive. The tax preference for employer-provided health insurance increased the prevalence of health insurance. However, it resulted in high health care prices, less access for those without employer-provided insurance, and often fewer choices for patients.

HSA's allow an individual to pay for out-of-pocket medical expenses with before-tax dollars. To qualify for an HSA, one must be ineligible for Medicare, maintain an HDHP, and have no other health plan. Potential advantages of HSA's include: increased patient choice, decreased health care prices, and more available services for individual patients.

ADDITIONAL READING

1. Clark C. Havighurst, *American Health Care and the Law*, in *THE PRIVATIZATION OF HEALTH CARE REFORM 1* (M. Greg Bloche, ed. 2003).
2. Paul Starr, *The Triumph of Accommodation*, in *THE SOCIAL TRANSFORMATION OF AMERICAN MEDICINE* 290 (1982).
3. David A. Hyman and Mark Hall, *Two Cheers for Employment Based Health Insurance*, 2 *Yale J. Health Policy L. Ethics* 23 (2001).

³⁶ Devon Herrick, *Why are Health Care Costs Rising?* Brief Analysis No. 437, National Center for Policy Analysis (May 7, 2003).

CHAPTER 3: REGULATION OF HEALTH CARE FINANCING: MEDICARE AND MEDICAID¹

Just as tax code revisions changed the way working Americans obtained health insurance, the establishment of Medicare and Medicaid changed the way older and low income Americans obtained health insurance. Medicare is a federal program that finances health care for persons 65 years of age or older, for disabled persons, and for patients with end-stage renal disease. Medicaid is a combined federal and state program that finances health care for low income citizens.

The statute establishing Medicare and Medicaid is a “spending” statute, not a “regulation” statute. However, because these programs have had a major influence on how physicians and hospitals provide care and because they have imposed administrative regulations on health care providers, a primer on health care regulation would be incomplete without a basic description of these programs. Since Medicaid is actually 50 separate state programs, this chapter deals primarily with Medicare.

Established in 1965, Medicare originally consisted of Part A, Hospital Insurance (HI), and Part B, Supplemental Medical Insurance (SMI).²

Congress added Part C, Medicare Advantage (MA), in the Balanced Budget Act (BBA) of 1997.³ Congress added Part D, Voluntary Prescription Drug Benefit (PDB), in the 2003 Medicare Prescription Drug Improvement and Modernization Act (MMA).⁴ The 1997 BBA contained a provision that amended the Social Security Act, prohibiting a physician from billing Medicare for two years if the physician contracts privately with a Medicare beneficiary for a Medicare covered service.⁵

Following the establishment of Medicare in 1965, Medicare Part A reimbursed hospitals on an “allowable cost” basis. Because of rapidly escalating Medicare costs, the Health Care Financing Administration (HCFA), the forerunner of the Centers for Medicare and Medicaid Services (CMS), initiated a prospective payment system (PPS) in 1983.⁶ Under PPS, CMS pays a hospital a predetermined fixed amount when a Medicare beneficiary is hospitalized. Introduction of PPS in 1983 decreased the rapid growth of hospitalization expenses for Medicare beneficiaries. Initially, Medicare reimbursed physicians on a “reasonable charge” basis. Because of widely vary-

¹ See Appendix A for related statutes; see Appendix B for related regulations.

² Pub. L. 89-97.

³ Pub. L. 105-33.

⁴ Pub. L. 108-173.

⁵ Pub. L. 105-33.

⁶ 42 C.F.R. Part 412.

ing fees for professional services that seemed to require similar expertise and effort, HCFA implemented the Resource-Based Relative Value Scale (RBRVS) fee schedule during the 1990s.⁷ The RBRVS schedule bases fees on an estimate of the resources required for the physician to provide the service.

A. MEDICARE AND MEDICAID

A1. *Medicare and Medicaid: Eligibility, Benefits, and Financing*

Medicare Part A is the hospital component of Medicare.⁸ When a person 65 years of age or older applies for Social Security benefits, that person is automatically enrolled in Medicare Part A. Part A covers inpatient hospital services, skilled nursing services, home health services, and hospice services. A payroll tax of 1.45 percent on American workers and 1.45 percent on American employers funds Medicare Part A. A Medicare beneficiary pays a deductible for each hospitalization; the 2006 deductible is \$952.00.⁹

Medicare Part B is the physician and outpatient component of Medicare.¹⁰ Each person enrolled in Medicare Part A is eligible to enroll in

Medicare Part B, but enrollment in Part B is voluntary. Part B covers inpatient and outpatient physician services, outpatient diagnostic tests, outpatient hospital services, renal dialysis, and outpatient rehabilitation services. The federal government funds 75 percent of the cost of Medicare Part B, and each beneficiary pays a monthly premium that covers 25 percent of the cost. For 2006, the monthly premium for beneficiaries is \$88.50 per month.¹¹ In addition to the premium, each beneficiary pays a \$124 per year deductible plus coinsurance equaling 20 percent of each Part B bill.

Medicare Part C provides Medicare beneficiaries the option to choose a private health plan for both Part A and Part B services.¹² Under Medicare Part C, beneficiaries may choose one of three options: a managed care plan, a fee-for-service plan, or a medical savings account (MSA) plan. For the first two options, Medicare contracts with private health plans to provide both hospital and medical services to beneficiaries. The private health plan determines the benefit package and administers the claims. To provide Part C benefits, the health plan's benefit package must equal or exceed the package provided by traditional Part A and Part B Medicare.

⁷ 42 C.F.R. Part 414.

⁸ 42 U.S.C. § 1395c et seq.

⁹ Centers for Medicare and Medicaid Services, *Medicare Premiums and Deductibles for 2006* (Sept. 16, 2005) at <<http://new.cms.hhs.gov/apps/media/press/release.asp?Counter=1557>>.

¹⁰ 42 U.S.C. § 1395j et seq.

¹¹ Centers for Medicare and Medicaid Services, *supra* note 9.

¹² 42 U.S.C. § 1395w-21 et seq.

Medicare Part D offers a prescription drug benefit (PDB) to enrollees in Medicare Parts A and B and to Part C enrollees who participate in a plan that does not provide prescription drug coverage.¹³ Each eligible Medicare enrollee may choose either a standard PDB or alternative prescription drug coverage that is actuarially equivalent to the standard benefit.

CMS, a component of the Department of Health and Human Services (HHS), administers Medicare.¹⁴ CMS determines coverage, fees, and regulatory issues. It contracts with fiscal “intermediaries,” usually health insurance companies, to process and pay Part A Medicare claims. CMS contracts with “carriers,” also health insurance companies, to process and pay Part B Medicare claims.

Medicaid is a combined federal and state program that provides payment for health care services to low income citizens.¹⁵ Similar to Part A and Part B Medicare, traditional state Medicaid programs pay physicians and hospitals directly for services they provide to a state’s low income citizens. Recently, many states have moved to managed care programs for Medicare beneficiaries. Eligibility criteria vary from state to state and

include age, family wealth, family income, and disability status. Covered services and fee schedules vary considerably among states.

A2. Hospital Billing and Payment

Prospective payment refers to a system of payment in which CMS pays a set fee per hospitalization, regardless of the services provided.¹⁶ The primary factor in determining the PPS fee is the patient’s diagnosis. The fee also varies among hospitals based on differing labor costs among different regions of the country and differing non-labor costs between urban and rural settings. Other factors include a hospital’s participation or lack of participation in medical education and the amount of uncompensated care the hospital provides. The rationale for providing a predetermined amount is to encourage the hospital to provide care in the most efficient manner possible, i.e. to use fewer resources, perform procedures in a more timely manner, and limit the length of hospital stay.

A3. Physician Billing and Payment

For the majority of Medicare patients, CMS pays physicians a fixed fee for each service. When a physician provides a service for a patient, in this instance a Medicare beneficiary, the physician

¹³42 U.S.C. § 1395w-101 et seq.

¹⁴ 42 C.F.R. § Part 400 et seq.

¹⁵ 42 U.S.C. § 1396 et seq.

¹⁶42 C.F.R. Part 412.

chooses one of over 7700 Current Procedural Terminology (CPT) codes to describe the service performed.¹⁷ The code determines the fee that Medicare will pay. For evaluation and management (E&M) services, there are different codes depending on the extent of history taken, the extent of the examination performed, and the complexity of the physician's decision-making process required for that clinical situation.

Using the RBRVS fee schedule, CMS determines fees for each code based on the relative value of the physician work required to perform that service, the value of the practice expense required, and the value of the medical malpractice expense for that physician.¹⁸ To arrive at the fee, one multiplies each factor by a geographic practice cost index (GPCI) based on practice location.

A4. Private Arrangements for Health Care

The Social Security Act (SSA), as amended by the 1997 BBA, prohibits a physician from entering into a private contract to provide services for a Medicare beneficiary, unless the physician signs an affidavit that he/she “will not submit any claim . . . for any item or service provided to any Medicare beneficiary . . . during the two year period beginning on the date that the affidavit is signed”¹⁹

In *United Seniors Ass'n, Inc. v. Shalala*, Medicare beneficiaries and the United Seniors Association challenged the constitutionality of this provision in federal court.²⁰ The statute was upheld as constitutional in the District Court. Pending appeal, Secretary Shalala issued an interpretation that the statute's restriction on physicians applied only to Medicare covered services. Since the plaintiffs were challenging the constitutionality of the statute with respect to services not covered by Medicare, the Appeals Court upheld the District Court judgment because there was no longer an injury to the plaintiffs. The Court of Appeals did not issue a ruling on the constitutional question.

B. EFFECTS OF MEDICARE

The benefits and costs of a spending program can be evaluated in a manner similar to the benefits and costs of regulations. With an entitlement spending program, there is essentially always a transfer of wealth from taxpayers to those who benefit from the program. Medicare results in such a transfer from workers and other taxpayers to persons over 65 years of age to pay for health care expenses.

B1. Effects on Prices

Similar to employer-provided insurance,

¹⁷ See Maxine Lewis and James B. Davis, *Medicare Coding Requirements*, in *MEDICARE COMPLIANCE MANUAL* 2005 127, 128 (2005).

¹⁸ See Maxine Lewis and James B. Davis, *Medicare Fee Schedule 2005*, in *MEDICARE COMPLIANCE MANUAL* 2005 493, 494 (2005).

¹⁹ 42 U.S.C. § 1395a(b)(3).

²⁰ See *United States Seniors Ass'n, Inc. v. Shalala*, 182 F.3d 965 (D.C. Cir. 1999).

Medicare increased the demand for health care services. As with employer-provided insurance, Medicare payments are tax-free to the beneficiary, Medicare pays for minor expenses, and Medicare costs are partially “hidden” from the persons receiving the services. As a result, there is an incentive for the beneficiary to overuse services. The increased demand from Medicare beneficiaries is one of the factors in the marked increase in health care prices. On the other hand, because each beneficiary pays a deductible for both hospital and physician services and coinsurance for physician services, there is more incentive for Medicare beneficiaries to control costs than for individuals who are covered by comprehensive employer-provided plans.

B2. Effects on Access

The establishment of Medicare immediately increased the prevalence of health insurance among persons 65 years of age and older from approximately 50 percent to essentially 100 percent.²¹ However, by increasing prices for health care, Medicare may be a factor in the large number of Americans under 65 years of age who remain uninsured.

B3. Effects on Choice and Competition

In effect, CMS is a single-payer of health care

services for most older Americans, and it does not compete with other insurers. As a result, it has less incentive than insurers to provide quality services to beneficiaries or pay market-based fees to physicians and hospitals.

Medicare does provide beneficiaries enrolled in Parts A and B a choice of physicians. However, because of low payment rates for many E&M services, in some locations, there is inadequate availability of generalist physicians for Medicare patients. Conversely, there is competition among physicians and hospitals for Medicare patients who require services for which the payment rate is greater than the costs to provide the service.

B4. Effects on Federal Budget

Medicare has a significant impact on the federal budget, an impact that will increase in future years. Medicare is a program in which this year’s payroll taxes, general tax revenues, and beneficiary premiums pay for health care for today’s senior citizens. Each year, the Medicare Trustees present an update on the status of the Medicare program and include projections of future spending. In the 2005 Annual Report, the trustees reported there were 41.7 million Medicare beneficiaries in 2004.²² Total expenditures were \$308.9 billion, \$170.6 billion for Part A and \$138.3 bil-

²¹ U.S. Department of Health, Education, and Welfare, *Family Hospital and Surgical Insurance Coverage, United States – July 1962-June 1963*, Public Health Service Publication No. 1000-Series 10 – No. 42 (Nov., 1967). These data were based on household interviews. The exact percentage is not available. Table I indicates that in 1962-1963, 53% of persons 65 years of age and older who lived alone or in two-person households had hospitalization insurance.

²² Centers for Medicare and Medicaid Services, *2005 Annual Report of the Board of Trustees of the Federal Hospital Insurance and Federal Supplementary Medical Insurance Trust Funds 2-4* (2005) at <<http://www.cms.hhs.gov/publications/trusteesreport/tr2005.pdf>>.

lion for Part B. For the first time since its inception, Part A expenditures in 2004 were greater than the income from payroll taxes.

One way to illustrate the economic effects for future generations is to compare Medicare spending with the entire U.S. economy. In 2004, the U.S. gross domestic product (GDP) was \$11,734 trillion, and Medicare spending represented 2.6 percent of GDP.²³ The trustees project that if Medicare benefits remain the same as those to which beneficiaries are now entitled, Medicare spending will increase to 3.3 percent of GDP in 2006, 7.5 percent of GDP in 2035, and 13.6 percent of GDP by 2079.²⁴

C. EFFECTS OF MEDICARE PAYMENT MECHANISMS

C1. Hospital Billing and Payment

As noted previously, in an effort to curb escalating costs, CMS introduced PPS for Medicare Part A payment in 1983. Unlike the Part B fee-for-service system, PPS provides an incentive for hospitals to provide care in the most efficient way possible. The introduction of PPS did promote hospital efficiency, and initially the rapidly increasing cost of providing hospital care to

Medicare beneficiaries slowed. For example, whereas 1980 Medicare hospital expenditures were 21.3 percent greater than 1979 expenditures, 1985 Medicare hospital expenditures were only 7.1 percent greater than 1984 expenditures.²⁵

C2. Physician Billing and Payment

Because the Medicare Part B payment structure is not based on market influences, it provides incentives that may negatively affect patient care. For Part B Medicare participants, CMS, through intermediaries, pays physicians a fee for each service performed. Each year CMS sets a relative value that determines the fee for each of the services a physician may provide. Thus, for the care provided to most Americans 65 years of age or older, physicians and patients operate in a price-controlled environment. Economic theory suggests that in a price-controlled environment, if the price is set above the market rate, there will be a surplus of goods or services provided. If the price is set below the market rate, there will be a shortage of goods or services provided.

One hypothetical situation illustrates the incentives provided by the Medicare Part B payment structure. Assume that patients with Alzheimer's disease and their families are best served when a

²³ See *supra* note 22 at 8; Centers for Medicare and Medicaid Services, *National Health Expenditures Aggregate and Per Capita Amounts, Percent Distribution, and Average Annual Percent Growth, by Source of Funds: Selected Calendar Years 1960-2004*, NHE Web Tables, Historical, National Health Expenditure Data, at <<http://www2.cms.hhs.gov/NationalHealthExpendData/downloads/tables.pdf>>.

²⁴ See *supra* note 22, at 8.

²⁵ Centers for Medicare & Medicaid Services, *National Health Expenditures by Types of Service and Source Of Funds: Calendar Years 1960-03*, at <<http://www.cms.hhs.gov/statistics/nhe/#download>>.

physician and support personnel spend considerable time with the patient and family, initially making an accurate diagnosis and later explaining symptoms and making management plans. In general, the fees for E&M services are much lower than fees for performing either diagnostic or therapeutic procedures. Spending additional time with a patient increases the fee slightly, but not enough to compensate for the additional time. Since patients with Alzheimer's disease do not require physician-performed procedures that generate higher fees, it is difficult for a physician to maintain a practice that involves managing a large number of Alzheimer's disease patients.

On the other hand, there are patients with conditions in which it is in the patient's interest for the physician to perform procedures, either to make a diagnosis or to monitor or treat the patient. In general, the Part B fees for performing these services are greater than the fees for E&M services. Physicians who build a practice managing patients who require procedures can generate the funds necessary to provide the services their patients require.

Because of these incentives, CMS fees may influence the availability of services for certain patients and may even influence the career paths that young physicians choose. These incentives also explain why many physician professional societies, and now professional "trade organizations," lobby Congress to ensure that Medicare fees are adequate for the services their physician members provide.

C3. Private Arrangements for Health Care

If a physician bills a Medicare patient outside the Medicare program for a Medicare covered service, the physician cannot bill Medicare for any patient for the next two years. Since most Americans 65 years of age or older receive their health care through the Medicare program, very few physicians who see adult patients can afford to refrain from billing Medicare for two years. As a result, if a Medicare beneficiary would prefer to see a physician for a Medicare covered service and pay for the service privately, the beneficiary is usually not able to find a physician who is willing to do so.

D. SUMMARY

Congress established Medicare in 1965 to finance health care for Americans 65 years of age or older. It established Medicaid to pay medical expenses for low income citizens. Medicare has four components. Part A pays for hospital care. Part B pays for physician and other services. Part C allows a Medicare beneficiary to choose a private plan for hospitalization and physician care, and Part D provides a prescription drug benefit. CMS administers Medicare. It pays hospitals a set fee for each hospitalization based on patient diagnosis and other factors. It pays physicians using a fee schedule based on a predetermined relative value for each service rendered.

Medicare has increased the percentage of older Americans with health insurance and thus has

increased access for many Americans. However, Medicare's payment structure has had adverse effects. These include: inadequate availability of some services and incentives for physicians that may negatively affect patient care. The Medicare

Trustees estimate that if beneficiary entitlements remain the same as those that are present today, Medicare expenditures will grow rapidly, reaching 7.5 percent of GDP in 30 years and 13.6 percent of GDP in 75 years.

ADDITIONAL READING

1. Barry R. Furrow, et al., *Medicare*, in *HEALTH LAW* 536 (2d ed. 2000).
2. Maxine Lewis and James B. Davis, *Medicare Coding Requirements*, in *MEDICARE COMPLIANCE MANUAL* 2005 127 (2005).
3. Maxine Lewis and James B. Davis, *Medicare Fee Schedule 2005*, in *MEDICARE COMPLIANCE MANUAL* 2005 493 (2005).
4. Centers for Medicare and Medicaid Services, *2005 Annual Report of the Board of Trustees of the Federal Hospital Insurance and Federal Supplementary Medical Insurance Trust Funds*, at <http://www.cms.hhs.gov/publications/trusteesreport/tr2005.pdf>.

CHAPTER 4: REGULATION OF PRIVATE HEALTH INSURANCE: THE HMO ACT AND ERISA¹

As noted earlier, the federal government has influenced health care financing through the tax code and the establishment of Medicare and Medicaid. During the 1970s, the federal government began regulating private health insurance directly. Congress passed the Health Maintenance Organization (HMO) Act in 1973 and the Employee Retirement Income Security Act (ERISA) in 1974.² Together, these Acts significantly changed the health insurance industry, and more importantly, they changed the way Americans received their health care.

As noted in Chapter 2, prior to 1930, employers in certain industries provided health care for their employees using direct service plans.³ Direct service plans were prepaid plans that provided comprehensive health services to the subscriber. Although most of the early plans did not survive World War II, after the war there was a resurgence of prepaid health plans.⁴ The most well known of these plans was the Kaiser-Permanente health plan. Prior to the 1970's, prepaid comprehensive plans were less common than Blue Cross,

Blue Shield, and commercial indemnity plans.

In the early 1970s, health care reformers were concerned that American health care emphasized episodic care and disease treatment, rather than health maintenance and disease prevention. Health maintenance organizations (HMOs) are prepaid health plans in which an individual or employer pays a fixed fee in exchange for comprehensive preventive, diagnostic, and treatment services. To encourage the growth of these plans, Congress passed the HMO Act in 1973.⁵ The HMO Act required employers with 25 or more employees to offer federally qualified HMO plans, if insurers offered these plans in the insurance market where the employees lived. The HMO Act also set forth a number of regulations governing HMOs and preempted many state HMO regulations.

In 1974, Congress passed ERISA to encourage employers to establish employee benefit plans and to require employers to better manage their plans.⁶ Since health benefit plans are a compo-

¹ See Appendix A for related statutes; see Appendix B for related regulations.

² Pub. L. No. 93-222; P.L. 93-406.

³ See Paul Starr, *The Triumph of Accommodation*, in *THE SOCIAL TRANSFORMATION OF AMERICAN MEDICINE* 290, 291-295 (1982).

⁴ *Id.* at 320-327.

⁵ Pub. L. No. 93-222.

⁶ Pub. L. No. 93-406.

ment of employee benefit plans, ERISA's rules apply to employer-provided health plans. Since the 1970s, Congress has passed two major amendments to ERISA. These were the Consolidated Omnibus Budget Reconciliation Act (COBRA) of 1985 and the 1996 Health Insurance Portability and Accountability Act (HIPAA).⁷

A. REGULATION OF HMOs

The Public Health Service Act defines an HMO as “a public or private entity which...provides basic and supplemental health services to its members”⁸ Basic health services include: physician services, inpatient and outpatient hospital services, medically necessary emergency services, short term mental health services, treatment for addiction to alcohol and drugs, diagnostic laboratory services, diagnostic and therapeutic radiology services, home health services, and preventive health services.⁹ Supplemental health services include “any health service which is not included as a basic health service”¹⁰

Each HMO must pay for basic services on a periodic basis, must fix the payment without regard to the services provided, and must fix the payment under a community rating system, except for

small additional amounts for certain services.¹¹ In addition, HMOs must make basic services available to each member in the area where the member lives. The HMO must make “medically necessary” services available 24 hours a day, seven days a week.¹²

In addition, HMOs must be fiscally sound, assume financial risk on a prospective basis, enroll persons who are representative of the area served, accept all applicants regardless of health status, provide a procedure for grievances, maintain a quality assurance program, and report data to the Department of Health and Human Services (HHS).¹³

B. ERISA: GENERAL PROVISIONS

The Employee Benefits Security Administration in the Department of Labor administers ERISA.

B1. Employee Welfare Benefit Plans

ERISA defines an employee welfare benefit plan as: “any plan . . . established or maintained by an employer or by an employee organization . . . for the purpose of providing for its participants . . . , through the purchase of insurance . . . medical, surgical, or hospital care or benefits”¹⁴ Thus,

⁷ See Chapter 5 for a discussion of COBRA and HIPAA.

⁸ 42 U.S.C. § 300e(a).

⁹ 42 U.S.C. § 300e-(b)(1).

¹⁰ 42 U.S.C. § 300e-(b)(2).

¹¹ 42 U.S.C. § 300e(b)(1).

¹² 42 U.S.C. § 300e(b)(4).

¹³ 42 U.S.C. § 300e(c).

¹⁴ 29 U.S.C. § 1002(1).

ERISA applies to employer-financed health benefit plans.

B2. ERISA Preemption

ERISA supersedes any state law that “relates to” an employee benefits plan.¹⁵ On the other hand, ERISA does not supersede a state law that regulates “insurance, banking or securities.”¹⁶ Thus, if the law considers a health plan to be an insurance plan, ERISA does not supersede state laws regulating the plan. Finally, a self-insured employee benefit plan shall not be “deemed” to be an insurance plan. Thus, if an employer self-insures, i.e. the employer funds the plan, assumes the risk of an employee’s illness, and pays the medical expenses of the participant, the plan is “deemed” not to be insurance, and ERISA preempts state law regulating the plans. Since ERISA regulations are less stringent than most states’ insurance regulations, employers have a strong incentive to self-insure.

Courts have also held that ERISA may preempt state law under implied or complete preemption. ERISA grants a participant or beneficiary of an ERISA-governed plan the right to sue to enforce rights guaranteed under ERISA.¹⁷ Also, ERISA provides for exclusive federal court jurisdiction

over certain claims against ERISA plans and concurrent state and federal jurisdiction over other claims.¹⁸ As a result of both federal jurisdiction and comprehensive federal remedies for claims against ERISA plans, some federal courts have allowed defendant ERISA-governed health plans to remove state contract and tort claims against them to federal courts, if the claims are related to plan benefits.¹⁹

C. ERISA: SUBSTANTIVE REGULATIONS

There are four types of substantive regulations under ERISA: (1) claims processing requirements, (2) fiduciary obligations, (3) information and disclosure requirements, and (4) coverage requirements.²⁰

C1. Claims Processing Requirements

ERISA mandates that fiduciaries of ERISA-governed health plans comply with two claims processing requirements.²¹ First, fiduciaries must provide notice in writing to beneficiaries if the fiduciary denies a claim. The notice must state clearly the specific reasons for denial. Second, the fiduciary must offer the claimant the opportunity for a full and fair review of the denied claim. The

¹⁵ 29 U.S.C. § 1144(a).

¹⁶ 29 U.S.C. § 1144(b)(2)(A).

¹⁷ 12 U.S.C. § 1132(a).

¹⁸ 29 U.S.C. § 1132(e)(1).

¹⁹ See Barry R. Furrow et al., *The Employee Retirement Income Security Act of 1974 and Health Plan Liability*, in *HEALTH LAW* 418, 432, 433 (2d ed. 2000).

²⁰ For a discussion of coverage requirements, see Chapter 5.

²¹ 29 U.S.C. § 1133.

fiduciary must identify the specific plan provision on which the denial was based within 60 days of the request for review.

A beneficiary may bring a civil suit in federal court under ERISA.²² Federal courts review claim denial disputes between beneficiaries and fiduciaries differently from the way state courts review similar disputes governed by state insurance law.²³ In state courts, courts decide the case based on preponderance of the evidence, and state courts tend to side with the insured in disputes over covered services. This is sometimes referred to as “judge-made insurance.”

On the other hand, for federal claims governed by ERISA, federal courts treat health plans more like administrative agencies than like defendants.²⁴ As a result, courts often defer to the judgment of the plan administrator in much the same way courts defer to the judgment of administrative agencies, i.e. did the administrator appropriately follow procedures? As a result, federal courts decide fewer disputes in favor of claimants.

One explanation for deference to plan administrators is that a claimant’s dispute against a welfare benefit plan is actually a dispute with other

members of the plan.²⁵ Thus, a judgment for the claimant increases the cost to other plan members. State courts adjudicating claims against an insurance company consider the claim to be against the company, not against other policyholders.

C2. Fiduciary Obligations

ERISA requires a plan fiduciary to “discharge his duties solely in the interest of the participants and beneficiaries” as would a prudent person in accordance with the documents governing the plan.²⁶ While ERISA requires the fiduciary to administer the plan to the benefit of all participants and beneficiaries, the fiduciary requirement differs from the traditional view of such responsibilities. Unlike an agent’s fiduciary responsibility to a principal, a plan administrator must consider other beneficiaries in deciding the entitlements of an individual beneficiary.²⁷

C3. Information and Disclosure Requirements

There are two major disclosure requirements for fiduciaries under ERISA.²⁸ Fiduciaries must provide beneficiaries with a summary plan description (SPD) that describes the primary features of the plan. In addition to providing SPDs, fiduciaries must provide accurate information to plan

²² 29 U.S.C. § 1132(a).

²³ See Barry R. Furrow et al., *supra* note 19 at 445-451.

²⁴ *Id.*

²⁵ *Id.*

²⁶ 29 U.S.C. § 1104(a).

²⁷ See Barry R. Furrow et al., *supra* note 19, at 454-455.

²⁸ *Id.*, at 455-459.

participants regarding the participant's rights and status under the plan.

Administrators must also respond to information requests from beneficiaries. ERISA makes administrators liable to beneficiaries up to \$100 per day if the administrator fails to respond to beneficiaries within 30 days of a request.²⁹

D. EFFECTS OF THE HMO ACT AND ERISA

D1. *Deregulatory Effect of ERISA*

As noted above, ERISA does not consider self-funded employer-financed health plans to be insurance. Thus, self-funded plans escape state insurance regulation. This provides a strong incentive for employers to self-insure. Precise data are not available as to the number of employees insured by self-funded plans. Prior to ERISA, self-funded plans were uncommon.³⁰ By 1996, approximately 40 percent of employees with employer-provided health insurance participated in self-funded plans.³¹

Because of both express and implied preemption,

ERISA has had a deregulatory effect on group health plans. Many states have fairly stringent regulations on health insurance companies doing business in their states. For example, states may mandate that insurers provide benefits for certain conditions or certain procedures, e.g. in vitro fertilization.³² States may also mandate that health plans include the services of certain providers, e.g. chiropractors or acupuncturists³³ ERISA allows health plans to escape these mandates.³⁴

One recent study attempted to estimate benefits and costs associated with health care regulation.³⁵ According to the study, the deregulatory effects of ERISA resulted in a net benefit to society of \$45.8 billion per year. This benefit is not because ERISA in itself produces a benefit. Instead, because it preempts state regulation, ERISA “blocks” \$45.8 billion of regulatory costs that health plans, and ultimately patients, would have to bear.

D2. *The Growth of Managed Care*

Following passage of the HMO Act and ERISA many employer-sponsored health plans became

²⁹ 29 U.S.C. § 1132(c).

³⁰ Richard Briffault and Sherry Glied, *Federalism and the Future of Health Care Reform*, in *THE PRIVATIZATION OF HEALTH CARE REFORM* 49, 63 (M. Gregg Bloche, ed., 2003).

³¹ United States General Accounting Office, *Employer-Based Managed Care Plans: ERISA's Effect on Remedies for Benefit Dividends and Medical Malpractice*, GAO/HEHS-98-154 (July, 1998).

³² The Council for Affordable Health Insurance, *Trends in State Mandated Benefits*, Trends and Ends (Dec., 2005) at <http://www.cahi.org/cahi_contents/resources/pdf/TrendsEndsDec2005.pdf>.

³³ *Id.*

³⁴ See Chapter 5 for a more complete discussion of health insurance mandates.

³⁵ Christopher J. Conover, *Health Care Regulation: A \$169 Billion Hidden Tax*, Policy Analysis No. 527, Cato Institute (October 4, 2004).

self-insured, and managed care began to replace fee-for-service as the primary type of health insurance for most Americans. Both developments were a result of multiple factors. These include: (1) disparate tax treatment favoring employer-provided group health insurance, (2) increasing health care prices, and (3) specific legislation favoring managed care and self-insured plans over traditional health insurance.

Managed Care Organizations (MCOs) are health plans that insure their beneficiaries, and to varying degrees, provide or manage the services provided. MCOs include HMOs, point-of-service plans (POS), and preferred provider organizations (PPOs). HMOs are prepaid plans that provide comprehensive preventive, diagnostic, and treatment services for a fixed fee. POS plans are HMOs that allow their participants to receive some services outside of network, but provide incentives for the participant to use an in-network HMO physician or service. For example, if a participant sees an out-of-network physician, the participant may be required to pay a higher co-payment for that service. A PPO refers to a network of health care providers who agree to provide health care services to subscribers on a negotiated fee basis. Subscribers may use providers outside the network, but there are financial incentives to remain in network.

Initially, there was a clear distinction between HMOs, which provide both insurance and health care, and insurance companies, which provide insurance, but do not provide or manage care. During the 1990s, this distinction became blurred. To control costs, most insurance companies developed plans that require prior approval for hospitalization and for some diagnostic and treatment procedures. In addition, most HMOs became less restrictive, allowing their participants more choices. At the present time, most insurers manage care to some extent. Of the approximately 156 million people insured by employer-sponsored health plans in 2003, 95 percent participated in some form of managed care.³⁶ Fifty-four percent participated in PPO plans, 24 percent in HMO plans, and 17 percent in POS plans. Only five percent had conventional fee-for-service plans.

The primary methods that MCOs have used in controlling costs are: restricting coverage of certain types of services; requiring prior approval for major diagnostic tests, hospitalization, or surgery; denying payment if the services are “medically unnecessary,” contracting with a restricted panel of physicians or hospitals to provide care at set fees, and providing incentives for physicians and other providers to provide care more efficiently. Since physicians are the primary “drivers” of

³⁶ Kaiser Family Foundation, *Exhibit 2.3 Health Plan Enrollment for Covered Workers, by Plan Type, 1988-2004*, Trends and Indicators in the Changing Health Care Marketplace, at <<http://www.kff.org>>.

health care costs, i.e. costs result from physician services and from physician-ordered testing, treatment, and hospitalization, MCOs have developed methods to encourage physicians to provide care more efficiently.³⁷ Financial incentives for physicians include capitation, withholds, bonuses, and payment that can be adjusted based on factors such as resource utilization, patient satisfaction, patient outcome, or physician productivity. Capitation refers to paying a physician a fixed amount per patient to provide all care for that patient during a given period. A “withhold” refers to paying a physician a percentage of the specified rate, e.g. 90 percent, and withholding ten percent to be paid if the physician achieves certain goals, e.g. minimizes diagnostic testing or minimizes referral to specialists. “Bonuses” refer to paying the physician an additional amount if the physician meets certain criteria.

In the late 1990’s there was a backlash among patients, physicians, and the public concerning many of managed care’s cost control measures.

Responding to pressures from their policyholders, as well as the threat of legal action, MCOs became less restrictive than they once were³⁸ Initially, managed care was partially successful in controlling the growth of health care expenditures. In both 1995 and 2000, health care expenditures were 13.8 percent of GDP.³⁹ However, since 2000, health care expenditures have again increased more rapidly than economic growth.⁴⁰ In 2004, health care expenditures were 16 percent of GDP.⁴¹

E. SUMMARY

To encourage preventive and comprehensive care, Congress passed the HMO Act in 1973. The HMO Act contains a number of regulatory provisions that require HMOs to offer certain benefits and to meet certain financial and procedural requirements. Congress passed ERISA in 1974. It requires health plans to meet claims processing requirements, fiduciary obligations, information and disclosure requirements, and coverage requirements.

³⁷ See Thomas Rice, *Financial Incentives as a Cost-Control Mechanism in Managed Care*, in *THE PRIVATIZATION OF HEALTH CARE REFORM 99* (M. Gregg Bloche, ed., 2003).

³⁸ See M. Gregg Bloche, *One Step Ahead of the Law: Market Pressures and the Evolution of Managed Care*, in *THE PRIVATIZATION OF HEALTH CARE REFORM 22* (M. Gregg Bloche, ed., 2003).

³⁹ *National Health Care Expenditures Projections 2004-2014*. Centers for Medicare and Medicaid Services, at <<http://www.cms.hhs.gov/statistics/nhe/projections-2004/proj2004.pdf>>.

⁴⁰ *Id.*

⁴¹ Centers for Medicare and Medicaid Services, Table 1, *National Health Care Expenditures Aggregate and Per Capita Amounts, Percent Distribution, and Average Annual Percent Growth by Source of Funds: Selected Calendar Years 1960-2004*, NHE Web Tables, Historical, National Health Expenditure Data, at <<http://www2.cms.hhs.gov/NationalHealthExpendData/downloads/tables.pdf>>.

ERISA preempts state insurance laws with respect to self-insured employer-sponsored health plans. In addition, some federal courts have interpreted ERISA to preempt state jurisdiction over contract and tort claims against ERISA-governed plans. By preempting state insurance regulation, ERISA has had a deregulatory effect on employer-provided health plans. There are data suggesting that the economic benefits of ERISA outweigh the costs.

The tax-preference for employer-sponsored insurance, the HMO Act, and ERISA have contributed to the growth of managed care. Initially, managed care restrained the growth of health care expenditures. In the late 1990's, managed care became less restrictive, and since 2000, health care expenditures have again grown more rapidly than the overall economy.

ADDITIONAL READING

1. M. Gregg Bloche, *One Step Ahead of the Law: Market Pressures and the Evolution of Managed Care*, in THE PRIVATIZATION OF HEALTH CARE REFORM 22 (M. Gregg Bloche, ed., 2003).
2. Richard A. Briffault and Sherry Glied, *Federalism and the Future of Health Care Reform*, in THE PRIVATIZATION OF HEALTH CARE REFORM 49 (M. Gregg Bloche, ed., 2003).
3. Barry R. Furrow, et al., *The Employee Retirement Income Security Act of 1974 and Health Plan Liability and Regulation*, in HEALTH LAW 418 (2d ed. 2000).
4. Thomas Rice, *Financial Incentives as a Cost-Control Mechanism in Managed Care*, in THE PRIVATIZATION OF HEALTH CARE REFORM 99 (M. Gregg Bloche, ed., 2003).
5. David A. Hyman, *Regulating Managed Care: What's Wrong with a Patient Bill of Rights?*, 73 S. Cal. L. Rev. 221 (2000).
6. Federal Trade Commission/Department of Justice, *Industry Snapshot: Insurance and Other Third Party Payment Programs*, IMPROVING HEALTH CARE: A DOSE OF COMPETITION, Chapter 5 (July 23, 2004).

CHAPTER 5: REGULATION OF PRIVATE HEALTH INSURANCE: ATTEMPTS TO INCREASE COVERAGE¹

During the 1980s and 1990s, Congress made two major attempts to increase health insurance coverage. In 1986, Congress passed the Consolidated Omnibus Budget Reconciliation Act (COBRA) of 1985, and in 1996, the Health Insurance Portability and Accountability Act (HIPAA).²

By the mid 1980s, most working Americans obtained health insurance through their employer. As a result, it was common for an employee to lose insurance coverage when changing or losing a job. If one became unemployed, if one's new employer did not offer coverage, or if the new employer's health plan required an exclusion period for preexisting illnesses, it was difficult and expensive for a person to obtain health insurance. To maintain insurance coverage, many employees remained in jobs they would have preferred to leave. This is sometimes referred to as "job lock."

Provisions within COBRA attempted to remedy this situation by requiring employers to continue health insurance for individuals leaving employment.³ Specifically, COBRA required government or private employers with 20 or more

employees to continue, at the beneficiary's option and expense, the beneficiary's health insurance for up to 18 months after termination of employment. COBRA required the terminating employee to pay the insurance premium, but the price could not exceed 102 percent of the price the employer paid for other beneficiaries.

While COBRA attempted to increase health insurance by guaranteeing the right to maintain one's previous coverage, provisions in HIPAA guaranteed availability of new health insurance to individuals losing group coverage.⁴ HIPAA also guaranteed certain individuals the right to renew health insurance. Finally, HIPAA limited the amount of time that a new policy could exclude coverage for preexisting illnesses, and in some instances it eliminated the right of an insurance company to exclude individuals based on health risks, preexisting illnesses, or claims experience.

Congress passed three additional insurance mandates in the late 1990s, the Mental Health Parity Act (MHPA) and the Newborn's and Mother's Health Protection Act (NMHPA) in 1996, and

¹ See Appendix A for related statutes; see Appendix B for related regulations.

² Pub. L. No. 99-272; Pub. L. No. 104-191.

³ Pub. L. No. 99-272.

⁴ Pub. L. No. 104-91.

the Women’s Health and Cancer Rights Act (WHCRA) in 1998.⁵

A. REGULATION OF HEALTH INSURERS TO INCREASE COVERAGE

A1. COBRA Continuation Coverage

COBRA continuation coverage applies to all employers who offer group health insurance and have 20 or more employees.⁶ It requires employers to offer continuation coverage for up to 18 months to any covered employee or qualified beneficiary, if the beneficiary loses coverage because of a qualifying event.⁷ A qualified beneficiary includes both an employee and a dependent family member covered by the employee’s health insurance.⁸ Qualifying events include termination of employment, divorce, death of the employee, eligibility for Medicare, and termination of eligibility because one is no longer a dependent.⁹

COBRA requires employers to offer qualified beneficiaries benefits identical to those offered to employees who continue in the plan.¹⁰ A qualified

beneficiary who obtains continuation coverage must pay for the coverage, but the plan cannot charge the beneficiary more than 102 percent of the charge for similarly situated employees.¹¹ If the employer self-insures or self-funds the plan, the cost per employee may not be obvious. In these circumstances, the employer must base the amount on actuarial tables or on prior group experience.¹²

A2. HIPAA: Limiting Use of a Preexisting Condition Exclusion Period

As amended by HIPAA, ERISA prohibits a group health insurer from imposing a preexisting condition exclusion except under the following conditions: (1) during the six months prior to the enrollment date, the beneficiary must have been treated or had treatment recommended for the preexisting condition, and (2) the exclusion period must extend no more than 12 months minus the time during which the participant or beneficiary had “creditable coverage.”¹³

Creditable coverage refers to health insurance by a standard group plan or COBRA continuation coverage.¹⁴ All group health plans must provide

⁵ Pub. L. No. 104-204; Pub. L. No. 105-277.

⁶ 29 U.S.C. § 1161.

⁷ 29 U.S.C. § 1162(2).

⁸ 29 U.S.C. § 1167(3).

⁹ 29 U.S.C. § 1163.

¹⁰ 29 U.S.C. § 1162(1).

¹¹ 29 U.S.C. § 1162(3).

¹² 29 U.S.C. § 1164(2).

¹³ 29 U.S.C. § 1181(a).

¹⁴ 29 U.S.C. § 1181(c)(1).

certification of creditable coverage to each beneficiary who leaves employment. When the terminating employee applies for new health insurance, the new insurer must reduce the preexisting condition exclusion period by the duration of creditable coverage. As a result of this requirement, the limitation on the preexisting condition exclusion places requirements on the terminating plan to document the period of creditable coverage as well as the issuing plan to limit the preexisting condition exclusion period.

A3. HIPAA: Prohibiting Discrimination Based on Health Status

As amended by HIPAA, ERISA prohibits a group health insurer from discriminating against a person based on health status, medical condition, claims experience, receipt of health care, medical history, genetic information, or evidence of disability.¹⁵ Discrimination refers to disparate treatment with respect to enrollment, effective date of coverage, benefits, continued eligibility, and terminating coverage.

In addition, HIPAA prohibits a group health insurer from charging an individual a higher premium because of health status than other similarly situated individuals enrolled in the plan.¹⁶ Thus, a group health plan may not use experience rating to determine the premium for

an individual. There are no limits on what the health plan may charge the employer for the group, and there are no requirements for the health plan to provide particular benefits.

A4. HIPAA: Guaranteed Availability and Guaranteed Renewability of Small Group Health Insurance

As amended by HIPAA, the Public Health Service Act (PHSA) provides that if a health insurer offers health insurance in a state's small group market, i.e. the market of employers with 2–50 employees, the health insurer must accept every small employer in the state that applies for coverage.¹⁷ The insurer also must accept any individual in a group who enrolls within the appropriate enrollment period.

In addition, HIPAA requires an insurer that provides small group insurance to renew the coverage for each group that it insures except under certain circumstances.¹⁸ For example, the insurer may terminate a group if the insurer terminates that type of coverage for all small groups. Similarly, the insurer may terminate a group if the employer fails to pay premiums, is guilty of fraud, or violates participation or contribution rules. If the insurer discontinues either a plan or all coverage in a service area, the insurer must provide adequate notice to all members of the plan.

¹⁵ 29 U.S.C. § 1182(a)(1).

¹⁶ 29 U.S.C. § 1182(b)(1).

¹⁷ 42 U.S.C. § 300gg-11.

¹⁸ 42 U.S.C. § 300gg-12.

A5. HIPAA: Guaranteed Availability and Guaranteed Renewability of Individual Health Insurance

HIPAA guarantees availability of individual health insurance for certain individuals. It requires insurers in the individual health insurance market to provide coverage to an individual who: (1) has maintained group health insurance coverage for at least 18 months, (2) is not eligible for another group plan, Medicare, or Medicaid, (3) has paid prior premiums, (4) has not committed fraud, and (5) has exhausted COBRA continuation coverage.¹⁹

The statute also requires insurers in the individual insurance market to offer renewal coverage for any individual the insurer covers.²⁰ However, HIPAA does not limit the premium that an insurer may charge an individual to whom the insurer must offer a policy. Exceptions to the guaranteed renewability requirement for individual health insurance include: nonpayment of premiums, fraud, termination of the plan by the insurer, or a move by the individual to another service area. If the insurer decides to discontinue a type of policy or to discontinue all insurance in a market, the insurer cannot reenter that market for five years.

¹⁹ 42 U.S.C. § 300gg-41.

²⁰ 42 U.S.C. § 300gg-42.

²¹ 45 C.F.R. § 148.120(a)-(c).

²² 45 C.F.R. § 148.120(a)(2).

²³ 29 U.S.C. § 1185(a).

²⁴ 29 U.S.C. § 1185a(a).

²⁵ 29 U.S.C. § 1185b(a).

HIPAA imposes other requirements on insurers in the individual health insurance market. An insurer must offer each eligible person either each type of policy that the insurer offers in that market or at least two representative types.²¹ An insurer cannot use a preexisting health condition to exclude an individual from coverage.²²

A6. Additional Coverage Mandates

Group health plans must provide coverage for at least 48 hours of hospital care associated with childbirth and 96 hours of hospital care associated with a Caesarean section.²³ In addition, a group plan that provides both medical/surgical benefits and mental health benefits in the same plan may not impose a different annual limit or aggregate lifetime limit on these two types of benefits.²⁴ Finally, health plans must provide benefits for patients who elect breast reconstruction surgery following a mastectomy.²⁵

B. EFFECTS OF REGULATIONS DESIGNED TO INCREASE COVERAGE

Most health insurance mandates represent a transfer of wealth from those policyholders who do not benefit from the mandate to those who do.

For example, a mandate that requires an insurance company to pay hospital expenses for three days after a procedure is a benefit to those who require the procedure and who use the three days of post-procedure hospitalization. On the other hand, all policyholders bear the costs in the form of higher prices. Thus a benefit to one subscriber is a cost to another.

In addition to transfers, there are economic costs associated with these regulations. Direct costs include the costs of the administrative agency that enforces the rule and the compliance costs of the regulated parties. Indirect costs are those associated with the behavioral changes that occur because of the regulation. For example, if the price increases, some employers on the margin may choose not to continue coverage for employees. Also, if the price increases for an employee, the employee may choose to discontinue coverage.

For health insurance mandates, indirect costs include those associated with “moral hazard” and “adverse selection.” Moral hazard refers to the incentives that insurance provides for policyholders to obtain the maximum benefit of their insurance coverage, e.g. to use the full three days of recovery when two would have been sufficient. Adverse selection refers to the tendency for high-risk individuals to maintain insurance whereas low-risk individuals discontinue coverage. Low-

risk individuals discontinue the coverage because the higher prices resulting from the mandate increase the costs above the expected benefits. Finally, health insurance mandates prevent an insurer from offering certain options that some individuals may prefer.

Congress’ goal in passing COBRA and HIPAA was to increase health insurance coverage, especially for an employee changing jobs or losing a job. Because the price for COBRA continuation coverage is often very high, many eligible individuals do not take advantage of it. Similarly, because HIPAA does not limit the premium that insurers are able to charge in the individual insurance market, costly premiums limit the number of persons who take advantage of guaranteed individual insurance.²⁶

Disparate tax treatment between employer-provided insurance and individually purchased insurance is the primary cause of job lock and lack of health insurance portability. Until the tax code treats individual health insurance in the same manner it treats employer-provided health insurance, job lock likely will remain a problem.

B1. COBRA Continuation Coverage

COBRA continuation coverage is especially costly because it represents a classic example of adverse selection. Because the cost of continua-

²⁶ See Mark V. Pauly, *Regulation of Bad Things That Almost Never Happen, but Could: HIPAA and the Individual Insurance Market*, 22 *Cato Journal* 59 (2002); Mark A Hall, *HIPAA’s Small-Group Access Laws: Win, Loss, or Draw?* 22 *Cato Journal* 71 (2002).

tion coverage is great, especially for one who has just lost a job, most low-risk individuals tend not to purchase COBRA continuation coverage. High-risk individuals, who will likely need frequent medical care, continue the coverage. One study found the average annual expense for COBRA patients ranged from 48 to 56 percent greater than the average annual expense for employees who remained on the job and were insured under the same policies.²⁷

B2. Guaranteed Renewability of Individual Health Insurance

HIPAA requires insurers in the individual health insurance market to guarantee renewal coverage to all policyholders. This rule may allow some people who would not otherwise have that option to renew their insurance coverage. However, this is likely to benefit only a small number of people.

Pauly estimated that prior to the HIPAA requirement, up to 80 percent of people with individual health insurance already enjoyed guaranteed renewability.²⁸ In addition, market-based guaranteed renewability usually included a guarantee that the insurer would base future premiums on the expected claims experience of the individual's rating class, not on the individual's claims experi-

ence.²⁹ This feature allowed individuals to maintain affordable premiums even if they experienced a serious illness that resulted in large health care expenses.

HIPAA's guarantee of renewability in the individual market does not require the insurer to guarantee that it will not base premiums on individual health experience.³⁰ It is possible that with the passage of HIPAA, insurers will choose to meet only the minimum standard required by HIPAA. If this occurs, the guaranteed renewability feature will be less attractive than it was prior to HIPAA. Approximately 20 percent of individuals with individual health insurance did not choose guaranteed renewability prior to HIPAA.³¹ It is possible they did not choose this feature because a policy guaranteeing renewability is more expensive than one without this requirement. The guaranteed renewability requirement increases the cost for those people who would not otherwise choose this feature. A law that makes uniform a feature that is already present in 80 percent of policies is unnecessary, decreases an individual's options, and increases prices.

B3. Other Features of HIPAA

Although data are limited, there are undoubtedly

²⁷ Stephen A. Huth, *COBRA Costs Continue to be High, Erratic*, 52 Employee Benefit Plan Review 36 (Sept., 1997).

²⁸ See Mark V. Pauly, *supra* note 26, at 64.

²⁹ *Id.* at 65.

³⁰ *Id.*

³¹ *Id.* at 64.

some people who benefit from the limitation on preexisting condition exclusion periods, the prohibition against discrimination based on health status, and the guaranteed availability and guaranteed renewability features of small group health insurance. On the other hand, it is likely the number of individuals who benefit is small.³²

The limitation on a preexisting condition exclusion period requires the previous employer to certify creditable coverage for every insured employee who leaves a position. This is true whether the person needs the information or not. The requirement that insurers provide documentation of creditable coverage places a significant compliance burden on all employers who maintain health insurance for their employees.

B4. Benefits and Costs

In his review of health care regulation, Conover estimated the benefits and costs of health insurance regulation, both federal and state. He estimated that continuation coverage requirements have expected annual benefits of \$29.3 billion per year, but expected costs of \$44.3 billion per year and that benefit mandates have expected annual benefits of \$17.1 billion and expected costs of \$30.6 billion.³³ “Insurance market reforms,” including the small group and individual reforms of HIPAA, have expected annual benefits of \$3.1

billion, but expected costs of \$5.4 billion. On the other hand, Conover estimated that health provider mandates, e.g. any willing-provider laws, and person mandates, e.g. mandates to cover adopted children, have net annual benefits of \$12.2 billion and \$9.7 billion respectively.³⁴

C. SUMMARY

Congress has enacted two laws specifically designed to increase health insurance coverage, COBRA and HIPAA. It has enacted three laws mandating specific benefits, MHPA, NMHPA, and WHCRA.

COBRA requires employers who have greater than 20 employees and who offer group health plans to offer continuation coverage for up to 18 months after the beneficiary becomes ineligible for group coverage. Provisions of HIPAA limit the preexisting condition exclusion period and prohibit discrimination based on health status. HIPAA also requires small group insurers and individual insurers to guarantee availability for certain individuals and renewability to all policyholders.

Data suggest that for most insurance mandates, the costs outweigh the benefits. More importantly, these requirements may decrease the insurance options available to America’s patients.

³² *Id.* at 63.

³³ Christopher J. Conover, *Health Care Regulation: A \$169 Billion Hidden Tax*, Policy Analysis, No. 527, Cato Institute (Oct. 4, 2004).

³⁴ *Id.*

ADDITIONAL READING

1. John A. Boni, et al., *THE HEALTH INSURANCE PRIMER*, The Health Insurance Association of America (2000).
2. Barry R. Furrow, et al., *Regulation of Private Health Care Financing*, in *HEALTH LAW* 461 (2d ed. 2000).
3. Daniel J. Swartz, *State and Federal Regulation of Health Insurance*, in *FUNDAMENTALS OF HEALTH LAW* 233 (Bernadette M. Broccolo, et al., ed., 3d ed. 2004).
4. Federal Trade Commission/Department of Justice, *Competition Law: Insurers*, in *IMPROVING HEALTH CARE: A DOSE OF COMPETITION*, Chapter 6 (July 23, 2004) at <http://www.ftc.gov/reports/healthcare/040723healthcarerpt.pdf>.
5. Federal Trade Commission/Department of Justice, *Industry Snapshot: Insurance and Other Third Party Payment Programs*, in *IMPROVING HEALTH CARE: A DOSE OF COMPETITION*, Chapter 7 (July 23, 2004), at <http://www.ftc.gov/reports/healthcare/040723healthcarerpt.pdf>.

CHAPTER 6: REGULATION OF BIOLOGICS, PHARMACEUTICALS, AND MEDICAL DEVICES¹

Federal regulation of American health care began with passage of the Biologics Control Act in 1902.² “Biologics” at that time referred to “any virus, therapeutic serum, toxin, antitoxin, or analogous product . . .”³ The Biologics Act required producers of biologics for human use to obtain a federal license prior to producing or selling a biologic product. It also authorized inspection of facilities used in producing a biologic product.

In 1906, Congress passed the Pure Food and Drugs Act, establishing for the first time federal regulation of non-biologic drugs.⁴ This act prohibited companies from producing or selling adulterated or misbranded drugs.

In 1938, Congress passed the Federal Food, Drug, and Cosmetic Act (FFDCA).⁵ This act required a sponsoring pharmaceutical company to file an application to the FDA before introducing a new drug to the U.S. market. The sponsor could market the drug 60 days after filing the application unless the FDA notified the sponsor that it planned to investigate the drug. If the FDA did not act, the company could market the new drug.

Thus, the 1938 FFDCA required pre-market notification of the FDA, but it did not require pre-market approval. While the FFDCA required that the sponsoring company demonstrate that the new drug was safe, it did not require the company to demonstrate effectiveness.

The regulatory environment for pharmaceuticals changed markedly in 1962, when Congress passed the Kefauver-Harris Drug Amendments.⁶ These amendments required sponsoring companies to obtain affirmative approval before introducing a new drug to the U.S. market. In addition, these amendments required sponsors to demonstrate by means of controlled studies that a new drug is both safe and effective. They also gave the FDA broad authority to regulate the new drug development process.

The 1938 FFDCA gave the FDA authority to regulate medical devices, but it did not require pre-market approval. The Medical Device Amendments of 1976 required pre-market notification for all new medical devices and pre-market approval for devices that carry a significant patient

¹ See Appendix A for related statutes; see Appendix B for related regulations.

² Pub. L. No.57-244.

³ *Id.*

⁴ Pub. L. No.59-384.

⁵ Pub. L. No.75-717.

⁶ *Id.*

risk.⁷ Congress added the Safe Medical Devices Act in 1990.⁸ This act required a user of medical devices to report within ten days all instances in which a device may have caused or contributed to a serious injury or death. It also established more stringent regulations for making changes to devices that were in existence prior to 1976.

Because of concern that the new drug approval process was decreasing access to therapeutically beneficial drugs, Congress passed a number of measures to expedite approval and increase access to drugs. These include the Orphan Drug Act in 1983, the Drug Price Competition and Patent Term Restoration Act of 1984, more commonly known as the Hatch-Waxman Act, the Prescription Drug User Fee Act (PDUFA) in 1992, and the Food and Drug Administration Modernization Act (FDAMA) in 1997.⁹

A. REGULATION OF PHARMACEUTICALS

A1. General Provisions

The FDCA defines a drug to include: “(A) articles recognized in the official United States

Pharmacopoeia, . . . ; and (B) articles intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease in man . . . ; and (C) articles . . . intended to affect the structure or any function of the body of man”¹⁰ If a drug is potentially harmful or requires professional supervision when used, the FDCA requires a prescription by a licensed professional.¹¹ Over-the-counter (OTC) drugs do not require a written prescription.

Drug manufacturers must register all manufacturing facilities with the FDA each year.¹² In addition, they must comply with good manufacturing practices and obtain approval for major changes in manufacturing processes.¹³

All drugs legally marketed in the U.S. must be either “new drugs” that require pre-market approval or drugs that are “generally recognized as safe and effective” (GRASE).¹⁴ The FDA considers all prescription drugs to be new drugs. Prior to marketing a new drug, the sponsor must conduct controlled studies demonstrating safety and effectiveness.¹⁵

The FDA regulates the label and labeling of prescription and nonprescription drugs.¹⁶ “Label”

⁷ Pub. L. No.94-295.

⁸ Pub. L. No.101-629.

⁹ Pub. L. 97-414; Pub. L. 98-417; Pub. L. 102-571; Pub. L. 105-115.

¹⁰ 21 U.S.C. § 321(g)(1).

¹¹ 21 U.S.C. § 353(b)(1).

¹² 21 U.S.C. § 360(b).

¹³ 21 U.S.C. § 351(a)(1)(B); 21 U.S.C. § 356a(c).

¹⁴ 21 U.S.C. § 321(p).

¹⁵ 21 U.S.C. § 355(d).

¹⁶ 21 U.S.C. § 352.

refers to information placed directly on the container of a drug.¹⁷ “Labeling” refers to information accompanying distribution of the product.¹⁸ The label must contain the established or generic name of the drug, the established name and quantity of each active ingredient, and the established name of each active ingredient on the outside container of the retail package.¹⁹ For a prescription drug, the label must bear the established name printed in type at least half as large as the brand name.²⁰ The labeling must contain adequate directions for use and a warning against risks.²¹ The FDA requires a company to include the words, “Rx only” on the label of all prescription drugs.²²

The FDA also regulates the advertising of prescription drugs.²³ Advertising must include the established or generic name of the drug printed prominently in type at least one half as large as the type used for the brand name, the formula showing each ingredient, and information related to effectiveness, side effects, and contraindications.

A2. Regulation of the Drug Development Process and New Drug Approval

For new drugs, the FFDCA requires sponsoring

companies to show that a drug is safe for human use and is effective for at least one clinical indication based on “adequate and well-controlled” investigations.²⁴ Prior to beginning human studies, a company must first submit an Investigational New Drug (IND) application.²⁵ To obtain approval to begin human studies, the sponsor must provide data from animal studies suggesting the drug will likely be safe in humans.²⁶

The FDA monitors the human testing of all new drugs. There are three categories of human studies.²⁷ Phase I studies involve a limited number of subjects to determine if a drug is safe. Phase II studies are multi-center studies, usually involving a few hundred patients, to determine safety and effectiveness. Phase III studies determine safety and effectiveness in a larger number of patients over longer periods of time.

After completion of clinical studies, and prior to actual marketing, a sponsoring company must submit a new drug application (NDA) that includes data from Phase I, II, and III clinical

¹⁷ 21 U.S.C. § 321(m).

¹⁸ 21 U.S.C. § 321(k).

¹⁹ 21 U.S.C. § 352(e)(1)(A).

²⁰ 21 U.S.C. § 352(e)(1)(B).

²¹ 21 U.S.C. § 352(f).

²² 21 U.S.C. § 353(b)(4)(A).

²³ 21 U.S.C. § 352(n).

²⁴ 21 U.S.C. § 355(d).

²⁵ 21 U.S.C. § 355(i)(1); 21 C.F.R. § 312.20.

²⁶ 21 U.S.C. § 355(i)(1).

²⁷ 21 C.F.R. § 312.21.

studies.²⁸ The data must demonstrate safety and effectiveness for at least one clinical indication. The FDA will not approve a drug for indications other than those specifically requested and supported by controlled clinical studies. Once a drug is approved for one indication, a physician may prescribe the drug for other indications, a process known as “off-label” usage.

A3. Regulation of Fast Track and Generic Drugs

The FDCA provides mechanisms for expedited approval of new drugs and for patient use of investigational drugs in certain circumstances.²⁹ For example, a pharmaceutical company may apply for fast track approval of a new drug, if the drug may be an effective treatment for a “serious or life threatening condition.”³⁰ Also, the FDA may permit a drug that is still under investigation to be used to treat a serious or life-threatening disease, if there is no satisfactory alternative.³¹

In order to obtain approval of a generic drug, a sponsor must submit an abbreviated new drug application (ANDA).³² If the active ingredient is the same as the active ingredient in a previously approved drug, the FDA does not require additional studies to demonstrate safety and effective-

ness. Approval requires only that the sponsor demonstrate bioequivalence between the generic drug and the previously approved drug.

A4. Post-Market Regulation of New Drugs

Following release of a new drug, the sponsoring company must conduct post-market surveillance and report serious and unexpected adverse events.³³ If a serious and unexpected adverse event occurs, the sponsor must report the event within 15 days.

Even though pre-market studies are extensive, the number of patients that take a drug prior to marketing may be no more than a few thousand. After approval, hundreds of thousands of patients may use the drug. As a result, rare complications may not become apparent until after approval. Post-market surveillance allows the sponsor to discover these rare complications.

To market an already approved drug for a new indication, the sponsor must submit a supplementary NDA.³⁴ To gain approval for a new indication, the sponsor may include data from the original NDA, but the sponsor must submit additional data from controlled studies that demonstrate effectiveness for the new indication.

²⁸ 21 U.S.C. § 355(a)-(b).

²⁹ 21 U.S.C. § 356(a)(1); 21 C.F.R. § 312.34.

³⁰ 21 U.S.C. § 356(a)(1).

³¹ 21 C.F.R. 312.34.

³² 21 U.S.C. § 355(j).

³³ 21 C.F.R. 314.80.

³⁴ 21 C.F.R. 314.70.

B. REGULATION OF MEDICAL DEVICES

The FDCA distinguishes a medical device from a drug by the fact that a device does not achieve its “intended purposes through chemical action” and is “not dependent upon being metabolized” in achieving its purpose.³⁵ The regulation of medical devices is similar to that of pharmaceuticals. Device manufacturers must register all manufacturing facilities and all devices with the FDA. They also must meet requirements for good manufacturing practices.³⁶

The FDA classifies devices based on risk to patients.³⁷ Class I devices are devices for which general FDA regulations “provide reasonable assurance of...safety and effectiveness”.³⁸ Examples include hospital beds, crutches, and nasogastric tubes. Regulations that apply to sponsors of Class I devices include: registration, good manufacturing practices, prohibitions against adulteration and misbranding, and pre-market notification. Class II devices are devices for which FDA’s “general controls...are insufficient to provide reasonable assurance of the safety and effectiveness of the device.”³⁹ Examples include x-ray equipment, MRI scanners, and other nonin-

vasive diagnostic equipment. Sponsors of Class II devices must comply with the regulations required of Class I sponsors and also with “special controls,” including performance standards, post-market surveillance, patient registries and guidelines. Class III devices are those that support or sustain human life or present a major risk of illness or injury.⁴⁰ Examples include ventilators, defibrillators, and implantable devices. Prior to marketing, a sponsor of Class III devices must obtain FDA approval based on controlled studies demonstrating both safety and effectiveness.

Prior to human studies on Class III devices, a sponsoring company must apply for an Investigational Device Exemption (IDE).⁴¹ The FDA may require post-market surveillance of Class II and Class III devices.⁴²

C. FDA ENFORCEMENT MECHANISMS

The FDA has the authority to promulgate rules by informal notice and comment rulemaking and also by formal, trial-type rulemaking.⁴³ In addition, the FDA uses guidance documents and occasionally publicity to encourage pharmaceutical manufacturers to follow certain

³⁵ 21 U.S.C. § 321(h).

³⁶ 21 U.S.C. § 360; 21 U.S.C. § 351(a).

³⁷ 21 U.S.C. § 360c.

³⁸ 21 U.S.C. § 360c(a)(1)(A).

³⁹ 21 U.S.C. § 360c(a)(1)(B).

⁴⁰ 21 U.S.C. § 360c(a)(1)(C).

⁴¹ 21 U.S.C. § 360j(g).

⁴² 21 U.S.C. § 360l.

⁴³ 21 U.S.C. § 371(a).

procedures.⁴⁴ Unlike regulations resulting from notice and comment rulemaking, these latter types of regulation do not bind the FDA or the regulated manufacturers.⁴⁵

In addition, the FDA may bring enforcement actions. If the FDA believes that a drug or device is misbranded or adulterated, it can initiate seizure proceedings against the product.⁴⁶ The FDA may also request a temporary restraining order to prevent shipment of an adulterated or misbranded drug in interstate commerce.⁴⁷ Should it become necessary, the FDA may report the results of an investigation to the Department of Justice for criminal proceedings.

D. EFFECTS OF FDA REGULATION OF PHARMACEUTICALS AND MEDICAL DEVICES

Risk reducing regulatory agencies act in one of two ways: (1) as a “gatekeeper,” granting or denying approval for use of a product in the marketplace, or (2) as a “standard setter,” setting standards and then comparing already marketed products to the standard, occasionally removing products that don’t meet standards.⁴⁸ Gatekeepers require the sponsor to demonstrate that the prod-

uct is “acceptability safe” before the product can be used. Standard setters must show that the product is “unacceptably hazardous” before the product can be removed. Gatekeeper regulation is more costly for a regulated entity than standard setting regulation for two reasons: (1) “acceptably safe” is a stricter standard than “unacceptably hazardous,” and (2) gatekeeper regulation places the burden of proof on the sponsor.⁴⁹

The FDA serves both a standard setting function and a gatekeeper function. It sets standards for drugs already on the market and for Class I and II devices. For new drugs and Class III devices, it serves a gatekeeper function. In addition, the FDA is the only gatekeeper for new drug approval. Unlike private entities that serve accrediting functions, the FDA does not compete for customers based on quality, service, or price. As a result, there is less incentive to speed approval or to limit costs for new product development.

D1. Historical Trends

Because biologics represent a very small portion of U.S. health care, the 1902 Biologics Control Act did not impose significant costs on U.S. health care.⁵⁰ Also, because the 1938 FFDCA did not require pre-market approval, it did not

⁴⁴ 21 U.S.C. § 371(h); 21 U.S.C. § 375.

⁴⁵ 21 U.S.C. § 371(h).

⁴⁶ 21 U.S.C. § 334.

⁴⁷ 21 U.S.C. § 332.

⁴⁸ See Peter Huber, *Exorcists vs. Gatekeepers in Risk Regulation*, Regulation 23 (Nov./Dec., 1983).

⁴⁹ *Id.*

⁵⁰ See Henry I. Miller, *The Birth and Growth of Premarket Regulation*, in TO AMERICA’S HEALTH: A PROPOSAL TO REFORM THE FOOD AND DRUG ADMINISTRATION 11 (2000).

initially impose significant costs on the pharmaceutical industry. Prior to 1962, the FDA served a “policing” function, i.e. the FDA investigated whether a drug was adulterated or misbranded, and if so, it brought an enforcement action to remove the drug from the market. In this way, the FDA served a useful role in removing unsafe and ineffective products at a relatively small cost to reputable pharmaceutical manufacturers.⁵¹

The 1962 Kefauver-Harris Amendments, which required a company to obtain pre-market approval, had a major effect on both pharmaceutical manufacturers and new drug development. Between 1963 and 1975, there was a 50 percent decrease in the number of INDs submitted by pharmaceutical companies for new chemical entities (NCEs).⁵² The number of INDs for NCEs increased in the 1980s, but by 1993, the number had not reached the 1963 level. In addition, the clinical development time for NCEs more than doubled between the 1960s and the late 1980s.⁵³ The decrease in INDs for NCEs was partly ame-

liorated by an increase in INDs for new biopharmaceutical entities (NBEs). Between 1981 and 1993, there was a steady increase in IND filings for NBEs, and after 1990 a marked increase in NBE approvals.⁵⁴ In addition, since the mid 1990’s, there has been a decrease in clinical development time for both NCEs and NBEs.⁵⁵

Between the mid 1970s and mid 1990s, the cost of developing a new drug increased.⁵⁶ One study estimated that the expected capitalized research and development cost per approved drug between 1990 and 2001 was \$897 million dollars. Almost 90 percent of the expected cost, \$802 million, occurred prior to approval.⁵⁷

D2. Benefits and Costs of Pre-market Approval

Potential benefits of the present system of pharmaceutical and medical device regulation include: (1) decreased morbidity and mortality secondary to fewer unsafe products being used to treat patients, (2) decreased morbidity and mortality secondary to fewer ineffective products being used to treat patients, (3) decreased mone-

⁵¹ *Id.*

⁵² See Joseph A. Dimasi, *New Drug Development in the United States from 1963 to 1999*, 69 *Clin. Pharm. Ther.* 286, 289, 290 (2001).

⁵³ *Id.* at 292.

⁵⁴ See Joseph A. Dimasi, *supra* note 52, at 289, 290; Janice M. Reichert, *Biopharmaceutical Approvals in the U.S. Increase*, *Reg. Aff. J. Pharmacol.* (July, 2004).

⁵⁵ See Janice M. Reichert, *Trends in Development and Approval Times for New Therapeutics in the United States*, 2 *Nature Reviews* 695, 697 (Sept. 2003).

⁵⁶ See Joseph A. Dimasi, Ronald W. Hansen, Henry G. Grabowski, *The Price of Innovation: New Estimates of Drug Development Costs*, 22 *J. Health Econ.* 151, 166, 173 (2003).

⁵⁷ *Id.*

tary costs secondary to fewer ineffective products being used to treat patients, (4) improved information for physicians and patients secondary to FDA requirements for registration, labeling, and information dissemination.

Potential costs include: (1) the cost to taxpayers to maintain the FDA regulatory structure, (2) the costs for pharmaceutical and device manufacturers to comply with FDA regulations, (3) increased morbidity and mortality secondary to fewer safe and effective products reaching the market, (4) increased morbidity and mortality secondary to delayed approval of safe and effective products, and (5) decreased information for physicians and patients secondary to FDA restrictions on information dissemination.

In his study of the benefits and costs associated with health care regulations, Conover estimated that in a typical year, the FDA regulation of pharmaceuticals and medical devices provides benefits of \$7.1 billion per year, but costs of \$49.0 billion per year.⁵⁸

E. SUMMARY

Based on the FDCA as amended by the 1962 Drug Amendments, the FDA regulates most aspects of the pharmaceutical and medical device industries. The FDA regulates manufacturing processes, product labeling, and, prescription drug advertising. The FDA regulates all aspects of the new drug approval process. Since 1976, the FDA has regulated the medical device industry in a similar manner.

With respect to the pre-market approval process for new drugs and Class III devices, the FDA serves a gatekeeper regulatory function. To market a drug or a Class III medical device, a sponsor must conduct controlled studies demonstrating safety in humans and effectiveness for at least one clinical indication.

After passage of the 1962 Drug Amendments, there was an increase in the cost and time required for new drug development. However, since the mid 1990s, clinical development time and FDA approval time have both decreased.

⁵⁸ Christopher J. Conover, *Health Care Regulation: A \$169 Billion Hidden Tax*, Policy Analysis No. 527, Cato Institute (October 4, 2004).

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CHAPTER 7: REGULATION OF HOSPITALS, FACILITIES, AND MEDICAL STAFF¹

Congress has regulated hospitals and other health care facilities for many different reasons. One early goal was to guarantee access to hospitals regardless of ability to pay. In 1946, Congress passed the Hill Burton Act.² This act provided funds for the construction of new hospitals and for the expansion of existing facilities. The act authorized regulations that required hospitals to provide care for low income citizens as a condition for receiving the funds.

In 1986, Congress passed the Emergency Medical Treatment and Active Labor Act (EMTALA).³ This act required hospitals with emergency departments to perform a screening examination on all patients presenting for treatment, regardless of ability to pay. It also required hospitals to stabilize those patients found to have an emergency medical condition.

The goal of many hospital and health facility regulations was to assure that Medicare and Medicaid beneficiaries receive high quality care. For example, the Centers for Medicare and

Medicaid Services (CMS) require each hospital that receives Medicare reimbursement to meet certain Conditions of Participation.⁴ In 1982, Congress enacted the Utilization and Quality Control Peer Review Organization (PRO) program.⁵ Under the PRO program, CMS contracts with organizations composed of physicians and other professionals to review health care facilities and their staff for quality and resource utilization.

Congress also has passed statutes designed specifically to improve medical staff quality. In 1986, it passed the Health Care Quality Improvement Act (HCQIA).⁶ Among other things, HCQIA established the National Practitioner Data Bank (NPDB), which maintains data on disciplinary and malpractice actions against physicians. Its purpose was to provide information to hospital credentials committees to improve their credentialing and disciplinary process. HCQIA also provided hospital credentials committees with limited immunity from antitrust laws, allowing a committee more freedom to prevent unqualified physicians from practicing in its hospital.⁷

¹ See Appendix A for related statutes; see Appendix B for related regulations.

² Pub. L. No.79-725.

³ Pub. L. No.99-272.

⁴ 42 C.F.R. Part 482.

⁵ Pub. L. No.97-248.

⁶ Pub. L. No.99-660.

⁷ *Id.*

Congress also has regulated hospitals in an attempt to decrease costs. During the 1970s, many health care reformers believed that limiting the supply of diagnostic and treatment facilities would decrease health care expenditures. They reasoned that because physicians and hospitals were paid on a fee-for-service basis, additional facilities and wide dissemination of technology would result in more procedures and thus increased expenditures. The idea that “a bed built is a bed filled is a bed billed” led Congress to pass the National Health Resources Planning and Development Act (NHRPDA) in 1974.⁸

One component of NHRPDA divided the country into Health Service Areas (HSAs) to oversee state Certificate of Need (CON) programs.⁹ This program required a hospital to obtain a CON from a state planning board before purchasing major equipment or expanding facilities. Because the CON program was not successful in limiting health care costs, Congress repealed it in 1986. However, a majority of states have continued CON programs.

Similar to hospitals, skilled nursing facilities (SNFs) and home health agencies (HHAs) must meet Conditions of Participation.¹⁰ Because of

concerns that SNFs were not providing high quality care, Congress passed additional regulations for SNFs in the Omnibus Budget Reconciliation Act (OBRA) of 1987.¹¹ This act strengthened a “resident’s bill of rights” for all patients in SNFs. In 1988, Congress passed the Clinical Laboratory Improvement Amendments (CLIA) to the Public Health Service Act.¹² CLIA established comprehensive regulations for clinical laboratories.

Title V of the Medicare Prescription Drug Improvement and Modernization Act (MMA) included a provision requiring the Medicare Payment Advisory Commission (MEDPAC) to study the effects of physician-owned single-specialty hospitals (SSHs) on full-service hospitals.¹³ In addition, Congress imposed a moratorium on Medicare payments to new SSHs until these effects were clear.

A. REGULATION OF HOSPITALS

A1. Hill Burton Act

To receive Hill Burton funds for the construction or expansion of facilities, a hospital must fulfill a community service obligation and an uncompensated care obligation.¹⁴ The commu-

⁸ The quote is attributed to Milton Roemer; 93 P.L. 641

⁹ Pub. L. No. 93-641.

¹⁰ 42 C.F.R. Part 483; 42 C.F.R. Part 484.

¹¹ Pub. L. No.100-203.

¹² Pub. L. No.100-578.

¹³ Pub. L. No. 108-173.

¹⁴ 42 U.S.C. § 291c(e).

nity service obligation, which continues indefinitely, requires the hospital to provide services to all persons living in the area on a nondiscriminatory basis.¹⁵ The uncompensated care obligation requires the hospital to provide a “reasonable volume of services to persons unable to pay. . . .”¹⁶ Once the hospital has met its required volume of uncompensated care, the requirement ends. Because Medicare and Medicaid pay for services provided for beneficiaries, services to Medicare and Medicaid patients do not qualify under the uncompensated care obligation.

A2. Emergency Medical Treatment and Active Labor Act

EMTALA requires all hospitals that participate in Medicare and have an emergency room to provide a medical screening examination for all persons that come to the hospital for examination and treatment.¹⁷ This requirement applies to all patients regardless of ability to pay. If an emergency medical condition is present, the hospital must attempt to stabilize the patient’s condition.¹⁸ The hospital may transfer the patient if the patient requests a transfer or if the examining physician certifies that the benefits of transfer outweigh the risks.¹⁹

If the hospital transfers a patient, the hospital must provide adequate equipment and personnel for the transfer, the receiving facility must agree to accept the patient, and the transferring hospital must provide all medical records to the accepting hospital.²⁰ Patients may refuse treatment, refuse transfer, or request transfer to another hospital.

EMTALA grants an injured party a private cause of action against a hospital that violates the act, but EMTALA does not grant a private cause of action against a physician.²¹ EMTALA also grants a private cause of action to a hospital that suffers a financial loss resulting from another hospital’s violation of the act. Finally, EMTALA provides civil monetary penalties against both hospital and physician for violation of the act.²²

One of EMTALA’s primary goals was to assure adequate delivery services to women in labor. Under EMTALA, a pregnant woman having contractions is in an emergency medical condition if transfer would threaten her health or the health of the unborn child.²³ Under EMTALA, a pregnant woman in labor is not considered stable until delivery.

¹⁵ 42 U.S.C. § 291c(e)(1).

¹⁶ 42 U.S.C. § 291c(e)(2).

¹⁷ 42 U.S.C. § 1395dd(a).

¹⁸ 42 U.S.C. § 1395dd(b).

¹⁹ *Id.*

²⁰ 42 U.S.C. § 1395dd(c).

²¹ 42 U.S.C. § 1395dd(d)(2).

²² 42 U.S.C. § 1395dd(d)(1).

²³ 42 U.S.C. § 1395dd(e)(1)(B).

A3. Conditions of Participation/Accreditation/ Provider Agreements

In order to provide care for Medicare patients, Part A providers must meet certain Conditions of Participation.²⁴ For example, hospitals must meet certain criteria with respect to governance, patient's rights, medical staff, nursing services, and medical records. Hospitals may undergo a state sponsored survey and audit to receive accreditation. However, this is a detailed and costly process, and hospitals rarely use this procedure. A hospital can also be "deemed" to meet these requirements if the hospital obtains accreditation from either the Joint Commission on Accreditation of Health Care Organizations (JCAHO) or the American Osteopathic Association.²⁵

To assure quality in the hospitals in which they operated, the American College of Surgeons (ACS) developed a process for the inspection and review of hospital facilities. The ACS carried out its first inspection in 1918.²⁶ This process evolved into the JCAHO process of today. To obtain accreditation, each hospital pays a fee to JCAHO to review and inspect its facilities and procedures. Each hospital must meet standards in several different areas, such as patient treatment, infection control, and patient rights.²⁷ JCAHO representa-

tives conduct a site visit and review the hospital's compliance with standards. If the hospital meets the criteria, JCAHO grants accreditation for up to three years. If the on-site visit reveals areas that need improvement, the hospital must address each deficiency before JCAHO will award accreditation.

Because JCAHO had been successful in providing accreditation prior to the establishment of Medicare, and because JCAHO is well-accepted by the medical and hospital communities, CMS allows hospitals accredited by JCAHO to have "deemed" status, i.e. a hospital that meets JCAHO accreditation standards is deemed to meet Medicare Conditions of Participation.²⁸

Hospitals and other facilities must sign provider agreements as a Condition of Participation.²⁹ In the provider agreement, hospitals must agree to provide certain services, to maintain contracts with PROs, to meet certain billing requirements, to disclose certain information to CMS, to disclose information to Medicare beneficiaries, and to comply with other laws.

A4. Medical Staff

As with hospital regulation, state and private reg-

²⁴ 42 C.F.R. § 482.1 et seq.

²⁵ 42 C.F.R. § 488.5(a).

²⁶ Joint Commission on Accreditation of Healthcare Organizations, *A Journey Through the History of the Joint Commission*, at <<http://www.jcaho.org/about+us/history.htm>>.

²⁷ Joint Commission on Accreditation of Healthcare Organizations, *Facts About the Joint Commission on Accreditation of Healthcare Organizations*, at <http://www.jcaho.org/about+us/jcaho_facts.htm>.

²⁸ 42 U.S.C. § 1395bb.

²⁹ 42 U.S.C. § 1395cc.

ulation of physicians preceded federal regulation. At this time, state governments license physicians and other health care professionals. Hospital credentials committees and hospital review committees review physician competence and quality, and private professional organizations test and certify physicians for specialty practice. Although states do not require board certification for specialty practice, board certification serves as an important means for assuring physician competence.

As noted above, the NPDB maintains data on disciplinary and malpractice actions against physicians.³⁰ A malpractice insurer must report to the NPDB any payment it makes as a result of a settlement or a judgment against a physician.³¹ A state licensing board must report to the NPDB all disciplinary actions and sanctions taken against a physician, if the action results from the physician's lack of competence or improper conduct.³² Similarly, hospitals must report actions that negatively affect a physician's clinical privileges, and professional societies must report professional review actions to state licensing boards.³³ Boards must then report these actions to the NPDB. There is no requirement that physicians report adverse actions against themselves to the NPDB.

NPDB data are accessible to: (1) hospitals and other health care entities as a part of a credentialing or formal professional review process, (2) state licensing boards, (3) a plaintiff in a malpractice action against a hospital if the hospital did not request information from the NPDB at the time it granted privileges to a physician, (4) individual practitioners on whom there are data in the NPDB, and (5) researchers who have access to de-identified information.³⁴ Medical malpractice insurers and the general public do not have access to NPDB data.

Hospitals must request information concerning a physician from the NPDB each time the physician applies for staff membership or clinical privileges and every two years thereafter.³⁵ Hospitals also must file a report with the NPDB if it takes an action against a practitioner based on the practitioner's professional competence or conduct.³⁶ If a practitioner agrees to a loss or restriction of privileges to avoid an unfavorable action, the hospital must report the agreement to the NPDB.

One of the goals of HCQIA was to strengthen the ability of a hospital's medical staff to discipline and sanction physicians. HCQIA provides

³⁰ 45 C.F.R. § 60.1.

³¹ 45 C.F.R. § 60.7.

³² 45 C.F.R. § 60.8.

³³ 45 C.F.R. § 60.9.

³⁴ 45 C.F.R. § 60.11.

³⁵ 45 C.F.R. § 60.10.

³⁶ 45 C.F.R. § 60.9.

limited immunity from antitrust violations if the credentials committee follows due process requirements.³⁷

B. REGULATION OF OTHER FACILITIES

As with full service hospitals, CMS requires specialty hospitals such as psychiatric hospitals, outpatient rehabilitation facilities, and hospice services to meet Conditions of Participation before providing services to Medicare patients.³⁸

B1. Skilled Nursing Facilities

SNFs must abide by a “resident’s bill of rights.” Resident rights include regulations related to privacy, access to visitors, access to services, the selection of a physician, transfer, discharge, and the use of physical and chemical restraints.³⁹ Rights include the right to exercise one’s rights free of coercion, to examine clinical records, to refuse treatment, and to refuse certain transfers.⁴⁰ The facility must provide information concerning Medicaid benefits, the services available at the facility, and the method for contacting the resident’s physician. The resident has the right to choose a personal physician, manage personal funds, send and receive mail, examine hospital

survey information, and have visitors.

A resident of a long-term care facility has a right to be free from physical or chemical restraint imposed for “discipline or convenience.”⁴¹ The resident also has a right to be free from verbal, sexual, physical, and mental abuse.

B2. Clinical Laboratories

HHS requires clinical laboratories to obtain a certificate to perform clinical laboratory testing.⁴² A clinical laboratory may obtain certification by HHS or may obtain “deemed” status if CMS approves the accrediting agency. Laboratories must meet performance standards related to facilities, equipment, personnel, records, and quality assurance.

C. EFFECTS OF CMS REGULATION OF HOSPITALS AND OTHER FACILITIES

C1. Certificate of Need and Single-Specialty Hospitals

The CON program serves a “gatekeeper” regulatory function. As noted above, gatekeeper regulations tend to be costly and serve as a barrier to entry. In general, barriers to entry decrease supply,

³⁷ 42 U.S.C. § 11111.

³⁸ 42 U.S.C. § 1395f; 42 U.S.C. 1395cc; 42 C.F.R. Parts 483-485.

³⁹ 42 C.F.R. § 483.10.

⁴⁰ *Id.*

⁴¹ 42 C.F.R. § 483.13.

⁴² 42 U.S.C. § 263a.

resulting in fewer available services and higher prices. The Federal Trade Commission conducted three studies of the CON program in the 1980's. None of these studies showed that the CON program decreased hospital costs, and two suggested that CON programs increased hospital costs.⁴³ Because the CON program was not successful in controlling health care costs, Congress repealed the federal CON program in 1986. However, as of 2002, state CON programs were still in place in a majority of states.⁴⁴

There are few data concerning the effect of limiting Medicare payment to new SSHs. Similar to the CON program, limiting payment to new SSHs decreases the incentive to develop these facilities, thus serving as a barrier to entry. Thus, one would expect that limiting these payments may decrease services available to Medicare patients. SSHs have developed primarily in states that have abolished their CON programs.⁴⁵ By introducing competition among hospitals for certain services, SSHs may lower prices and improve quality.

C2. Benefits and Costs

In his study of the benefits and costs associated with health care regulation, Conover divided

state and federal facility regulations into three categories: (1) patient access, including requirements to provide care, (2) costs, e.g. requirements designed to decrease prices, control fraud and abuse, and increase privacy, and (3) requirements to meet quality standards.⁴⁶ He estimated that requirements for health care facilities to provide access have a net cost of \$8 billion per year and requirements to control costs have a net benefit of \$0.7 billion per year. The latter figure includes a net benefit from pharmaceutical price regulation of \$2.0 billion per year. Conover estimated the cost of state and federal regulations to improve quality at \$21.8 billion per year. Because he was unable to quantify benefits associated with most quality regulations, he was unable to determine whether there were net benefits or net costs.

D. SUMMARY

The federal government regulates hospitals to ensure patient access regardless of ability to pay and to ensure quality of care for Medicare beneficiaries and other patients.

Each hospital that provides care for Medicare beneficiaries must meet certain Conditions of

⁴³ See Federal Trade Commission/Department of Justice, *Miscellaneous Subjects*, in *IMPROVING HEALTH CARE: A DOSE OF COMPETITION*, Chapter 8 (July 23, 2004).

⁴⁴ See Federal Trade Commission/Department of Justice, *supra* note 43.

⁴⁵ U.S. General Accounting Office, GAO -04-167, *Specialty Hospitals: Geographic Locations, Services Provided and Financial Performance 3-4* (2003), at <<http://www.gao.gov/new.items/d04167.pdf>>.

⁴⁶ Christopher J. Conover, *Health Care Regulation: A \$169 Billion Hidden Tax*, Policy Analysis No. 527, Cato Institute, (October 4, 2004).

Participation. CMS requires a hospital to report to the NPDB actions taken against staff physicians, if the action is a result of a physician's lack of competence or improper conduct. HCQIA provides hospital credentials committees with limited antitrust immunity for actions it takes to sanction a physician or limit privileges. CMS

requires other types of provider facilities to meet Conditions of Participation, and CMS requires SNFs to abide by a resident's bill of rights.

The data suggest that federal regulation of hospitals results in significant costs. It is likely these costs outweigh the benefits.

ADDITIONAL READING

1. Barry R. Furrow et al., *Regulation of Health Care Institutions*, in HEALTH LAW 1 (2d ed. 2000).
2. Robert G. Hoban and Monte Dube, *Regulation of Hospitals*, in FUNDAMENTALS OF HEALTH LAW 295 (Bernadette M. Broccolo et al., ed., 3d ed. 2004).
3. Federal Trade Commission/Department of Justice, *Industry Snapshot: Hospitals*, in IMPROVING HEALTH CARE: A DOSE OF COMPETITION, Chapter 3 (July 23, 2004).
4. Federal Trade Commission/Department of Justice, *Competition Law: Hospitals*, in IMPROVING HEALTH CARE: A DOSE OF COMPETITION, Chapter 4 (July 23, 2004).

CHAPTER 8: REGULATION OF MEDICARE BILLING: FRAUD AND ABUSE¹

Because of a number of well publicized cases of fraud involving Medicare and Medicaid, the federal government has devoted significant resources to combating “fraud and abuse” in its health care programs. Fraud and abuse covers a wide variety of activities, U.S. laws, and enforcement actions. Some of these laws apply generally to areas other than health care. Other laws were enacted specifically to combat health care fraud and abuse.

The primary statutes used to combat Medicare fraud and abuse are the federal False Claims Act (FCA) and three provisions of the Social Security Act (SSA).² The FCA prohibits a person from submitting a false claim to an officer of the U.S. government for payment.³ The SSA provides civil penalties for submitting a false claim to a federal health care program and criminal penalties for making a false statement or representation concerning claims or benefits under a federal health care program.⁴

In addition to prohibiting false claims and state-

ments, Congress has enacted several measures to combat certain financial practices involving federal health care programs. In 1987, Congress passed the Medicare and Medicaid Patient Protection Act (MMPPA), commonly known as the “Anti-Kickback Statute.”⁵ This statute makes it a felony to solicit or receive money in return for referring a patient, if the referral is to a party who will submit a bill to a federal health care program.

In the Omnibus Budget Reconciliation Act (OBRA) of 1989, Congress included a provision that prohibits a physician from referring a Medicare patient to a clinical laboratory in which the physician has a financial interest.⁶ “Stark I” Regulations, named after Congressman Stark who sponsored the original legislation, became effective in August, 1995.⁷ In the Omnibus Budget Reconciliation Act (OBRA) of 1993, Congress expanded the prohibition to referrals for services other than clinical laboratory procedures.⁸ Regulations implementing these provisions, known as the “Stark II” Regulations, became

¹ See Appendix A for related statutes; see Appendix B for related regulations.

² 37 U.S.C. § 3729-33; 42 U.S.C. 1320a-7a, 1320a-7b, 1395nn.

³ 37 U.S.C. § 3729.

⁴ 42 U.S.C. 1320a-7a(a); 42 U.S.C. 1320a-7b(a).

⁵ Pub. L. No.100-93.

⁶ Pub. L. No. 101-239.

⁷ 60 Fed. Reg. 41,914 (1995).

⁸ Pub. L. No. 103-66..

effective in January 2001 and July 2004.⁹

In 1996, Congress passed the Health Insurance Portability and Accountability Act (HIPAA).¹⁰ One of the three primary purposes of HIPAA was to combat fraud and abuse in both public and private health care programs. HIPAA amended the U.S. Criminal Code, creating four new “health care criminal offenses.”¹¹ HIPAA also created three new fraud control programs—the Fraud and Abuse Control Program, the Medical Integrity Program, and the Beneficiary Incentive Program. More importantly, HIPAA authorized additional funds to investigate and bring either civil or criminal actions against those violating fraud and abuse statutes.¹²

A. REGULATION OF FALSE CLAIMS AND FINANCIAL TRANSACTIONS

A1. *False Claims and Statements – Civil Penalties*

Enforcement actions brought against health care providers usually relate to false claims and statements. The FCA provides for civil penalties if a person knowingly presents a “false or fraudulent

claim for payment or approval” to an officer of the U.S. or makes a “false record or statement to get a false or fraudulent claim paid.”¹³ The penalty is \$5,000 to \$10,000 per claim plus three times the actual amount of damages for each false claim.¹⁴ While the statute requires that a person “knowingly” submit a false claim, the definition of knowingly states, “no proof of specific intent to defraud is required.”¹⁵

The FCA also provides for *qui tam* actions.¹⁶ *Qui tam* actions are those in which an individual citizen brings an action against another person, alleging that the defendant violated a law. The purpose is to provide an incentive for “whistle blowers” to bring wrongdoing to the attention of the federal government. The individual bringing the action, known as the *qui tam* relator, files a complaint in federal court, and the Department of Justice decides whether or not to join the suit. If the suit is successful, the relator receives a portion of the damages.

The SSA provides for civil money penalties against a claimant if: (1) the claimant did not provide the service as claimed, (2) the claim is false or fraudulent, (3) the physician did not have a license or falsely claimed to be board cer-

⁹ 66 Fed. Reg. 856 (2001); 69 Fed. Reg. 16,054 (2004).

¹⁰ Pub. L. No.104-191.

¹¹ *Id.*

¹² *Id.*

¹³ 31 U.S.C. § 3729(a).

¹⁴ *Id.*

¹⁵ 31 U.S.C. § 3729(b).

¹⁶ 31 U.S.C. § 3730(b), (c).

tified, but was not, (4) the physician or other professional was not a provider for the health care program, or (5) the service was “not medically necessary.”¹⁷

A2. False Claims and Statements – Criminal Penalties

In addition to statutes providing civil penalties, there are a number of criminal laws that may apply to false claims and statements by health care providers. The SSA makes it a felony when one: (1) “makes or causes to be made any false statement or representation . . . in any application for any benefit or payment under a Federal health care program,” (2) makes a false statement with respect to determining “rights to such benefit or payment,” (3) fails to disclose material information affecting rights to benefits or payments, (4) converts a benefit or payment designed for one person to the “use and benefit” of another person, (5) submits a claim for a physician’s service when a person other than a licensed physician provided the service, and (6) counsels or assists an individual to dispose of assets to qualify for Medicaid.¹⁸

HIPAA amended the U.S. criminal code to provide criminal penalties for “whoever . . . executes, or attempts to execute . . .” an action (1) “to

defraud any health care benefit program; or (2) to obtain, by means of false . . . pretenses . . . money or property . . . under the custody or control of . . . any health care benefit program, in connection with the delivery of or payment for health care benefits . . .”¹⁹ Unlike the prohibitions contained in the SSA, this statute applies to fraudulent claims submitted to both public and private payers. Violation of this statute may result in imprisonment for up to ten years. Other provisions of HIPAA prohibit health care theft or embezzlement, false statements, and obstruction of criminal investigations.²⁰

The Mail Fraud Act provides criminal penalties for “having devised . . . for obtaining money or property . . . by means of false or fraudulent pretenses . . . , places in any post office . . . any matter . . . to be sent or delivered by the Postal Service.”²¹ There are similar prohibitions against wire fraud.²²

A3. Bribes and Kickbacks

The federal Anti-Kickback Statute prohibits a person from soliciting or receiving remuneration in return for referring a patient to receive services or to purchase goods, if Medicare or another federal health care program is the payer.²³

¹⁷ 42 U.S.C. § 1320a-7a(a).

¹⁸ 42 U.S.C. § 1320a-7b(a).

¹⁹ 18 U.S.C. § 1347.

²⁰ 18 U.S.C. § 669, 1035, 1518.

²¹ 18 U.S.C. § 1341.

²² 18 U.S.C. § 1343.

²³ 42 U.S.C. § 1320a-7b(b).

Violation of this statute is a felony and may result in a fine of up to \$25,000 or imprisonment for up to five years.

The Anti-Kickback Statute contains a number of exceptions.²⁴ These include: (1) a price discount if disclosed and reflected in the costs or charges made by the provider, (2) wage payments made from an employer to an employee, (3) a waiver of coinsurance under Medicare Part B, and (4) remuneration based on certain types of risk-sharing agreements.

The Office of the Inspector General (OIG) has issued regulations providing additional safe harbors for: (1) certain investment interests, (2) space and equipment rentals, (3) personal services and management contracts; (4) sale of a practice, (5) referral services, and (6) warranties.²⁵ The OIG has also published safe harbors for various managed care practices, including waivers of deductibles and incentives for beneficiaries to use a physician within a preferred provider network.²⁶

A4. Stark Physician Referral Law

The Stark Law prohibits referrals by a physician to an entity for “designated health services,” if the

physician has a financial relationship with the entity.²⁷ A financial relationship includes an ownership interest, an investment interest, or a compensation arrangement. Designated health services include clinical laboratory services, physical or occupational therapy, radiology, parenteral nutrition, and home health services.

The primary exceptions to the Stark Law are physician services and in-office ancillary services.²⁸ For example, even though there is a financial arrangement between physicians in a group practice, a physician may refer a patient to a physician in another specialty within the same group practice. Also, a physician may refer a patient for laboratory services or radiology services, if the physician or physician group provides the services within the office. Similarly, a physician in an academic medical center may refer a patient to a specialist within the same center.

B. INVESTIGATION AND ENFORCEMENT

Abuse with respect to a billing practice is defined as a billing practice that does not conform to accepted practice when there is no intent to defraud or misrepresent the facts.²⁹ Examples

²⁴ 42 U.S.C. § 1320a-7b(b)(3).

²⁵ 42 C.F.R. § 1001.952.

²⁶ *Id.*

²⁷ 42 U.S.C. § 1395nn.

²⁸ 42 U.S.C. § 1395nn(b).

²⁹ Maxine Lewis and James B. Davis, *Medicare Audits, Fraud, and Abuse*, in *MEDICARE COMPLIANCE MANUAL 2005* 439, 452 (2005).

include billing for unnecessary services or improper coding. “Upcoding,” refers to submitting a claim for a higher level of service than justified. Fraud refers to intentionally misrepresenting or deceiving in order to gain more payment than one deserves.³⁰ If done intentionally, improper coding may represent fraud.

CMS contracts with carriers to process and pay claims, and carriers must serve as the first line of defense against fraud and abuse.³¹ Carriers have primary responsibility for investigating and correcting abuse and initial responsibility for detecting and investigating fraud. Carriers must maintain two separate units to detect abuse and fraud, a Medical Review Unit (MRU) and a Medicare Fraud and Abuse Unit (Fraud Unit).³² MRU personnel analyze claims data. If the data suggest a provider is submitting improper claims, the MRU may notify the provider to correct the problem. If the practice does not change, the MRU may refer the information to the Fraud Unit.³³

Fraud Unit personnel investigate further and develop cases for referral to a regional Office of Investigation Field Offices (OIFO) under the direction of the OIG.³⁴ In cases suggesting poten-

tial fraud from the outset, carriers refer the information directly to the OIFO. The OIG has the authority to bring both civil and criminal charges against physicians. In addition, the FBI may investigate cases, and the Department of Justice (DOJ) may prosecute cases.

HIPAA created three new fraud control programs. The Fraud and Abuse Control Program coordinates the efforts of HHS and DOJ for combating health care fraud.³⁵ The Medicare Integrity Program allows HHS to contract with private entities to audit and investigate for fraud.³⁶ The Beneficiary Incentive Program provides monetary incentives to Medicare beneficiaries to report potential violations of Medicare payment rules.³⁷

C. EFFECTS OF FRAUD AND ABUSE APPLIED TO PHYSICIAN BILLING

There are few data concerning the incidence of fraud or abuse associated with hospital or physician billing. Congress passed the additional legislation primarily because there were a number of egregious cases of fraud, even completely fraudulent entities billing Medicare.³⁸

³⁰ *Id.* at 448.

³¹ *Id.* at 444.

³² *Id.* at 446.

³³ *Id.* at 463.

³⁴ *Id.*

³⁵ 42 U.S.C. § 1320a-7e.

³⁶ 42 U.S.C. § 1395ddd.

³⁷ 42 U.S.C. § 1395b-5.

³⁸ See Grace-Marie Turner, *HIPAA and the Criminalization of American Medicine*, 22 *Cato Journal* 121, 129-30 (2002).

C1. Enforcement Actions

During the mid to late 1990s, the OIG and DOJ increased fraud and abuse enforcement efforts.³⁹ In addition to clear instances of fraud, enforcement efforts were often directed at well-respected hospitals and physician groups. One set of audits that received a great deal of attention was the Physicians at Teaching Hospitals (PATH) audits. Following OIG audits, the practice groups of the University of Pennsylvania Hospital and Thomas Jefferson University Hospital agreed to return to CMS \$30 million and \$12 million respectively.⁴⁰ In each instance, the groups did not admit wrongdoing, but settled with the OIG to avoid the expense of litigation and potentially higher penalties.

As a part of the PATH audit program, HHS conducted a ten month audit of Dartmouth-Hitchcock Medical Center's billing operations.⁴¹ Dartmouth-Hitchcock estimated that the audit cost \$1.7 million. After the 10 month audit, the federal auditors concluded that Dartmouth-Hitchcock physicians had over-billed the government a total of \$778.00.⁴²

As a result of investigations and penalties

against well-respected physician groups, there was a backlash among the medical and hospital communities against these enforcement efforts. As a result, federal enforcement efforts against major providers have decreased.

C2. Benefits and Costs

In his review of health care regulations, Conover estimated that enforcement actions related to fraud and abuse by health care professionals result in an annual net benefit of \$65 million. However, with respect to hospitals and other facilities, the costs outweigh the benefits by an estimated \$1.1 billion.⁴³

C3. Discussion

To one not familiar with the Medicare program, it may seem puzzling that Congress would pass laws creating "health care offenses" and devote significant resources to investigating well-respected physicians and hospitals. There are at least three factors associated with the Medicare payment process that may be partly responsible: (1) third party payment for minor services, (2) specific Medicare payment practices, and (3) coding complexity.

³⁹ See David A. Hyman, *HIPAA and Health Care Fraud: An Empirical Perspective*, 22 *Cato Journal* 151 (2002).

⁴⁰ *Id.* at 166.

⁴¹ *Id.*

⁴² *Id.*

⁴³ Christopher J. Conover, *Health Care Regulation: A \$169 Billion Hidden Tax*, Policy Analysis, No. 527, Cato Institute (October 4, 2004).

C3-1. Third Party Payment for Minor Services

In most two party transactions, the recipient of a service knows in advance the price and nature of the service to be provided. The recipient can ask the rationale for the service and make an informed decision. If choices are available, the recipient can choose among competing providers based on quality and price. After the provider has performed the service, the provider and recipient know what service was provided and know the previously agreed on price. There is usually little room for disagreement.

When a third party is the payer, the recipient has less incentive to determine in advance the service to be performed and its price. After the provider has completed the service, the recipient has less incentive to determine what the provider actually did. Also, when a provider is billing a third party, and the price only partially affects the recipient, the provider has less incentive to charge a competitive price or to provide the least costly service that will meet the recipient's needs. Finally, the third party payer is not present at the time of the service and can not know what service the provider actually performed.

In third party payer transactions, such as insurance reimbursements, it is in the third party's interest to investigate and pay only appropriate claims. Property and automobile insurance companies employ claims adjusters to investigate damage and determine appropriate payment. As a result, these forms of insurance represent an efficient method for managing the risk of uncertain

loss. However, it is not possible for third party payers to investigate the millions of health care services provided each day. As a result, third party payments for minor services are likely to be inefficient, and they may lead to disputes, allegations of fraud and abuse, as well as actual fraud and abuse.

C3-2. Specific Medicare Payment Practices

CMS procedures differ from those used by most private health insurers. In general, private managed care companies make decisions related to coverage and medical necessity prior to performance of the service. If the company determines that a service is not covered or is unnecessary, it refuses to pay. One can appeal these decisions prior to or after performance of the service. For most Medicare patients, CMS does not use a prior approval mechanism, pays when the bill is submitted, and then investigates after-the-fact for errors and fraud. Although not as effective as patient refusal, prior refusal by a managed care company is more effective at eliminating unnecessary services or inappropriate charges than investigation after the payment.

C3-3. Coding Complexity

Health care payment disputes often deal with differences of opinion, not fraud or abuse. There are over 7,700 potential procedures that a physician may perform, each represented by a Current Procedural Terminology (CPT) code. When a physician provides a service, the physician or physician staff decides which code to use for billing the third party payer, in this instance Medicare.

Many disagreements deal with evaluation and management (E&M) codes. In general, each time a physician sees a patient, the physician must choose an E&M code based on three primary factors: the extent of the medical history taken, the extent of the examination performed, and the complexity of the decision-making process required for that visit. Each of these primary factors has four subcategories, e.g. the history is either a problem focused, expanded problem focused, detailed, or comprehensive history. The decision-making process is either straightforward, of low complexity, of moderate complexity, or of high complexity. There are guidelines that define each of these subcategories. As one might expect, there are often differences of opinion concerning whether the history taken was detailed or comprehensive, whether the decision-making process was of low or moderate complexity, and so on. As with third party payments for minor services, determination of fees based on complex rules leads to disputes and may lead to allegations of fraud and abuse or actual fraud and abuse.

ADDITIONAL READING

1. Barry R. Furrow et al., *Medicare and Medicaid Fraud and Abuse*, in *HEALTH LAW* 625 (2d ed. 2000).
2. David E. Matyas, *Fraud and Abuse*, in *FUNDAMENTALS OF HEALTH LAW* 117 (Bernadette M. Broccolo et al., ed., 3d ed. 2004).
3. Maxine Lewis and James B. Davis, *Medicare Audits, Fraud, and Abuse*, in *MEDICARE COMPLIANCE MANUAL* 2005 439 (2005).
4. David A. Hyman, *Health Care Fraud and Abuse: Market Change, Social Norms, and the Trust “Reposed in the Workmen,”* 30 *J. Leg. Stud.* 531 (June 2001).

D. SUMMARY

To combat Medicare fraud and abuse, Congress has enacted a number of statutes with civil and criminal penalties. Specific statutes supplement general statutes related to fraud in dealing with the federal government. Statutes prohibit health care providers from submitting false claims, referring patients in return for remuneration, and referring patients to a facility in which the physician has a financial interest. Congress and the OIG have developed exceptions and safe harbors to allow physicians to carry out many routine business practices.

HIPAA provided the OIG and the DOJ with additional funding to combat health care fraud and abuse. Enforcement actions increased in the mid to late 1990s. The perception of a need and the actual need for extensive fraud and abuse control may be partially related to the third party payment structure for minor services, the inability of Medicare to use prior approval to limit inappropriate payment, and the complexity of the process for determining the appropriate fee.

CHAPTER 9: REGULATION OF HEALTH INFORMATION: SECURITY AND PRIVACY¹

In 1996 Congress passed the Health Insurance Portability and Accountability Act (HIPAA).² One component of HIPAA, the Administrative Simplification Provisions, authorized the Department of Health and Human Services (HHS) to develop standards for health information transactions and data elements. It also provided penalties for wrongful disclosure of individually identifiable health information.

To carry out this mandate, HHS has promulgated three major sets of regulations, the Transactions Rule, the Privacy Rule, and the Security Rule.³ HHS issued the Transactions Rule in August 2000. Implementation was effective in October 2002. HHS issued the first final Privacy Rule in December, 2000. The Bush Administration reopened the rule for additional comments in early 2001. HHS issued the second final Privacy Rule in August 2002. The compliance date for most covered entities was April 2003. HHS issued the final Security Rule in February 2003. The compliance date for most covered entities was April 2005.

The Privacy Rule is the most costly of the three rules and has generated the most controversy.

A. ADMINISTRATIVE SIMPLIFICATION PROVISIONS OF HIPAA

A1. General Provisions

The administrative simplification provisions of HIPAA apply to three types of covered entities: (1) health plans; (2) health care clearinghouses; and (3) health care providers.⁴ HIPAA defines a health plan as an entity that “provides, or pays the cost of, medical care.”⁵ Health plans include entities that either issue insurance or provide medical services for beneficiaries. A health care clearinghouse is an entity that “processes or facilitates the processing of nonstandard data elements of health information into standard data elements.”⁶ Health care clearinghouses include businesses that perform information services and some businesses that perform billing services. HIPAA defines a health care provider as a “provider of medical or other health services.”⁷ Providers include physicians, other health care

¹ See Appendix A for related statutes; see Appendix B for related regulations.

² Pub. L. No. 104-191, 110 Stat. 1936 (1996).

³ 45 C.F.R. Parts 160-164.

⁴ 42 U.S.C. § 1320d.

⁵ 42 U.S.C. § 1320d(5).

⁶ 42 U.S.C. § 1320d(2).

⁷ 42 U.S.C. § 1320d (3).

professionals, hospitals, and other organizations that provide health care services or products to patients.

“Business associates” are individuals and businesses that use protected health information because of their business dealings with covered entities.⁸ There are two primary types of business associates: (1) those that provide business services, *e.g.* claims processing, quality assurance, billing, and benefit management services, and (2) those that provide professional services, *e.g.* legal, accounting, financial, and management services.

HIPAA defines “individually identifiable health information” as information that is created or received by a covered entity, can be used to identify an individual, and relates to either the health or condition of the individual or to the provision of or payment for the individual’s health care.⁹ Individually identifiable health information includes medical records and claims submitted to third party payers. In addition, because a name, address, or social security number is related to the payment for services, HIPAA considers these items to be “individually identifiable health information.”

⁸ 45 C.F.R. § 160.103.

⁹ 42 U.S.C. § 1320d(6).

¹⁰ 45 C.F.R. § 162.1101 et seq.

¹¹ *Id.*

¹² 42 C.F.R. § 162.1102.

¹³ 42 C.F.R. § 162.1102(b)(1).

A2. Transactions Rule

The purpose of the Transactions Rule is to improve the efficiency of electronic transactions by establishing uniform standards for all covered entities. The Transactions Rule requires uniform standards for electronic transactions involving: (1) health care claims, (2) eligibility for a health plan, (3) referral certification and authorization, (4) health care claim status, (5) enrollment and disenrollment in a health plan, (6) health care payment and remittance advice, (7) health plan premium payments, and (8) coordination of benefits.¹⁰

The Transactions Rule divides the eight topics listed above into subtopics.¹¹ For example, under the general topic, health care claims, there are subtopics, including retail pharmacy drug claims, dental claims, professional health care claims, and institutional health care claims.¹² For each of these items, HHS has chosen a set of published transactions standards for covered entities to follow. For example, for retail pharmacy drug claims, each covered entity must follow the standards set forth in “The National Council for Prescription Drug Programs (NCPDP) Telecommunication Standards Implementation Guide, Version 5, Release 1, September 1999 . . .”¹³

A3. Privacy Rule

The Standards for Privacy of Individually Identifiable Health Information are commonly referred to as the Privacy Rule. Its goal is to assure that covered entities and business associates protect individually identifiable health information from inappropriate disclosure and use. In general, HIPAA and the Privacy Rule establish a floor of regulation below which a state cannot fall. One can organize the Privacy Rule under four sections: (1) administrative requirements, (2) uses and disclosures, (3) patient access to information, and (4) agreements with business associates.

A3-1. Administrative Requirements

The Privacy Rule requires most covered entities, to meet the following requirements: (1) establish policies and procedures to assure protection of patient health information, (2) appoint a privacy official to implement and assure compliance, (3) conduct training for employees who may come in contact with protected health information, (4) implement sanctions for an employee who violates the policies or procedures, (5) take measures to mitigate the harm if a violation occurs, (6) develop a complaint process for a person who believes his/her privacy has been violated, and (7)

maintain documentation of all actions with respect to the Privacy Rule for at least six years.¹⁴

A3-2. Uses and Disclosures

Under the Privacy Rule, covered entities must disclose protected health information if the individual requests the information and if HHS requests the information to monitor compliance.¹⁵ In addition, the Privacy Rule does not alter the requirement that health care providers must disclose information when required by law.

Covered entities may disclose information in a number of other situations.¹⁶ Some disclosures require patient authorization, whereas others do not. For example, covered entities must obtain authorization to disclose psychotherapy notes.¹⁷ On the other hand, they may disclose information without authorization for treatment, payment, or health care operations.¹⁸ If the covered entity has a direct treatment relationship with the patient, it may obtain consent for treatment, payment, or health care operations, but the Privacy Rule does not require it to do so.¹⁹

A covered entity may disclose protected information without authorization in a number of other

¹⁴ 45 C.F.R. § 164.530.

¹⁵ 45 C.F.R. § 164.502(a)(2).

¹⁶ 45 C.F.R. § 164.502(a)(1).

¹⁷ 45 C.F.R. § 164.508(2).

¹⁸ 45 C.F.R. § 164.506.

¹⁹ 45 C.F.R. § 164.506(b).

situations if the disclosure meets certain guidelines.²⁰ For example, a covered entity may disclose protected health information for public health activities, health oversight activities, judicial and administrative proceedings, law enforcement purposes, tissue donation purposes, research purposes, avoidance of a serious threat to health or safety, and certain other government functions.²¹

When obtaining authorization, the covered entity must obtain written authorization containing: (1) a specific description of the information to be disclosed, (2) identification of those authorized to make the disclosure, (3) identification of those to whom the covered entity will disclose the information, (4) the purpose of the disclosure, (5) an expiration date beyond which the covered entity will not disclose the information, (6) the patient's signature and date or the signature and date of an authorized person signing on behalf of the patient, (7) a statement or notice that the patient may revoke the authorization, and (8) a statement that the covered entity may not condition treatment or eligibility on an authorization unless permitted.²²

In addition to the specific requirements listed

above, the Privacy Rule requires covered entities to make "reasonable efforts" to limit the use and disclosure of protected health information to the "minimum amount necessary" for the intended purpose.²³ This requirement, known as the "minimum necessary standard," applies to those instances in which the covered entity has authorization or permission to use or disclose the information. It does not apply to uses or disclosures for treatment, payment, or health care operations or to disclosures when the patient has requested the disclosure.

A3-3. Patient Rights and Access

Under the Privacy Rule, a patient has the following rights: (1) to receive from a covered entity a written notice explaining the entity's procedures with respect to the use and disclosure of protected health information, (2) to authorize or withhold authorization for uses and disclosures of protected health information, except for treatment, payment, or health care operations, (3) to inspect and copy all personal health information that the covered entity uses to make decisions about the patient's medical care, (4) to request that the covered entity amend the information if the patient believes the information is inaccurate, (5) to request that the covered entity restrict the

²⁰ 45 C.F.R. § 164.512.

²¹ *Id.*

²² 45 C.F.R. § 164.508(c).

²³ 45 C.F.R. § 164.502(b).

information to certain persons or uses, (6) to receive an accounting of all disclosures other than those for which the patient gives authorization and those used for treatment, payment, or health care operations, and (7) to complain to HHS or to the covered entity about the appropriate use of one's protected health information.²⁴

A3-4. Business Associates

The Privacy Rule sets out specific requirements for covered entities that release information to business²⁵ associates. It requires covered entities to specify in a contract the terms under which the business associate may use or disclose protected health information. The contract must require the business associate to follow the same rules on uses and disclosures that the covered entity follows. Also, it must require the business associate to notify the covered entity if a violation occurs. The rule does not require the covered entity to monitor the conduct of the business associate.

A3-5. Enforcement

The Office of Civil Rights in HHS is responsible for enforcing the Privacy Rule. HIPAA states that “the Secretary shall impose on any person who violates a provision . . . a penalty of not more than \$100 for each such violation,” and the “total

amount imposed” for similar violations in one “calendar year may not exceed \$25,000.”²⁶

HIPAA states that the penalty should not be imposed if the violator “did not know” that a violation was taking place or “the failure to comply was due to a reasonable cause . . . ; and the failure to comply is corrected . . .” during the 30 days after the person knows of the violation.²⁷ In addition, HIPAA imposes a fine of up to \$50,000 and imprisonment for not more than one year for a knowing violation of the act, up to \$100,000 and not more than five years if committed under false pretenses, and up to \$250,000 and not more than 10 years if for commercial gain.²⁸

A4. Security Rule

The purpose of the Security Rule is to assure the security of electronic protected health information.²⁹ While the Privacy Rule applies to paper as well as electronic information, the Security Rule applies to electronic information only. Also, while the Privacy Rule applies to the covered entity's responsibilities to the patient, the Security Rule applies to its responsibility to maintain the security of its information systems.

The rule divides security standards into: adminis-

²⁴ 45 C.F.R. § 164.506, 520, 522, 524, 526, 528, 530; Sharon L. Vickers et al., *HIPAA Primer* (2d ed. 2003).

²⁵ 45 C.F.R. § 164.504(e).

²⁶ 42 U.S.C. § 1320d-5(a)(1).

²⁷ 42 U.S.C. § 1320d-5(b)(3).

²⁸ 42 U.S.C. § 1320d-6.

²⁹ 45 C.F.R. § 164.306(a)(1).

trative, physical, and technical.³⁰ Administrative standards include those related to risk analysis, risk management, adverse incident response and reporting, backup plans, and sanctions for violations. Physical standards include those related to facility workstation security, disposal of health information, and media for storage of health information. Technical standards include items such as uses, identification, person authentication, and encryption.

In each category of standards, some are mandatory and some are “addressable.”³¹ A covered entity must evaluate each addressable standard with respect to the covered entity’s own circumstances. If the standard is reasonable and appropriate for the entity, it must implement the standard. If not appropriate, the entity must document the reasons for not implementing that standard. Allowing addressable standards provides some flexibility for covered entities.

B. EFFECTS OF REGULATIONS TO ENHANCE PRIVACY

A patient’s right to confidentiality of medical information is enshrined in the Hippocratic Oath as well as in ethical guidelines for physicians.³²

³⁰ 45 C.F.R. § 164.308, 310, 312.

³¹ 45 C.F.R. § 164.306(d).

³² See Hippocratic Oath: Classical Version; American Medical Association, E-5.05 *Confidentiality*, CODE OF MEDICAL ETHICS, at <www.ama-assn.org/ama/pub/category/8353.html>.

Maintaining the confidentiality of personal health information is essential for establishing an effective patient-physician relationship. The HIPAA disclosure requirements were enacted not because there were data suggesting significant privacy violations, but because of concern that growth in the use of electronic data posed special problems with respect to the privacy of health information.

Because the Privacy Rule was recently implemented, there are few data concerning the actual costs and benefits of these provisions. Because of the Privacy Rule, essentially all physicians and other providers reviewed their standards for maintaining privacy, and many undoubtedly improved their practices. However, the Privacy Rule has made health information more accessible to public use than it was prior to HIPAA. For example, while covered entities must obtain authorization for most disclosures, the Privacy Rule does not require authorization for disclosing information for health oversight activities and other public functions.

B1. Benefits and Costs of the Transaction Rule

In his study of health care regulations, Conover estimated the benefits and costs for health insur-

ance companies resulting from the “administrative simplification provisions” of HIPAA.³³ Although Conover did not define “administrative simplification provisions,” he was likely referring to the Transactions Rule. He estimated that the benefits outweighed the costs by an expected \$2.4 billion annually.

B2. Benefits and Costs of the Privacy Rule

The benefit of the Privacy Rule is the deterrent effect it has on violations of patient confidentiality. One can estimate the benefit by multiplying the number of privacy violations prevented by the rule by the value of each prevented violation. Costs of the Privacy Rule include HHS costs to monitor and enforce the rule, compliance costs of covered entities, and the cost of the loss of privacy for those whose privacy is compromised by the rules. Compliance costs will likely be passed on to patients in the form of higher prices.

Conover estimated the benefits and costs of the Privacy Rule for health insurance companies, health care facilities, and professionals.³⁴ He estimated that the annual expected benefits of the Privacy Rule, by decreasing privacy violations,

outweigh the costs by \$154 million per year for health care facilities, \$236 million for professional offices, and \$1.2 billion for health insurers.

On the other hand, Cochran, prepared comments for HHS after the initial notice of proposed rulemaking and again when HHS asked for additional public comment.³⁵ He considered the benefits of the Privacy Rule to be limited. He noted that some of the benefits suggested by HHS were actually wealth transfers in which the gains to some were costs to others.³⁶ Because the rule increased access to protected health information for some government agencies, he speculated that there may actually be a decrease in patient privacy.³⁷

Cochran estimated that the present value of start up and ongoing compliance costs for covered entities would be in the range of \$25 billion to \$30 billion.³⁸ He believed a more effective way to ensure a balance between the use of health information and the maintenance of privacy would be to clearly delineate property rights with respect to personal health information. Well-defined property rights would allow patients to contract with

³³ Christopher J. Conover, *Health Care Regulation: A \$169 Billion Hidden Tax*, Policy Analysis No. 527, Cato Institute (October 4, 2004).

³⁴ *Id.*

³⁵ See Jay Cochran, *The Department of Health and Human Services, Standards for Privacy of Individually Identifiable Health Information*, Regulatory Studies Program, Mercatus Center (February 17, 2000); Jay Cochran, *Standards for Privacy of Individually Identifiable Health Information*, Regulatory Studies Program, Mercatus Center, (March 31, 2001)).

³⁶ See Jay Cochran 2001, *supra* note 35.

³⁷ See Jay Cochran 2000, *supra* note 35.

³⁸ See Jay Cochran 2001, *supra* note 35.

physicians and other providers for the degree of privacy desired.³⁹

C. SUMMARY

Based on authorization provided by HIPAA, HHS has promulgated three major regulations related to health information, the Transactions Rule, the Privacy Rule, and the Security Rule. These rules apply to health plans, health care clearinghouses, and health care providers.

The Transactions Rule lists published standards adopted by HHS to govern electronic health care transactions. The Privacy Rule sets out requirements governing the use and disclosure of

protected health information for covered entities that create or use individually identifiable health information. It provides patients with the right of access to their own health information, and it requires covered entities to specify within a contract the rules business associates must follow with respect to protected health information. The Security Rule sets out standards for covered entities to use for securing their information systems that maintain protected health information.

There are differences of opinion whether the Privacy Rule will provide significant benefits for patients. Observers agree that the Privacy Rule will result in large costs for covered entities.

ADDITIONAL READING

1. Susan O. Scheutzow, *Patient Care*, in *FUNDAMENTALS OF HEALTH LAW* 37 (Bernadette M. Broccolo et al., ed., 3d ed., 2004).
2. Jay Cochran, *The Department of Health and Human Services' Standards for Privacy of Individually Identifiable Health Information*, Mercatus Center (Feb. 17, 2000).
3. Jay Cochran, *Standards for Privacy of Individually Identifiable Health Information*, Mercatus Center (Mar. 31, 2001).
4. Fred H. Cate, *Principles for Protecting Privacy*, 22 *Cato Journal* 33 (2002).
5. Sharon L. Vickers et al., *HIPAA PRIMER* (2d ed. 2003).

³⁹ See Jay Cochran 2000, *supra* note 35.

CHAPTER 10: ALTERNATIVES TO FEDERAL REGULATION OF HEALTH CARE

During the twentieth century, U.S. health care underwent dramatic changes. Rapid progress in science, nutrition, public health, and health care resulted in continuing improvement in the nation's health and life expectancy. Despite these outstanding achievements, problems continue to plague U.S. health care. Many Americans have inadequate insurance and substandard care, prices for both health insurance and health care are expensive, and many patients have limited choices. While well-intentioned, administrative regulations are costly, tend to increase prices, and may limit the ability of physicians and other professionals to provide care. Altering the present regulatory structure may allow more effective health care and also may improve Americans' health.

This chapter discusses six types of alternatives to our present regulatory structure: (1) alternatives to disparate tax treatment between employer-provided health insurance and other health care expenses, (2) alternatives to Medicare's direct payment system, (3) alternatives to federal insurance mandates, (4) alternatives to the present new drug approval process, (5) alternatives to federal regulation of hospitals and physicians, and (6) alternatives to federal regulation of health information.

A. ALTERNATIVES TO DISPARATE TAX TREATMENT BETWEEN EMPLOYER-PROVIDED HEALTH INSURANCE AND OTHER HEALTH CARE EXPENSES

The tax-preference for employer-financed health insurance has increased access to health insurance for most working Americans. However, because individually purchased health insurance and out-of-pocket expenses are not tax-advantaged, there is decreased access for those without employer-sponsored insurance. Also, the tax-preference for employer-provided insurance has increased prices for health care. One important step in reforming U.S. health care would be to eliminate the disparate tax treatment between employer-financed group health insurance and both individually purchased health insurance and out-of-pocket expenses.

Congress could eliminate disparate tax treatment in several ways. Most proposals for major income tax reform, e.g. a national sales tax that abolished the income tax or a flat income tax that abolished individual exclusions and deductions, would eliminate disparate tax treatment.¹ Congress also could eliminate disparate tax treatment while retaining the present tax code.

¹ See Michael F. Cannon and Michael D. Tanner, *Tax Policy and Health Care*, in *HEALTHY COMPETITION* 61 (2005).

A1. Eliminating the Income Exclusion of Employer-Purchased Health Insurance

Some have proposed eliminating the exclusion of employer-provided insurance from income.² Eliminating this exclusion would increase the likelihood that individuals would choose individual health insurance, and this would increase individual control over health care expenditures. It also would decrease the demand for health care and likely lower health care prices. Because of decreased prices, this proposal may encourage some people to purchase health insurance who are presently uninsured.

On the other hand, because there would no longer be a tax advantage for employer-provided insurance, it is likely that many employers and employees would choose to discontinue insurance coverage. Since this proposal would have at least a temporary negative effect on Americans who obtain insurance through their employer, it is unlikely Congress would adopt it.

A2. Enhanced Health Savings Accounts

Another method for eliminating the disparate tax treatment between employer-provided insurance and other health care expenses would be to expand health savings accounts (HSAs). Enhanced HSAs could serve to equalize the tax treatment of health care expenses, should be politically feasible, and may provide a smooth transition to individually directed and patient-centered health care.

There are a number of enhancements to HSAs that would increase their benefits. These include: (1) increasing the annual contribution limit for HSAs, (2) eliminating the annual maximum for out-of-pocket expenses, (3) allowing one to use HSA funds to purchase one's health insurance policy, (4) allowing one to use HSA funds to purchase health insurance that is not high deductible, and (5) allowing individuals and organizations to deduct from their own income funds contributed to another person's HSA.

Increasing the annual contribution limit would allow an HSA owner to pay for more health care expenses on a before-tax basis, obtain additional tax savings, and accumulate more before-tax funds to pay for health care in future years. Eliminating the maximum for out-of-pocket expenses would allow individuals to purchase less expensive insurance policies more adaptable to their individual needs. Also, eliminating the annual out-of-pocket maximum would provide an incentive for insurance companies to develop more varied types of insurance.

Allowing an HSA owner to purchase a health insurance policy using HSA dollars would allow the owner to pay more health care expenses on a before-tax basis, thus approximating tax parity with employer-purchased insurance. Allowing individuals to combine an HSA account with health insurance that is not high deductible

² See Robert B. Helms, *Tax Reform and Health Insurance*, Health Policy Outlook, American Enterprise Institute for Public Policy Research (Jan.-Feb., 2005).

would promote competition within the health insurance industry to design more varied insurance products and allow individuals to choose the type of health insurance that best meets their needs. Some persons would choose managed care plans, including health maintenance organizations (HMOs). Others would choose high deductible health plans (HDHPs).

One additional HSA enhancement would be especially beneficial for low income Americans. At this time, contributions to an HSA are deductible only for the owner of the HSA and for the HSA owner's employer. Allowing taxpayers other than the HSA owner to deduct from their income a contribution to another person's HSA would encourage family, friends, philanthropists, and charitable organizations to contribute to a low income person's HSA. It is possible that HSAs funded by individuals, employers, and donors could increase the number of low income Americans who receive health care and gradually decrease the need for federal and state contributions to low income citizens' health care.

B. ALTERNATIVES TO MEDICARE'S DIRECT PAYMENT SYSTEM

Medicare has made health insurance and health care available for many Americans. However, Medicare's payment system has had a number of adverse effects. These include limited availability

of some services, physician incentives that may negatively affect patient care, and extensive regulation of physicians and hospitals. Also, Medicare is actuarially unsound. If not reformed in some way, it will have a negative effect on America's economic future.

Congress could reform Medicare in various ways. Proposals have included increased taxes, lower payments to physicians and hospitals, more efficient use of resources, and better enforcement against fraud and abuse. Congress has tried varying combinations of these measures since Medicare's inception. The prospective payment system did promote hospital efficiency. However, other reforms have had limited success.

Recently, many observers have recommended changing Medicare's defined benefit structure to a defined contribution system. This would allow beneficiaries to choose private health insurance among competing options. The two major proposals incorporating defined contributions are the Federal Employee Health Benefit Plan (FEHBP) and enhanced HSAs.

B1. Federal Employee Health Benefit Plan

Some reformers have proposed that Medicare beneficiaries be allowed to participate in the FEHBP.³ This plan offers each participant a choice among competing health plans. The federal government pays up to 75 percent of the

³ See R E Moffit, *A Road-Map to Medicare Reform: Building on the Experience of the FEHBP*, Testimony before the U.S. Senate Special Committee on Aging (May 6, 2003).

plan premium, and the participant pays the remainder. The government's cost each year is a defined contribution based on the weighted average premium of the participating health plans.

The FEHBP offers many advantages over the present Medicare program. Advantages include more beneficiary options, a superior benefit package, and a more flexible regulatory environment for providers. Because CMS would make a defined contribution each year instead of paying directly for services, the government's financial risk would be no more than the defined contribution each year. The FEHBP model offers the added benefit of decreasing the federal government's administrative costs. For those seniors choosing a private plan, CMS would no longer need to determine coverage, pay claims, or audit providers. Physician and hospital compliance costs would decrease significantly.

On the other hand, the FEHBP limits beneficiaries to selected plans, requires plans to offer a basic set of benefits, and requires plans to charge each beneficiary the same premium as other beneficiaries regardless of health status.⁴ As a result, FEHBP limits plan competition and beneficiary choices, features that if not limited could lead to lower prices.

B2. Enhanced Health Savings Accounts

As noted above, enhanced HSAs offer a number

of advantages for working Americans. Similarly, enhanced HSAs would offer seniors many advantages over Medicare as it is now structured. Congress could structure seniors' HSAs so that CMS makes an annual contribution to a beneficiary's HSA, which the beneficiary could supplement with an additional contribution. Congress also could increase the maximum contribution limit, allow HSA owners to purchase health insurance with HSA funds, and allow individuals or charitable organizations to make tax free contributions to low income seniors' accounts. If Congress allowed seniors to use HSA funds to purchase the type of health insurance they desired, there would be competition among insurance companies to develop better insurance products for seniors.

B3. Personal Accounts for Retirement Health Care

The Medicare program, as it is now structured, cannot be sustained without harm to tomorrow's workers and taxpayers. Recently, reformers have proposed allowing today's workers to prefund their retirement health care using personal accounts, similar to the proposed personal accounts for Social Security.⁵ Under this proposal, working individuals could place an amount equal to the Medicare payroll tax into a tax free savings and investment account they would own, accumulating funds during working years to provide for the health insurance and health care they will require during retirement.

⁴ See Michael F. Cannon and Michael D. Tanner, *How Not to Reform Health Care*, in *HEALTHY COMPETITION* 33 (2005).

⁵ See Michael F. Cannon and Michael D. Tanner, *Government Health Programs*, in *Healthy Competition* 75 (2005).

C. ALTERNATIVES TO FEDERAL INSURANCE MANDATES

Federal measures to increase insurance coverage have had limited benefits and significant costs. Insurance mandates rarely achieve their intended purpose. Despite attempts to improve access and portability through COBRA and HIPAA, job lock remains a problem, and the uninsured population continues to increase.⁶

The primary cause of inadequate insurance portability is disparate tax treatment between employer-provided insurance and other health care expenses. Eliminating this disparity would increase portability and may increase the percentage of the population with health insurance.

Eliminating federal insurance mandates also may increase the percentage of Americans with health insurance. Insurance mandates are costly. Eliminating mandates should reduce health insurance prices, making insurance available to more individuals. Removing mandates also may stimulate the development of more flexible insurance products to meet the widely varying needs of individual Americans.

As noted in Chapter 5, many mandated insurance features were available to purchasers prior to

their becoming mandates. Thus, eliminating mandates will not prevent individuals from choosing these features. Instead, it will offer them additional options. Subsidizing at risk individuals to purchase health insurance or health care may be more effective in providing the insurance or care they need than regulating insurance markets, rendering these markets less efficient for others.

In addition to removing specific regulatory burdens, Congress could facilitate state competition to provide a more beneficial regulatory structure for both patients and insurers. One such proposal would allow an individual in one state to purchase health insurance from a company whose insurance policies are governed by the regulatory structure of another state.⁷ States that provide a structure with limited regulation of health insurance may attract both insurers and purchasers and may facilitate more desirable insurance than is presently available.

D. ALTERNATIVES TO THE PRESENT NEW DRUG APPROVAL PROCESS

Following passage of the Kefauver-Harris Drug Amendments of 1962, the number of drugs entering clinical studies for new drug approval decreased, and the cost of developing a new drug increased. Recently, because of actions by both

⁶ Bureau of the Census, Table HI05: Health Insurance Coverage Status and Type of Coverage by State and Age for All People: 2003 , Current Population Survey, 2004 Annual Social and Economic Supplement ,at http://pubdb3.census.gov/macro /032004/health/h05_000.htm.

⁷ See Tom Miller, *A Regulatory Bypass Operation* , 22 Cato Journal 85 (2002); Michael F. Cannon and Michael D. Tanner, *Choice and Competition, or Controls?* in HEALTHY COMPETITION 111 (2005).

Congress and the FDA, clinical development times and approval times have decreased. Reformers have proposed additional measures to make new drugs more available at lower cost. This chapter discusses two relatively recent proposals.

D1. Drug Certifying Bodies

Under the first proposal, Congress would maintain the statutory requirement that sponsors demonstrate safety and effectiveness prior to market release.⁸ However, private drug certifying bodies (DCBs) would provide oversight of drug development and testing. Under this proposal, new drug sponsors would contract with DCBs to oversee drug development.⁹ DCBs would compete for new drug sponsors on the basis of quality and price. By decreasing the FDA's involvement in each aspect of new drug development, the FDA could concentrate on certifying DCBs and on providing final approval for new drugs. Potential advantages include competition among DCBs for sponsors, more rapid drug development, and lower costs.

There are a number of reasons to think this proposal may be successful. There are clinical research organizations presently carrying out

many of the functions of the proposed DCBs. Thus, the expertise for establishing private DCBs is readily available. In the 1990s, the FDA authorized a pilot program in which non-FDA third party reviewers successfully reviewed applications for new medical devices.¹⁰ Finally, the European Union uses the equivalent of DCBs for approval of high-risk devices, successfully approving new devices without sacrificing safety.¹¹

D2. Dual Track System

Another proposal involves a “dual track system” for the approval of new drugs.¹² Under this proposal, the FDA would maintain the present regulatory process as one track. For the second, a pharmaceutical company could offer informed patients the option to choose an investigational drug, provided studies had already demonstrated adequate safety. A pharmaceutical company would post all experimental data on the Internet so that patients and their physicians could make an informed choice. If the sponsor provided all known data and fully explained the risks, the patient would assume the risk for potential harm. In essence, this proposal makes the present “compassionate use” exception to NDA approval into a more formal and widely used system.

⁸ See Henry I. Miller, *A Proposal for Regulatory Reform ,To America's Health: A Proposal to Reform the Food and Drug Administration* 83 (2000).

⁹ *Id.*

¹⁰ See Henry I. Miller, *A Spectrum of Possibilities, To America's Health: A Proposal to Reform the Food and Drug Administration* 71, 79 (2000).

¹¹ *Id.* at 74.

¹² See Bartley J. Madden, *A Clinical Trial for the FDA's Clinical Trial Process, A Working Paper in Regulatory Studies , Mercatus Center* (June 2005), at <<http://www.mercatus.org/pdf /materials/1239.pdf>>.

Each of these proposals would maintain the requirement for safety. The first would open a portion of the approval process to competition and the second would allow informed patients earlier access to new drugs.

E. ALTERNATIVES TO FEDERAL REGULATION OF HOSPITALS AND PHYSICIANS

Based on the available data, federal regulations involving hospitals and physicians have limited benefits and significant costs. Eliminating these regulations may allow state and private regulatory bodies to provide more effective regulation at a significant decrease in cost.

Hospital accreditation, physician credentialing by hospitals, and physician specialty certification all existed prior to federal regulation. Even today, private entities are more rigorous in assessing, monitoring, and disciplining poor quality than federal or state regulatory bodies. In addition, an increasing number of organizations provide quality information to the public. Decreasing federal regulation may allow these private regulatory bodies to become even more effective.

Regulations and enforcement actions related to Medicare and Medicaid billing have been costly and at times have had adverse effects on very high quality physicians and hospitals. Most billing and financial regulation of physicians and hospitals would be unnecessary if CMS funded beneficiaries' health care using a defined

contribution approach. Defined contributions would allow beneficiaries to choose among competing private insurers that use market mechanisms to control fraud and abuse. Criminal fraud statutes that are applicable to all private entities could be used to prosecute actual fraud.

F. ALTERNATIVES TO FEDERAL REGULATION OF HEALTH INFORMATION

There are limited data concerning the benefits and costs associated with the newly implemented Privacy Rule. Although there is disagreement concerning potential benefits, all agree the costs are likely to be large. One reason Congress authorized privacy regulations was to prevent an employer from making employment-related decisions based on an employee's health information. If Congress eliminated the disparate tax treatment between employer-provided insurance and other health care expenses, more people would choose individual insurance, there would be less concern about an employer's misuse of employee health information, and there would be less need for the Privacy Rule.

In authorizing privacy regulations, Congress was also concerned about the increasing use and transmission of electronic health information. Third party payment for minor services results in more exchange of confidential medical information between professionals and third party payers than when patients pay directly for minor services. The institution of enhanced HSAs may

allow individuals to choose less third party payment for minor services, and this may result in more patient privacy for those who choose this method of payment.

Finally, eliminating or narrowing the scope of the Privacy Rule may lead to a better delineation of property rights with respect to health information. Better defined property rights would allow a patient and provider to contract for the degree of privacy the patient desired. Existing property, contract, and tort law could be used to maintain the privacy of patients' health information.

G. SUMMARY AND CONCLUSION

During the twentieth century, federal regulation replaced state and market regulation as the primary means for regulating both health care financing and health care providers. In well meaning attempts to correct problems, some of which may have resulted from prior federal inter-

vention, the federal government developed comprehensive regulations for physicians, hospitals, insurers, and pharmaceutical companies. Today, compliance with federal regulations constitute a significant portion of physician, hospital, insurer, and manufacturer activity.

There are a number of alternatives to our present federal regulatory structure that may improve health care access, increase quality, and lower prices. These include: (1) eliminating the disparate tax treatment between employer-provided health insurance and other health care expenses, (2) replacing the Medicare direct payment system with defined contributions, (3) eliminating federal health insurance mandates, (4) allowing competition in a portion of the new drug approval process, (5) returning regulation of hospitals and physicians to states and private regulatory bodies, and (6) decreasing federal regulation of health information by eliminating or narrowing the scope of the Privacy Rule.

APPENDIX A

HEALTH CARE STATUTES IN THE UNITED STATES CODE

| CHAPTER | STATUTE NAME AND TOPIC | TITLE, CHAPTER, & CITATION |
|------------------|--|-----------------------------|
| <i>Chapter 2</i> | <i>Internal Revenue Code (IRC)</i> | <i>Title 26</i> |
| | Contributions by Employer to Accident and Health Plans | 26 U.S.C. 106 |
| | Medical, Dental, etc., Expenses | 26 U.S.C. 213 |
| | Archer MSAs | 26 U.S.C. 220 |
| | Health Savings Accounts | 26 U.S.C. 223 |
| <i>Chapter 3</i> | <i>Social Security Act (SSA)</i> | <i>Title 42, Chapter 7</i> |
| | Health Insurance for the Aged and Disabled | 42 U.S.C. 1395 – 1395hhh |
| | Grants to States for Medical Assistance Programs | 42 U.S.C. 1396 – 1396v |
| <i>Chapter 4</i> | <i>Employee Retirement Income Security Program (ERISA)</i> | <i>Title 29, Chapter 18</i> |
| | All Provisions | 29 U.S.C. 1001 – 1461 |
| | <i>Public Health Service Act (PHSA)</i> | <i>Title 42, Chapter 6A</i> |
| | Health Maintenance Organizations | 42 U.S.C. 300e – 300e-17 |
| <i>Chapter 5</i> | <i>Employment Retirement Income Security Program (ERISA)</i> | <i>Title 29, Chapter 18</i> |
| | Continuation Coverage and Additional Standards for Group Health Plans | 29 U.S.C. 1161 – 1169 |
| | Group Health Plan Requirements | 29 U.S.C. 1181 – 1191c |
| | <i>Public Health Service Act (PHSA)</i> | <i>Title 42, Chapter 6A</i> |
| | Requirements for Certain Group Health Plans for Certain State and Local Employees. | 42 U.S.C. 300bb-1 – 300bb-8 |
| | Requirements Relating to Health Insurance Coverage | 42 U.S.C. 300gg – 300gg-92 |
| <i>Chapter 6</i> | <i>Federal Food, Drug, and Cosmetic Act (FDCA)</i> | <i>Title 21, Chapter 9</i> |
| | Definitions | 21 U.S.C. 321 |
| | Prohibited Acts and Penalties | 21 U.S.C. 331 – 337 |
| | Drugs and Devices | 21 U.S.C. 351 – 360bbb-3 |
| | General Administrative Provisions | 21 U.S.C. 371-379a |

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| Chapter 7 | <i>Public Health Service Act (PHSA)</i> | <i>Title 42, Chapter 6A</i> |
| | Clinical Laboratories | 42 U.S.C. 263a – 263a-7 |
| | Grants and Loans for Construction...Hospital...Facilities | 42 U.S.C. 291a – 291j |
| | <i>Social Security Act (SSA)</i> | <i>Title 42, Chapter 7</i> |
| | General Provisions, Peer Review, and Administrative Simplification | 42 U.S.C. 1301-1320d |
| | Health Insurance for the Aged and Disabled | 42 U.S.C. 1395 – 1395hhh |
| | Grants to States for Medical Assistance Programs | 42 U.S.C. 1396 – 1396v |
| | <i>Social Security Act (SSA)</i> | <i>Title 42, Chapter 7</i> |
| | Conditions of and Limitations on Payment for Services | 42 U.S.C. 1395f |
| | Requirements...Skilled Nursing Facilities | 42 U.S.C. 1395i-3 |
| | Examination and Treatment...Emergency Medical... Women in Labor | 42 U.S.C. 1395dd |
| | Hospital Providers of Extended Care Services | 42 U.S.C. 1395tt |
| | Conditions of Participation for Home Health Agencies;... | 42 U.S.C. 1395bbb |
| | <i>Encouraging Good Faith Professional Review Activities</i> | <i>Title 42, Chapter 117</i> |
| | All Provisions | 42 U.S.C. 11101 – 11152 |
| Chapter 8 | <i>Crimes and Criminal Procedure</i> | <i>Title 18</i> |
| | False, Fictitious, or Fraudulent Claims | 18 U.S.C. 287 |
| | Conspiracy to...Defraud The United States | 18 U.S.C. 371 |
| | Theft or Embezzlement...Health Care | 18 U.S.C. 669 |
| | False Statements Relating to Health Care Matters | 18 U.S.C. 1035 |
| | Frauds and Swindles | 18 U.S.C. 1341 |
| | Fraud By Wire, Radio, or Television | 18 U.S.C. 1343 |
| | Health Care Fraud | 18 U.S.C. 1347 |
| | Obstruction of Criminal Investigations of Health Care Offenses | 18 U.S.C. 1518 |
| | <i>Claims</i> | <i>Title 31, Chapter 37</i> |
| | False Claims | 31 U.S.C. 3729 |
| | Civil Actions for False Claims | 31 U.S.C. 3730 |
| | False Claims Procedure | 31 U.S.C. 3731 |

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| | False Claims Jurisdiction | 31 U.S.C. 3732 |
| | Civil Investigative Claims | 31 U.S.C. 3733 |
| | <i>Social Security Act (SSA)</i> | <i>Title 42, Chapter 7</i> |
| | Civil Monetary Penalties | 42 U.S.C. 1320a-7a |
| | Criminal Penalties...Federal Health Care Programs | 42 U.S.C. 1320a-7b |
| | Health Care Fraud and Abuse Data Collection Program | 42 U.S.C. 1320a-7e |
| | Limitation on Certain Physician Referrals | 42 U.S.C. 1395nn |
| <i>Chapter 9</i> | <i>Social Security Act (SSA)</i> | <i>Title 42, Chapter 7</i> |
| | Administrative Simplification | 42 U.S.C. 1320d–1320d-8 |

APPENDIX B

HEALTH CARE REGULATIONS IN THE U.S. CODE OF FEDERAL REGULATIONS

| CHAPTER | AGENCY NAME AND TOPIC | TITLE, CHAPTER, & CITATION |
|------------------|--|---|
| Chapter 2 | <i>Internal Revenue Service (IRS)</i> | <i>Title 26, Chapter 1</i> |
| | Contributions by Employer to Accident and Health Plans | 26 C.F.R. 1.106-1 |
| | Medical, Dental, Etc., Expenses | 26 C.F.R. 1.213-1 |
| Chapter 3 | <i>Centers for Medicare and Medicaid Services (CMS)</i> | <i>Title 42, Chapter IV</i> |
| | General Provisions | 42 C.F.R. 400 – 403 |
| | Medicare Program | 42 C.F.R. 405 – 426 |
| | Medical Assistance Programs | 42 C.F.R. 430 – 456 |
| | State Children’s Health Insurance Programs | 42 C.F.R. 457 |
| | Programs of All-Inclusive Care for the Elderly | 42 C.F.R. 460 |
| | Quality Improvement Organizations | 42 C.F.R. 475 – 480 |
| | Standards and Certification | 42 C.F.R. 482 – 498 |
| Chapter 4 | <i>Employee Benefits Security Administration (EBSA)</i> | <i>Title 29, Subtitle B, Chapter XXV</i> |
| | General Provisions | 29 C.F.R. 2509 – 2590 |
| | <i>Centers for Medicare and Medicaid Services (CMS)</i> | <i>Title 42, Chapter IV</i> |
| | Health Maintenance Organizations | 42 C.F.R. 417 |
| Chapter 5 | <i>Employee Benefits Security Administration (EBSA)</i> | <i>Title 29, Subtitle B, Chapter XXV</i> |
| | Rules and Regulations for Group Health Plans | 29 C.F.R. 2590 |
| | <i>Department of Health and Human Services (HHS)</i> | <i>Title 45, Subtitle A</i> |
| | Requirements Relating to Health Insurance Coverage | 45 C.F.R. 144 |
| | Requirements for the Group Health Insurance Market | 45 C.F.R. 146 |
| | Requirements for the Individual Health Insurance Market | 45 C.F.R. 148 |
| | CMS Enforcement in Group and Individual Insurance Markets | 45 C.F.R. 150 |

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| Chapter 6 | <i>Food and Drug Administration (FDA)</i> | <i>Title 21, Chapter 1</i> |
| | General | 21 C.F.R. 1 – 99 |
| | Drugs: General | 21 C.F.R. 200 – 299 |
| | Drugs for Human Use | 21 C.F.R. 300 – 448 |
| | Biologics | 21 C.F.R. 600 – 680 |
| | Medical Devices | 21 C.F.R. 800 – 898 |
| Chapter 7 | <i>Centers for Medicare and Medicaid Services (CMS)</i> | <i>Title 42, Chapter IV</i> |
| | Quality Improvement Organizations | 42 C.F.R. 475 |
| | Utilization and Quality Control Review | 42 C.F.R. 476 |
| | Reconsideration and Appeals | 42 C.F.R. 478 |
| | Acquisition, Protection, and Disclosure of Peer Review Information | 42 C.F.R. 480 |
| | Conditions of Participation for Hospitals | 42 C.F.R. 482 |
| | Requirements for States and Long Term Care Facilities | 42 C.F.R. 483 |
| | Home Health Services | 42 C.F.R. 484 |
| | Conditions of Participation: Specialized Providers | 42 C.F.R. 485 |
| | Conditions for Coverage of Specialized Services Furnished by Suppliers | 42 C.F.R. 486 |
| | Survey, Certification, and Enforcement Procedures | 42 C.F.R. 488 |
| | Provider Agreements and Supplier Approval | 42 C.F.R. 489 |
| | Certification of Certain Health Facilities | 42 C.F.R. 491 |
| | Laboratory Requirements | 42 C.F.R. 493 |
| | <i>Department of Health and Human Services (HHS)</i> | <i>Title 45, Subtitle A</i> |
| | National Practitioner Data Bank... | 45 C.F.R. 60 |
| | Healthcare Integrity and Protection Data Bank... | 45 C.F.R. 61 |
| Chapter 8 | <i>Centers for Medicare and Medicaid Services (CMS)</i> | <i>Title 42, Chapter V</i> |
| | Civil Money Penalties, Assessments, and Exclusions | 42 C.F.R. 402 |
| | Services...Supervising Physicians in Teaching Settings... | 42 C.F.R. 415 |
| | <i>Office of Inspector General (OIG) – Health Care</i> | <i>Title 42, Chapter V</i> |

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| | General Provisions | 42 C.F.R. 1000 |
| | Authorities | 42 C.F.R. 1001 – 1008 |
| Chapter 9 | <i>Department of Health and Human Services (HHS)</i> | <i>Title 45, Subtitle A</i> |
| | General Administrative Requirements | 45 C.F.R. 160 |
| | Administrative Requirements | 45 C.F.R. 162 |
| | Security and Privacy | 45 C.F.R. 164 |

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MERCATUS CENTER
GEORGE MASON UNIVERSITY

3301 North Fairfax Drive
Arlington, Virginia 22201
Tel: 703-993-4930
Fax: 703-993-4935