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NOTES AND COMMENTS

BRIEF INSIGHT

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From the Editor in Chief

The *Journal of Health & Life Sciences Law* celebrates AHLA's 50th Anniversary with both a new look and a special issue. This issue features content planned, written, and reviewed by the Association's Fellows, respected leaders in the health law community recognized for their career achievements and contributions to the Association. We thank the Fellows who shared their perspectives on the past 50 years of health law, setting the stage for changes ahead.

With this edition, we say goodbye to some of this publication's key volunteers. This issue of the AHLA *Journal* will be the last one published under the direction of Editor in Chief Cindy Wisner, whose letter you are accustomed to reading on this page. The Association owes Cindy a huge debt of gratitude. She has served as Editor in Chief for six years, shaping every issue with her leadership, ideas, and detailed recommendations on untold submissions. During her tenure as Editor, she led efforts to educate AHLA members and the public about the *Journal*'s value, initiating new channels of communication to promote the quality analysis in these pages. She also ensured that the *Journal* serves the diverse needs of the AHLA membership—longtime members and young professionals included. You will see the results of her dedication to excellence in health law discourse for many issues to come.

We would also like to thank outgoing AHLA *Journal* Editorial Board members. Tom Mayo's experience, standard of scholarship, and eye for emerging issues have benefitted many editions of the *Journal*, including this one. Holley Lutz contributed important topics and authors in life sciences law, enhancing the scope of this publication's coverage. Thank you.

Finally, we thank and welcome Susan Scheutzow, a longstanding member of the *Journal* Editorial Board and its next Editor in Chief. An AHLA Fellow herself, Susan's broad experience and keen perspective will be assets to this publication, which we hope will continue to be an asset to you in the next 50 years of health law.

Sincerely,

Charlene L. McGinty

Charlene L. McGinty
President, American Health Lawyers Association

Advancing Health Care Quality? From Medicare's Passage to the 2016 Election

Douglas A. Hastings

What is the issue? Health care quality has improved over the past 50 years as a result of collaboration between government and private industry, political compromise, and advances in science. Some degree of uncertainty is always inevitable when administrations change, but there is a real question now as to whether the bipartisan commitment to achieving health care quality improvement will hold.

What is at stake? Political events may impact the slow but steady progress and evolution of health care quality measures and, ultimately, the overall health of America's population. What that impact may be will depend on whether our "learning health care system" will continue, both in the short term and longer run.

What do you need to know? This country's 50-year journey from enactment of the Medicare Law to the election of President Trump illustrates the significant advances made thus far. The similarity of arguments and tensions experienced then and now in our pursuit of better and more efficient health care for all foreshadow how the future of health care quality may be affected.

Douglas A. Hastings, *Advancing Health Care Quality? From Medicare's Passage to the 2016 Election,* J. Health & Life Sci. L., June 2017 at 1.

Hastings: Health Care Quality

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Introduction

The 50-year journey of health care quality in America from the passage of the Medicare Law to the election of Donald Trump is now in the history books. For the most part, that journey has been a steadily positive one based on a willingness of the health care system's component parts to learn from experience and from each other through innovation, testing, and the acceptance of evidence. The commitment to quality has been steady, bipartisan, and collaborative between the public and private sectors. It is this author's hope that the United States will continue to vigorously pursue quality innovations; science and evidence will continue to advance and prevail in health care policy, business, and law; and we will see measurable improvements in the overall health of the U.S. population as the health care and social service sectors better coordinate their efforts. It will take the combined commitment of payers, providers, regulators, employers, and consumers, but there really is no obstacle to continued progress other than intentional obstruction for private gain or a collective failure of will.

In 1965, an activist Democratic-led Congress with a supportive President passed the Medicare Law, representing a watershed in the evolution of the federal role in health care.[1] Fast-forward 51 years to 2016: America has elected a President and re-elected a Republican-led Congress bent on undoing the 2010 Affordable Care Act (ACA)[2] and potentially making dramatic changes to the Medicare program itself. Notions related to the capabilities of modern medicine, the federal role in health care, and the definition of health care quality have evolved on the roller coaster ride of administrations and congresses since the assassination of John F. Kennedy galvanized the Johnson presidency and the 98th Congress to pass Medicare and other seminal social legislation.

Fifty years ago, medicine was on the cusp of evolving permanently from relatively ineffective emergency measures to a science-based system that could

1 Social Security Amendments of 1965, Pub. L. No. 89-97, 79 Stat. 286 (1965) (codified as amended at 42 U.S.C. § 426a).
2 Patient Protection & Affordable Care Act of 2010, Pub. L. No. 111-148, 124 Stat. 119 (2010).

extend life expectancy. Health care quality in 1965 was primarily focused on refining interventional techniques to address acute and dangerous health conditions. Today, at least as of this writing in early 2017, quality remains best captured by the multi-factor definition in the Institute of Medicine's *Crossing the Quality Chasm* (The Chasm Report)—care that is safe, effective, patient-centered, timely, efficient, and equitable[3]—evidencing a more fully-developed sense of health care quality as life enhancing as well as life extending. Health care quality today, then, is actually more fully focused on overall patient "health" than it is solely on one's immediate "medical care."[4] One can argue that our current posture on quality is a synthesis of 19th century notions of public health and 20th century developments in science and technology into a 21st century focus on the triple aim of better care, better health, and lower costs. This historical synthesis evidences what has been labeled a "learning health care system."[5]As we review the journey of health care quality over the last 50 years, an underlying question is whether that learning will continue, both in the short term and longer run.

This Comment will discuss the early concepts of quality improvement in health care and the evolution of quality measures and standards throughout the decades, starting in the 1960s during the activist era of the Kennedy and Johnson administrations. The Comment will describe how the 70s and 80s saw the dawn of comprehensive federal regulation of health care and health

3 Inst. of Med., Crossing the Quality Chasm: A New Health System for the 21st Century (Nat'l Acads. Press 2001), *available at* www.nap.edu/read/10027/chapter/1. The Institute of Medicine (IOM), now the National Academy of Medicine, is a non-profit, non-governmental organization that is part of the National Academies of Sciences, Engineering, and Medicine. As such, it is an independent organization serving as an adviser to the nation and to the international community to address critical issues in health, medicine, and related policy.

4 Recent estimates of the factors influencing population health status put medical care at around 11%, with behaviors (36%), social circumstances (24%), genetics (22%), and physical environment (7%) constituting the other factors. *See* Laura McGovern et al., Altarum Inst., *The Relative Contribution of Multiple Determinants to Health Outcomes*, Health Aff. Aug. 24, 2014, *available at* http://healthaffairs.org/healthpolicybriefs/brief_pdfs/healthpolicybrief_123.pdf; Harry J. Helman & Samantha Artiga, Kaiser Comm'n on Medicaid & the Uninsured, Issue Brief: Beyond Health Care: The Role of Social Determinants in Promoting Health and Health Equity (2015), *available at* http://files.kff.org/attachment/issue-brief-beyond-health-care.

5 Inst. of Med., The Learning Health Care System Workshop Summary (Nat'l Acads. Press, 2007).

care quality, followed by the Clinton administration's significant effort but ultimate failure to implement comprehensive health care reform and the rise of the market model. This Comment will then discuss the influence of the Institute of Medicine's report, *Crossing the Quality Chasm*, the impact of the Affordable Care Act during the early 2000s, and end with a discussion about the current state of our learning health care system and its future.

Quality and the Federal Role Prior to Medicare

Throughout the 19th century, medical practice remained a very private affair between physician and patient. Medical practice was capable of very little in terms of providing real aid to the sick. Medical science still relied on blistering, bleeding, and purging. Rural populations got by with greater success using traditional roots, herbs, and midwives.[6] Any effectiveness of governmental activity, even in the public health field, was limited by its reliance on the miasmata theory of disease—i.e., that diseases came from the air by way of bad odors.[7]

The optimism and crusading spirit of the Progressive movement of the early 20th century brought increased attention to the health needs of the public. The long hours and unsafe working conditions in factories and mines, the foul conditions in urban ghettoes, the unsanitary practices in food processing and waste disposal, among other social issues impacting health, came under attack. A clear link was made between the ills of society and the impaired health of the individual. In 1910, the Flexner Report exposed the unhealthy and unsafe conditions existing in most medical schools at the time.[8] Authored by Abraham Flexner, the lengthy report shed light on the true state of medical schools in the United States and Canada and called for higher admission and graduation standards as well as strict adherence to mainstream

6 W.G. Charleton, *Government and Health Before the New Deal*, 72 Current Hist. 196 (1977).

7 *See generally* David Oshinsky, Bellevue: Three Centuries of Medicine and Mayhem at America's Most Storied Hospital (2016).

8 Abraham Flexner, Medical Education in the United States and Canada: A Report to the Carnegie Foundation for the Advancement of Teaching, Bulletin No. 4 (1910), *available at* http://archive.carnegiefoundation.org/pdfs/elibrary/Carnegie_Flexner_Report.pdf.

science in medical education.[9] As a result, licensing standards became stricter and more pervasive during the early years of the 20th century, and specialty medical practice became formally recognized and subject to regulation by specialty boards.[10] Because of these and other reforms, "[s]omewhere between 1910 and 1912 in this country, a random patient, with a random disease, consulting a doctor chosen at random, had, for the first time in the history of mankind, a better than fifty-fifty chance of profiting from the encounter."[11]

It was with the passage of the Social Security Act in 1935 that the federal government undertook a more comprehensive program in health and established a permanent program of cooperation with the states.[12] This federal/state partnership was reinforced in succeeding years as the national government initiated new grant programs to assist states on a problem-by-problem basis.

The 1960s—Kennedy-Johnson Era Activism, Medicare, and Early Federal Attention to Quality Improvement

By the time of John F. Kennedy's election as President in 1960, federal health care policy and its impact on health care quality fell into three quite limited categories: i) direct provision of health care, mainly veterans care; ii) limited grants to states contained in the Social Security Act of 1935 for children's health services, medical research, and public health services; and iii) support for hospital construction and the education and training of health professionals. The passage of Medicare and Medicaid in 1965 added a fourth, and much larger, category—the direct financing of health care services purchased by consumers. The road to that historical step was rocky, with debates that echo until today.

Political support for national health insurance and a stronger focus on federal oversight of quality increased after World War II as the nation sought

9 *Id.*
10 Rosemary Stevens, American Medicine and the Public Interest 55 (1971) [hereinafter Stevens].
11 Herman L. Blumgart, *Caring for the Patient*, 270 New Eng. J. Med. 449 (1964).
12 Social Security Act of 1935, Pub. L. No. 74-271, 49 Stat. 620 (1935), *available at* http://legcounsel.house.gov/Comps/SSA_CMD.pdf.

to rebuild its infrastructure to align with peacetime needs. Organized medicine bitterly opposed any notion of public insurance, however. President Franklin D. Roosevelt's State of the Union message in 1944 mentioned the right to quality health care,[13] and President Harry S. Truman (1945–1953) took a strong position favoring national health insurance. The resulting national health bill called for a compulsory comprehensive national health insurance system and precipitated one of the major political battles of the Truman administration. The tone of the debate was bitter, with the American Medical Association (AMA) labeling the bill "totalitarian" and Senator Robert A. Taft (R-Ohio) calling it "the most socialistic measure that this Congress has ever had before it."[14] Claiming the end of free enterprise if the measure passed, organized medicine effectively promulgated the false view that all physicians would be forced to work for the federal government. The bill failed, as did similar attempts in 1947 and 1949. By 1951, both the Truman administration and the Congress backed away from this battle for the time being and favored more limited goals.

Through all of this, while health care quality considerations remained focused primarily on individual physicians and individual patients in acute care settings, quality regulation was starting to become institutionalized in certain areas. For example, state licensing programs had begun in the late 1800s. In 1906, national regulation of medication was undertaken by the Food and Drug Administration.[15] In 1935, the Social Security Act set standards for maternal and children's services,[16] and in 1946, the Hill-Burton Act[17] required states to apply minimum building codes for new structures built with federal financial assistance. In addition, the Department of Health, Education and Welfare was created in 1953.[18] The creation of this new agency established a

13 President Franklin D. Roosevelt, State of the Union Message to Congress (Jan. 11, 1944), *available at* www.fdrlibrary.marist.edu/archives/address_text.html.
14 Stevens, at 273.
15 John K. Inglehart, *The Food and Drug Administration and Its Problems*, 325 New Eng. J. Med. 217 (1991).
16 Social Security Act, 42 U.S.C. §§ 701–12 (1935).
17 Hospital Survey and Construction Act of 1946, Pub. L. No. 79-725, 60 Stat. 1040 (1946).
18 Reorganization Plan No. 1 of 1953, *reprinted in* 5 U.S.C. app., *and in* 18 Fed. Reg. 2053 (Apr. 11, 1953), 67 Stat. 631 (1953), *available at* www.gpo.gov/fdsys/pkg/USCODE-2010-title5/pdf/USCODE-2010-title5-app-reorganiz-other-dup48.pdf.

permanent and centralized administrative mechanism for the rapidly expanding activities of the federal government in health care.

Then came the Kennedy-Johnson years, which began with a brief era of great optimism characterized by a creative outpouring of social legislation. The nation's mood was confident and vigorous. There was widespread commitment to collectively forge a better society and a willingness to commit substantial amounts of public funds to solve social problems. One commentator wrote, "These were gloriously idealistic times in which we were determined to eliminate poverty, abolish racial discrimination, do away with substandard housing, revitalize our cities, and provide first class educational opportunities and good medical care for all."[19] Following the national emotional outpouring brought on by President Kennedy's assassination, the election of President Lyndon B. Johnson in 1964, and the installation of the 98th Congress, the Social Security Amendments of 1965[20]—Medicare and Medicaid—were passed despite continued opposition by the AMA and some Congressional Republicans and southern Democrats. Medicare and Medicaid did not require radical changes in the health care system. Rather, they provided a financial mechanism for the elderly and poor to purchase health care services, previously only available to the relatively wealthy through private health insurance.

As part of the Medicare Law, Congress enacted the Medicare Conditions of Participation, which mandated certain quality-based principles central to operating a hospital safely and efficiently, such as medical staff credentials, 24-hour nursing services, and fledgling utilization review.[21] Acute care general hospitals accredited by the then Joint Commission on Accreditation of Hospitals (now the Joint Commission) were deemed to have met the regulatory requirements of the Medicare Law. The Joint Commission had been formed in 1952, but the enactment of Medicare greatly enhanced the rigor of its requirements. In 1966, Avedis Donabedian penned his classic article, "Evaluating the Quality of Medical Care," which summarized and extended what had been

19 David E. Rogers, American Medicine: Challenge for the 1980s 9 (1978).
20 Social Security Amendments of 1965, Pub. L. No. 89-97, 79 Stat. 286 (1965), *available at* www.gpo.gov/fdsys/pkg/STATUTE-79/pdf/STATUTE-79-Pg286.pdf.
21 *Id.* § 1861.

learned about the techniques used to assess and improve quality to that point.[22] Donabedian asserted that quality could and should be measured in three areas: i) structure, the physical and staffing characteristics of caring for patients; ii) process, the method of delivery; and, for the first time, iii) outcomes, the results of care. The Joint Commission and other groups embraced the structure, process, outcomes model, and the real beginning of modern health care quality improvement and the concept of a "learning health care system" was launched.

The 1970s and 1980s—The Dawn of Comprehensive Federal Regulation of Health Care and Health Care Quality

The Great Society optimism of 1964–65 did not last much beyond 1966. Societal unrest over the Vietnam War and other issues helped lead to an overall frustration by the time Richard Nixon became President in 1968. Further, the Great Society programs had been unable to swiftly and simply accomplish the social goals of the Kennedy-Johnson years. Serious doubts about the efficacy of federal spending in the health care field were being expressed by the late 1960s, which only escalated in the early 1970s. As early as 1969, governmental officials in the new Nixon administration and conservative political commentators were declaring that the health care system was in crisis, a view echoed by the media. Blame was freely distributed and the rhetoric became increasingly bitter.

At their core, these concerns were about rising costs. Total societal health care expenditures tripled between 1965 and 1975, rising from $39 billion to $118.5 billion.[23] Federal expenditures in health increased sevenfold during the eleven year period between 1960 and 1971.[24] While the dollar amounts of these expenditures seem small today, they seemed dramatic at the time, creating anxiety in Congress and elsewhere. As one commentator wrote in 1971, "The

22 Avedis Donabedian, *Evaluating the Quality of Medical Care*, *reprinted in* 83 Milbank Q. 691 (2005), *available at* www.ncbi.nlm.nih.gov/pmc/articles/PMC2690293/pdf/milq0083-0397.pdf.

23 Lawrence D. Brown, *The Scope and Limits of Equality as a Normative Guide to Federal Health Care Policy*, 26 Pub. Pol'y 481 (1978) [hereinafter *Brown*]; Stevens, at 501.

24 Stevens, at 501.

increasing demand for services accompanied by crippling inflation in medical costs (both in part attributable to Medicare and Medicaid) were . . . not only causing vast increases in governmental health expenditures for little return, but also—and significantly—raising private health insurance premiums."[25] Thus, as wealthier Americans began to feel the pinch of health care costs, the volume of calls to action rose as well.

At the same time, even as costs rose, those concerned with the quality of care being provided were disappointed, viewing the maldistribution of services, bad management of medical care institutions, and poor quality of care as continuing major problems. This led to early expressions of the need to focus on behavioral and environmental determinants of health, not only interventional care for acute conditions, as well as the need for increased involvement by individuals in their own health and well-being, both themes we see at the forefront again today. Thus, during the Nixon years, the popular sentiment at the policy level was that Medicare and Medicaid spending was growing unchecked and yet millions of individuals remained underserved. This remained true when President Jimmy Carter was elected in 1976. As a commenter pointed out at the time, the health care system had become a runaway due to "the ultimate unaccountability of medical care policy, which derives from complex interactions among individuals and institutions that are in many ways insulated from the impact of consumer choice expressed in the private market and from collective choice expressed in the political process."[26] It is interesting to note that this is essentially the same debate we are having today over the future of the Affordable Care Act.

The government's response in the 1970s

Interestingly, the federal government's response under both Republican and Democratic administrations went beyond the subsidizing and financing of health care. Rather, the federal government responded by enacting a blizzard of legislation regarding the reorganization and regulation of the U.S. health

25 *Brown*, at 498.
26 *Id*. at 502.

care system. Reorganization came through the establishment of the National Health Services Corps in 1970,[27] the Comprehensive Health Manpower Training Act of 1971,[28] the Health Professions Education Assistance Act of 1976,[29] and most importantly, the Health Maintenance Organization Act of 1973.[30] Regulation took form through the Occupational Safety and Health Act in 1970,[31] the establishment of Professional Standards Review Organizations (PSRO) in the Social Security Amendments of 1972,[32] and the National Health Planning and Resources Development Act of 1974.[33] What a blizzard of legislation looking back on it now! This bundle of new laws represented the beginning of health law as a legal specialty.

In the early 1970s, Congress sought to regulate both the cost and quality of health care services, the view in 1973 being that by building on the evolution of group practice in medicine and the experience of certain large industrial insurance plans, entities like health maintenance organizations (HMOs) could offer an alternative to the traditional fee-for-service system, one better suited to patient-centered care and cost efficiency; however, the original law was a political compromise among hostile forces that had to be amended in both 1976 and 1978.

The PSRO law was designed to help keep costs under control and assure quality of care for federally-funded medical services. This was, in hindsight, a quite radical step of government-sponsored oversight of the medical profes-

27 National Health Services Corps establishment: Emergency Health Personnel Act Amendments of 1972, Pub. L. No. 92-585, 86 Stat. 1290 (1972), *available at* http://uscode.house.gov/statutes/pl/92/585.pdf.

28 Comprehensive Health Manpower Training Act of 1971, Pub. L. No. 92-157, 85 Stat. 431 (1971), *available at* http://uscode.house.gov/statutes/pl/92/157.pdf.

29 Health Professions Education Assistance Act of 1976, Pub. L. No. 94-484, 90 Stat. 2243 (1976), *available at* www.gpo.gov/fdsys/pkg/STATUTE-90/pdf/STATUTE-90-Pg2243.pdf.

30 Health Maintenance Organization Act of 1973, Pub. L. No. 93-222, 87 Stat. 914 (1973), *available at* www.gpo.gov/fdsys/pkg/STATUTE-87/pdf/STATUTE-87-Pg914.pdf.

31 Occupational Safety and Health Act of 1970, Pub. L. No. 91-596, 84 Stat. 1590 (1970), *available at* www.gpo.gov/fdsys/pkg/STATUTE-84/pdf/STATUTE-84-Pg1590.pdf.

32 Social Security Amendments of 1972, Pub. L. No. 92-603, 86 Stat. 1329 (1972), *available at* www.gpo.gov/fdsys/pkg/STATUTE-86/pdf/STATUTE-86-Pg1329.pdf.

33 National Health Planning and Resources Development Act of 1974, Pub. L. No. 93-641, 88 Stat. 2225 (1974), *available at* www.gpo.gov/fdsys/pkg/STATUTE-88/pdf/STATUTE-88-Pg2225.pdf [hereinafter *National Health Planning and Resources Development Act*].

sion, sponsored by a Republican administration. The principal feature of the PSRO program was the establishment of regional and local groups of practicing physicians who carried out the regulatory functions. These physician groups, receiving grants from Department of Health Education and Welfare (now the Department of Health and Human Services or HHS), reviewed professional services rendered by practitioners in their area to determine whether the services were necessary, of acceptable quality, and reasonably priced. To make these determinations, each PSRO was required to develop criteria and standards for the diagnosis and treatment of the cases it reviewed. Failure by a physician to meet the applicable criteria could result in denial of federal reimbursement and/or fines and public exposure.[34] The National Health Planning Law of 1974[35] set forth ambitious regulatory responsibilities for state-level and sub-state regional health planning agencies, and it established a strong national role in directing these activities. Health Systems Agencies were the planning agencies provided for in the Act. They were required to have a significant consumer component among its members and were given broad responsibility to develop and implement statewide services and facilities plans and to review the appropriateness of existing facilities and services as well as proposals for expansion.

The early 1980s

By 1981, PSROs were established in 187 of 195 designated areas throughout the country.[36] Unfortunately, they never met governmental expectations and were consistently opposed by the AMA, state medical societies, and some state governments. Further, Congress became concerned that PSROs were not demonstrating cost savings, and even supporters were becoming concerned that, due to governmental pressure, they were emphasizing cost containment

34 Douglas A. Hastings, *Professional Standards Review Organizations and Confidentiality: The Question of Public Access to Medical Peer Review Data Through the Freedom of Information Act*, 6 J. Health Pols., Pol'y & Law 136, 139 (1981) [hereinafter *Hastings*].

35 *National Health Planning and Resources Development Act*.

36 John M. Luce et al., *A Brief History of Health Care Quality Assessment and Improvement in the United States*, 160 W. J. Med. 263, 265 (1994), *available at* www.ncbi.nlm.nih.gov/pmc/articles/PMC1022402/pdf/westjmed00067-0065.pdf.

over quality. These concerns led to the establishment of peer review organizations (PROs), which replaced PSROs. PROs were given a broader scope of review of medical records based on six criteria: i) the adequacy of discharge planning; ii) medical stability at discharge; iii) unexpected deaths; iv) nosocomial infections; v) unscheduled returns to surgery; and vi) trauma suffered in the hospital. These criteria clearly anticipated today's Centers for Medicare and Medicaid Services (CMS) payment policies related to readmissions, hospital acquired conditions, and "never events." From the start of the program through 1989, PROs conducted over 6 million reviews and denied payment in more than 4% of those cases.[37] PROs also identified more than 87,000 physicians with quality problems in their care during the same period. Almost all of these problems were resolved through early interventions and threat of sanctions, with few being referred to the Office of Inspector General.[38] Thus, as of the late 1980s, a debate that continues today was already in full swing—some argued that this level of enforcement was insufficient, while others railed against the growth in governmental bureaucracy and oversight of the private practice of medicine. There also were significant legal battles over the privacy vs. public access of medical peer review data.[39]

Yet, overall, the 1980s evidenced relative bipartisan consensus around Medicare and quality assurance. Medicare and Medicaid had come to be accepted as permanent federal programs valued by constituents, and even issues that arose regarding benefits, financing, and regulation were for the most part addressed on a bipartisan basis.[40] For example, Republican presidents joined congressional Democrats in adopting significant payment reforms—the Prospective Payment System for hospitals in 1983[41] and the

37 *Id.*
38 *Id.*
39 *See Hastings*.
40 Jonathan Oberlander, *The Politics of Medicare Reform*, 60 Wash. & Lee L. Rev. 1095, 1103 (2003), *available at* http://scholarlycommons.law.wlu.edu/cgi/viewcontent.cgi?article=1248&context=wlulr [hereinafter *Oberlander*].
41 Social Security Amendments of 1983, Pub. L. No. 98-21, 97 Stat. 65 (1983), *available at* www.gpo.gov/fdsys/pkg/STATUTE-97/pdf/STATUTE-97-Pg65.pdf.

Medicare Fee Schedule for physicians in 1989[42]—which included both cost efficiency and quality components.

The 1980s closed with a bipartisan Congress asking the Health Care Financing Administration (now CMS) to sponsor a study by the Institute of Medicine (IOM) on quality assurance for Medicare. The IOM's report, *Medicare: A Strategy for Quality Assurance*[43] supported the continuation of the PRO program but only if it were restructured and strengthened to look more closely at clinical outcomes. The report also sought to strengthen the Medicare Conditions of Participation and the quality improvement methods of the Joint Commission.

The 1990s—The Failure of the Clintons' Health Security Plan and the Rise of the Market Model

The bipartisan consensus of the 1980s did not last much longer. According to Paul Starr, an advisor to President Clinton in 1993, "It was one year from euphoria to defeat."[44] A detailed retelling of the fascinating story of the Clinton health care reform initiative's failure to pass Congress is beyond the scope of this Comment on quality, but it remains interesting to read contemporary accounts as they echo so much of the current debate over the Affordable Care Act. The Clintons' health care reform initiative was another story of seeming consensus on the need for reforms at the start of an administration that fell apart in the execution.

> In 1993, 23 Republican senators, including then-Minority Leader [Bob] Dole, cosponsored a bill introduced by Senator John Chafee that sought to achieve universal coverage through a mandate on individuals to buy insurance. Nearly every major health care interest group had

42 *Oberlander.*

43 Inst. of Med., Medicare: A Strategy for Quality Assurance, Volume 1 (Kathleen N. Lohr, ed., National Academies Press 1990).

44 Paul Starr, *What Happened to Health Care Reform?*, 20 Am. Prospect 20 (1995), *available at* www.princeton.edu/~starr/20starr.html [hereinafter *Starr*].

> endorsed substantial reforms []. The [AMA] and Health Insurance Association of America [], the two great, historic bastions of opposition to compulsory health insurance, both went on record in support of an employer mandate and universal coverage.[45]

But once embraced and sponsored by the new Clinton administration, such support vanished; *The President's Health Security Plan: The Clinton Blueprint*[46] was rejected by Congress, leading to recriminations, left and right.

Among the criticisms made by supporters of universal coverage was that the administration had failed to explain the complexity of health care sufficiently, thereby allowing opposition groups to obfuscate the truth and discredit the proposal, such as through the "Harry and Louise" ads and other efforts.[47] The same things are being said today as President Trump and the Republican Congress set about to dismantle the Affordable Care Act.

45 *Id.*

46 White House Domestic Policy Council–A Draft Report, The President's Health Security Plan the Clinton Blueprint (Times Books 1993) [hereinafter White House Domestic Policy Council].

47 *Starr.*

A major component of the Clinton Plan was managed competition. HMOs had matured and become more common by the 1990s, along with Preferred Provider Organizations (PPOs) and other variants. The major insurers had largely gone into the HMO business after fighting it through much of the 1980s. Indeed, the failure of the Clinton plan led to a private market-led, managed care dominant environment in the second half of the 1990s that some have labeled "the managed care revolution."[48] The expectation had been, even after the sweeping Republican gains in the election of 1994, that tightly managed health plans would prevail, driving better quality management and cost effectiveness.

> However, unlike the Jackson Hole Group model that served as the intellectual underpinning for much of the Clinton plan [], very few employers offered their employees a choice of plans with a fixed contribution. Many employers simply replaced traditional indemnity offerings with only managed care options, in some cases offering only a single option for coverage []. This approach disenfranchised consumers and contributed to the growth of intense consumer backlash that sent managed care into retreat []. It also diminished incentives for health plans to compete on the basis of quality—one of the major promises of the managed competition theory.[49]

Thus, Harry and Louise came back to haunt their original purveyors in the health insurance industry.

Yet quality initiatives did advance slowly in quiet ways during this politically turbulent decade. The Clinton Plan had a chapter entitled "Quality Management and Improvement," which envisioned coordinated national, state, and private market efforts "focused on performance measures and continuous

48 Cara S. Lesser et al., *The End of an Era: What Became of the "Managed Care Revolution" in 2001?*, 38 Health Servs. Res. 337, 338 (2003), *available at* www.ncbi.nlm.nih.gov/pmc/articles/PMC1360889/pdf/hesr_119.pdf.

49 *Id.* at 338–39.

improvement."[50] And although no comprehensive reform legislation emerged, every major reform bill considered presumed that health care could be improved by formulating the best methods of treatment and putting greater emphasis on quality. Again, a learning health care system was the underlying assumption.

What really emerged in the 1990s as the leading edge of the quality movement was the concept of clinical practice guidelines. Rising health care costs had driven the managed care revolution in the early part of the decade, which produced the backlash against constrained choice in the latter years. The driving force behind the development and proliferation of clinical practice guidelines was public and private concern about the consequences of inappropriate medical care. According to a 1990 IOM panel, concerns about inappropriate care had arisen from "wide variations in medical practice patterns, evidence that some health services are of little or no value, and claims that various kinds of financial, educational and organization incentives can reduce inappropriate utilization."[51] Such guidelines became the starting point of identifying and seeking the adoption of sustained, evidence-based practices that could be tested, applied, and re-tested. In a subsequent 1992 report, the IOM outlined five major purposes for guidelines: i) assisting clinical decision-making by patients and practitioners; ii) educating consumers; iii) assessing and assuring the quality of care; iv) guiding allocation of resources for health care; and v) reducing the risk of legal liability for practitioners.[52] Simply put, guidelines were intended to bring the best medical evidence, buttressed by expert opinion, to bear on questions of what course of treatment to follow in particular clinical situations.

In the absence of comprehensive national legislation, however, clinical practice guidelines could only advance the ball up to a point. Guidelines also created their own controversies by the end of the decade. After years of

50 White House Domestic Policy Council, ch. 14, at 111–22.
51 Inst. of Med., Clinical Practice Guidelines: Directions for a New Program 2 (Marilyn J. Field & Kathleen N. Lohr, eds., Nat'l Acad. Press 1990).
52 Inst. of Med., Guidelines for Clinical Practice: From Development to Use 1 (Marilyn J. Field & Kathleen N. Lohr, eds., Nat'l Acad. Press 1992).

resistance, medical professional societies began cautiously embracing the guidelines movement. The AMA helped establish various groups and collaboratives of trade groups and specialty societies to study and promulgate guidelines. In 1994, the National Health Lawyers Association held a colloquium on "Legal Issues Related to Clinical Practice Guidelines," building on the pioneering work of Alice Gosfield in this area.[53] Federal agencies also sought a leading role in guideline development, particularly after passage of the Omnibus Reconciliation Budget Act (OBRA) in 1989, which created the Agency for Health Care Policy and Research (AHCPR). The legislation gave AHCPR a broad mandate to enhance the "quality, appropriateness and effectiveness of health care services . . . through the establishment of a broad base of scientific research and through the promotion of improvement in clinical practice. . . ."[54] This led to AHCPR's active involvement in guideline development, including commissioning two major reports from the IOM on how to go about the daunting task of developing "standards of quality, performance measures, and medical review criteria through which health care providers and other appropriate entities may assess or review the provision of health care and assure the quality of such care."[55] But with the excitement about the ability of guidelines to solve major problems in the health care system and the proliferation of published protocols came disappointment, resistance, and backlash both in government and the private sector—seemingly the inevitable ebb and flow of change in health care. High hopes led to frustration, variously, at the slow pace of change, bureaucratic micromanagement, and impingement on patient and provider choice, to name a few. Although progress was made, the 1990s ended with a great deal of uncertainty about the future of health care quality improvement as well.

53 Alice Gosfield, *Clinical Practice Guidelines and the Law: Applications and Implications*, *in* Health Law Handbook, Clark Boardman Callaghan (1994).

54 Omnibus Budget Reconciliation Act of 1989, Pub. L. No. 101-239, 103 Stat. 2106, 2189 (1989), *available at* https://www.gpo.gov/fdsys/pkg/STATUTE-103/pdf/STATUTE-103-Pg2106.pdf.

55 *Id.*

The 2000s—From *Crossing the Quality Chasm* to the Affordable Care Act

Once again, the IOM is at the center of this story. Its 1999 publication, *To Err is Human*,[56] had been a bombshell, and it was the first IOM report to be widely covered in the mainstream media. *To Err* was about only one element of quality—patient safety—but the idea that 100,000 Americans were unnecessarily dying every year in U.S. hospitals due to medical errors shocked the nation. That report was followed in 2001 by the IOM's much broader, more comprehensive, and still seminal study on the systemic flaws in U.S. health care and how the delivery system must be redesigned to innovate and improve care. The IOM's *Crossing the Quality Chasm* (Chasm Report) begins with this now famous statement, "Quality problems are everywhere, affecting many patients. Between the health care we have and the care we could have lies not just a gap, but a chasm."[57] The report's findings and recommendations set the tone and provided the intellectual underpinning for essentially everything that followed in the decade ahead related to health care quality in America, culminating in the payment and delivery reform sections of the Affordable Care Act.

Importantly, the IOM provided a six-part definition of health care quality that remains central to the progress that has been made to date. According to the IOM, health care should be:

- *Safe*—avoiding injuries to patients from the care that is intended to help them.
- *Effective*—providing services based on scientific knowledge to all who could benefit and refraining from providing services to those not likely to benefit (avoiding underuse and overuse, respectively).

56 Inst. of Med., To Err is Human: Building A Safer Health System (Linda T. Kohn et al., eds., Nat'l Acad. Press 2000).

57 Inst. of Med., Crossing the Quality Chasm: A New Health System for the 21st Century 1 (Nat'l Acad. Press 2001), *available at* https://www.nap.edu/read/10027/chapter/1.

- *Patient-centered*—providing care that is respectful of and responsive to individual patient preferences, needs, and values and ensuring that patient values guide all clinical decisions.
- *Timely*—reducing waits and sometimes harmful delays for both those who receive care and those who give care.
- *Efficient*—avoiding waste, including waste of equipment, supplies, ideas, and energy.
- *Equitable*—providing care that does not vary in quality because of personal characteristics such as gender, ethnicity, geographic location, and socioeconomic status.[58]

This definition and the Chasm Report's recommendations led to a decade of progress, innovation, and learning related to health care quality.

The major piece of federal health care legislation passed during the Bush administration (2002–8) was the Medicare Modernization Act (2003),[59] which greatly expanded Medicare by including an optional prescription drug benefit (Part D) and also introduced the Medicare Advantage program (Part C). Part C brought health plan principles related to care management into the Medicare program. Medicare Advantage has continued to grow since then, and through both private plan innovations and CMS efforts, has provided a laboratory for the expansion of value-based payment and coordinated care delivery principles in Medicare. By 2005, CMS had commenced the Physician Group Practice Demonstration, a physician pay-for-performance initiative that continued until 2010 and was extended by the Affordable Care Act.

Also by mid-decade, a consensus was forming among diverse health care constituencies, based on Chasm Report principles, that the U.S. health care system as a whole was greatly underperforming. Don Berwick, then head of

58 *Id*. at 5–6.

59 Medicare Prescription Drug, Improvement, and Modernization Act of 2003, Pub. L. No. 108-173, 117 Stat. 2066 (2003), *available at* www.gpo.gov/fdsys/pkg/PLAW-108publ173/pdf/PLAW-108publ173.pdf.

the Institute for Healthcare Improvement, stated in *Health Affairs* in 2005 that "Right from the start it has been one of the great illusions in the reign of quality that quality and cost go in opposite directions."[60] A scorecard developed by the Commonwealth Fund in 2006 showed the following results, among others:

- For 37 key indicators in 5 health care system dimensions (quality, access, equity, outcomes, and efficiency), the overall U.S. score was only 66 out of a possible 100.
- Efficiency was the single worst score among the five dimensions, with the U.S. ranking 16th out of 20 countries in use of electronic health records.
- The U.S. was the worldwide leader in costs.
- The U.S. scored 15th out of 19 countries in mortality attributable to health care services.
- Basic tools were missing to track patients through their lives.
- The U.S. did poorly at transition stages, thus evidencing, for example, high hospital readmissions rates from nursing homes.
- Improving performance in key areas would save 100,000 to 150,000 lives and $50-100 billion annually.[61]

The report included several key recommendations: the U.S. should expand health insurance coverage; implement major quality and safety improvements; work toward a more organized delivery system that emphasizes primary and preventive care that is patient-centered; increase transparency and reporting on quality and costs; reward performance for quality and efficiency; expand

60 Interview by Robert Galvin with Donald Berwick, President & CEO, Inst. for Healthcare Improvement, in *Health Affairs Web Exclusive* W5-1, W5-7 (Jan. 12, 2005), *available at* http://content.healthaffairs.org/content/early/2005/01/12/hlthaff.w5.1.2./suppl/DC1.

61 The Commonwealth Fund Comm'n on a High Performance Health System, The Commonwealth Fund, Why Not the Best? Results from a National Scorecard on U.S. Health System Performance (2006), *available at* www.commonwealthfund.org/~/media/files/publications/fund-report/2006/sep/why-not-the-best--results-from-a-national-scorecard-on-u-s--health-system-performance/commission_whynotthebest_951-pdf.pdf.

the use of interoperable information technology; and encourage collaboration among stakeholders.

That same year, Dr. Elliott Fisher coined the term "accountable care organization" (ACO) during a public meeting of the Medicare Payment Advisory Committee.[62] Dr. Fisher and others began putting forth the argument in the public policy arena that to significantly improve health care quality and cost efficiency, accountability for each patient's care should be shared across the continuum of providers participating in that care. Shortly thereafter, the IOM stated in a follow-up report in its Chasm series that the Medicare payment system does not reward efficiency and provides few disincentives for overuse, underuse, or misuse of care.[63] The IOM further proposed that incentives should encourage providers to assume shared accountability for transitions between care settings and to coordinate care for patients with chronic disease. During this same time period, purchasers, payers, state governments, the Joint Commission, and others greatly increased their quality-related reporting requirements, particularly related to outcomes for various hospital procedures and stays. A new generation of gainsharing proposals and demonstrations emerged.

In 2006, the American Academy of Family Physicians launched the first large-scale demonstration of the patient-centered medical home.[64] In early 2007, HHS Secretary Mike Leavitt unveiled a quality-improvement plan called "Value Exchanges" that would establish local quality-improvement collaborations. In December 2008, the Congressional Budget Office included in its budget options the idea of "bonus-eligible organizations" based on early accountable care organization principles.[65] Finally, throughout 2008, both

62 Medicare Payment Advisory Comm'n Public Meeting (Nov. 8, 2006), *available at* www.medpac.gov/docs/default-source/meeting-materials/november-2006-meeting-transcript.pdf?sfvrsn=0.

63 Inst. of Med., Rewarding Provider Performance: Aligning Incentives in Medicare (Nat'l Acad. Press 2007).

64 Paul A. Nutting et al., *Transforming Physician Practices To Patient-Centered Medical Homes: Lessons From The National Demonstration Project*, 30 Health Aff. 439 (March 2011), *available at* http://content.healthaffairs.org/content/30/3/439.full.pdf+html.

65 Congressional Budget Office, Budget Options, Volume 1: Health Care (2008), *available at* www.cbo.gov/sites/default/files/110th-congress-2007-2008/reports/12-18-healthoptions.pdf.

Presidential candidates, Barack Obama and John McCain, and their health policy experts, emphasized the importance of achieving better quality and value from our health care system and put forward proposals to do so.[66]

The policy debate and political hostilities around the Affordable Care Act have related primarily to the expanded coverage and tax provisions. The components of the law related to payment and delivery reform contained in Title III of the Act and featuring numerous provisions promoting quality have remained for the most part free of major controversy and subject to bipartisan support. Title III included a multi-year rollout of provisions seeking to advance health care quality based largely on the Chasm Report's framework. A multi-year timeline was reflected in key provisions:

- 2010—Patient-centered outcomes research; community transformation grants; extension of gainsharing demonstration; Medicaid global payment system demonstration
- 2011—National strategy for improvement in health care, establishment of the Center for Medicare and Medicaid Innovation (CMMI) within CMS; plans for value-based purchasing programs for skilled nursing facilities, home health agencies, and ambulatory surgical centers; community-based collaborative care networks
- 2012—Medicare shared savings program; hospital value-based purchasing program; hospital readmissions reduction program; independence at home demonstration program; pediatric accountable care organization demonstration project; demonstration project to evaluate integrated care around a hospitalization
- 2013—National pilot program on payment bundling
- 2014—Quality reporting for long-term care hospitals, inpatient rehabilitation hospitals, and hospice programs

list continues

66 Jonathan Oberlander, *The Partisan Divide–The McCain and Obama Plans for U.S. Health Care Reform*, 359 New Eng. J. Med. 781 (2008).

- 2015—Payment adjustment for conditions acquired in hospitals; improvements to the physician quality reporting system[67]

Also during the Obama administration, legal issues related to quality measurement and improvement were, for the most part, addressed constructively. Beginning in 2003, following passage of the Sarbanes-Oxley Act the prior year,[68] HHS, through its Office of Inspector General (OIG), made a push for health care organization boards to become more actively involved in compliance oversight, including compliance with evolving health care quality expectations and measurement requirements. The OIG collaborated with the American Health Lawyers Association (AHLA) for several years during the decade to produce publications providing guidance for health care boards in this important evolving area, even as enforcement initiatives related to poor quality and quality reporting continued.[69] Right after passage of the ACA in 2010, Don Berwick, during his brief tenure as head of CMS, led a multi-agency effort, working with the private sector as well, to address questions related to the implications of accountable care implementation for enforcement of the antitrust, fraud and abuse, and exempt organization tax laws. Generally helpful guidance was produced, and the significant inter-agency collaboration during this period was important.

The Affordable Care Act contemplated a framework for a learning health system for quality. As Dr. Atul Gawande said at the time, "History . . . suggests that you can have transformation . . . without knowing all the answers up front. [] Transforming health care everywhere starts with transforming it

67 *See* Douglas A. Hastings, *The Timeline for Accountable Care: The Rollout of the Payment and Delivery Reform Provisions in the Patient Protection and Affordable Care Act and the Implications for Accountable Care Organizations*, 19 BNA's Health Law Reporter, Mar. 25, 2010, *available at* www.ebglaw.com/content/uploads/2014/06/38833_BNA-Article-The-Timeline-for-Accountable-Care-3-25-10.pdf.

68 Sarbanes-Oxley Act of 2002, Pub. L. No. 107-204, 116 Stat. 745 (2002), *available at* www.gpo.gov/fdsys/pkg/PLAW-107publ204/pdf/PLAW-107publ204.pdf.

69 *See* Arianne N. Callender et al., U.S. Dep't of Health & Human Servs. Office of Inspector Gen. & Am. Health Lawyers Ass'n, Corporate Responsibility and Health Care Quality: A Resource for Health Care Boards of Directors (2007), *available at* https://oig.hhs.gov/fraud/docs/complianceguidance/Corporate%20Responsibility%20and%20Health%20Care%20Quality%206-29-07.pdf.

somewhere."[70] The aim of Title III was to take the IOM's ideas and spur a transformation. The comprehensive provisions in the ACA regarding payment and delivery reform reflected both the payment system continuum—from fee-for-service to bonus incentives for quality to bundled payments to partial and full global payments—as well as delivery system continuum—from independent clinicians and hospitals to small group practices to multi-provider networks to partially or virtually integrated organizations to fully integrated systems with common ownership and employment. Despite continued controversy over the insurance and coverage provisions of the ACA, the first decade of the 21st Century ended with much optimism about advances in quality.

The 2010s—The Present and Future of a Learning Health Care System

The evidence-based push for quality improvement began aggressively in 2010 after passage of the ACA. Don Berwick was appointed to head CMS and immediately began to articulate broadly and publicly the "Triple Aim"—better health, better care, and lower costs—a distillation of the Chasm Report's six aims. As the first director of CMMI, Rick Gilfillan, previously the head of Geisinger Health Plan, moved quickly to develop innovative models for improving care and reducing costs. The momentum continued for the first half of the decade.

By January 2015, there were approximately 744 accountable care entities, 404 with government contracts, 217 with commercial contracts, and 103 with both governmental and commercial contracts.[71]

> Early drivers of the growth of the movement can be attributed to a combination of conscientious acknowledge-

70 Atul Gawande, *Testing, Testing*, New Yorker, Dec. 14, 2009, *available at* www.newyorker.com/magazine/2009/12/14/testing-testing-2.

71 Tianna Tu et al., Leavitt Partners & Robert Wood Johnson Found., The Impact of Accountable Care: Origins and Future of Accountable Care Organizations 7 (2015), *available at* www.rwjf.org/content/dam/farm/reports/issue_briefs/2015/rwjf420213 [hereinafter Tu et al.].

> ment of the need to improve care delivery and a desire to seek first-mover advantage in new types of contracts. Some commercial initiatives moved toward accountable care because they believe it represents a better care delivery process. Others sought to prepare for inevitable future risk-bearing.[72]

The federal government played a critical and important role in driving adoption of value based-payment and accountable care methodologies in both payment and delivery, but the private sector's uptake of these innovations in quality was essential as well. For several years after the ACA's legislative embrace of a value-based agenda, the testing of new payment models and coordinated care delivery mechanisms advanced steadily in both sectors, notwithstanding the continued political debate over coverage expansion and Republican criticism of the ACA.

At the same time, it was becoming clearer that the greatest opportunities for the health care system to improve quality of lives, lower costs, and reduce disparities lay in addressing the health care of highly vulnerable populations, such as the frail elderly, the homeless, dual-eligibles, at-risk young children, those with multiple chronic conditions, and the mentally or cognitively impaired. The work of Jeffrey Brenner in Camden, New Jersey, originally highlighted in Dr. Atul Gawande's "The Hot Spotters" article in *The New Yorker,* provided evidence of the phenomenal quality and cost savings results that can come from aggressively working with the poor, homeless, and other super-utilizers in the community outside of the acute setting.[73] In 2011, the American Hospital Association published *Caring for Vulnerable Populations*,[74] which, among other recommendations, encouraged hospitals and health systems to develop community partnerships with public health departments and other community organizations and to provide non-health care services,

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72 *Id.*

73 Atul Gawande, *The Hot Spotters*, New Yorker, Jan. 24, 2011, *available at* www.newyorker.com/magazine/2011/01/24/the-hot-spotters.

74 AHA Comm. on Research, Am. Hosp. Ass'n, Caring for Vulnerable Populations (2011), *available at* www.aha.org/research/cor/content/caring_vulnerable_populations_report.pdf.

such as transportation. The ACA requirement that hospitals conduct community needs assessments on a regular basis lent important support to this necessary connection between medical care and social service. In further support of this perspective, the Robert Wood Johnson Foundation in 2014 published a report called *A Time to Act: Investing in the Health of Our Children and Communities*, which stated in its introduction:

> Our nation is unhealthy, and it is costing us all through poorer quality of life and lost productivity. Health in America is worse than in other developed nations on more than 100 measures. [] To become healthier and reduce the growth of spending on both public and private medical care, we must create a seismic shift in how we approach health and the actions we take. As a country, we need to expand our focus to address how to stay healthy in the first place. This will take a revolution in the mindset of individuals, community planners and leaders, and health professionals. It will take new perspectives, actors, and policies, and will require seamless integration and coordination of a range of sectors and their work. The shift is critical for both the health and economic well-being of our country.[75]

As we enter 2017, we can look back at seven years of ACO development, bundled payment demonstrations, hospital readmissions penalties, state-based community care innovations, dual-eligible care improvements, and numerous other quality improvement efforts emanating from the Chasm Report and the ACA. During this period, the IOM continued its groundbreaking work in quality, including a report on geographic variation in health care across the U.S. and a report on errors in the diagnostic process, both of which had past presidents of AHLA on their study committees.[76] The U.S. health care system has been testing and learning, and evidence has been in the forefront.

75 RWJF Comm'n to Build a Healthier America, Robert Wood Johnson Found., Time to Act: Investing in the Health of our Children and Communities 5 (2014).

76 Inst. of Med., Variation in Health Care Spending: Target Decision Making, Not Geography (Nat'l Acads. Press 2013); Nat'l Acads. of Scis., Eng'g, & Med., Improving Diagnosis in Health Care (Nat'l Acads. Press 2015).

Chapter 6 of the Chasm Report is entitled "Applying Evidence to Health Care Delivery" and focuses on the importance of further developing and refining quality measures. Through the efforts of CMS, the National Quality Forum, the Institute for Health Care Improvement, the Leapfrog Group, and others, quality measures and metrics have come a long way since 2001. Debates and controversies still remain as to their application, but these metrics provide a critical tool in achieving the six aims. We have developed enough evidence in this evolving area of science to double down on our application of them.

From a policy standpoint, quality measures can demarcate the pathway to value-based payment that works, informing decisions as to which measures and benchmarks are driving health care delivery organizations to better and better performance and, ideally, fair payment for that performance. From a business standpoint, quality measures can serve as the constructive pathway to better cooperation and fewer unhelpful disputes between payers and providers. They can also guide payer and provider board members in their oversight responsibilities. From a legal and regulatory standpoint, quality measures can help separate "good" collaboration from "bad" in antitrust, fraud and abuse, and other enforcement protocols in need of updating, and provide some rational basis for fair allocation of resources in connection with medical errors while reducing the number of such errors.

All, of course, has not been smooth or without controversy in quality improvement and value-based payment implementation in the years since 2010. The health care antitrust policy community, both in and out of government, have debated whether the ACA's incentivization of greater collaboration among providers to reduce fragmentation of services and bring about greater care coordination also has triggered too much provider consolidation. CMS's structuring of its accountable care programs has engendered controversy as to the fairness of measures and benchmarks used, particularly the thresholds required to actually share in savings. Fraud and abuse enforcement has come under criticism for being an obstacle to coordinated care and having a chilling effect on the success of value-based payment implementation. In addition, the exposure of providers to compliance issues related to quality and quality reporting has been an increasing concern.

Nevertheless, analysis by both the Brookings Institution and Leavitt Partners in 2015 suggested that, overall, both commercial and public accountable care organizations—among the most important vehicles to test value-based payments—have seen success at reducing costs and improving quality.[77] The data also showed that while the majority of ACOs were able to realize quality improvements, reducing costs was more difficult, especially in their first years of operation. Brookings and Leavitt concluded their 2015 report by stating that ACOs will be more likely to earn shared savings in the long term and will continue existing as a viable payment model. They concluded their report with optimism, stating:

> In less than five years, accountable care has transformed from an academic idea to a tangible model that has been implemented across the nation. Accountable care represents a fundamental restructuring of the fragmented U.S. health care delivery system to promote the triple aim of improved patient care experiences, outcomes, and clinical costs of care. [] Both commercial and public ACOs have seen success at reducing costs and improving quality, which will encourage more ACOs to enter the market in the near future.[78]

Final Comments

When this commentary was being written, the then newly-elected Trump administration was about to take office in an environment of potentially sweeping change in federal policy. In many ways, this is reminiscent of the expectation of change the Reagan administration experienced in 1981. Nevertheless, health care in the 1980s evidenced relative bipartisan consensus. Whether this will be the case for health care quality 36 years later remains to be seen. Most health care policy experts, both Republican and Democrat, believe that the consensus around the need to reduce fragmentation and

77 Tu et al., at 8.
78 *Id.*

improve outcomes and efficiency through value-based payment and care coordination will hold. They point to, among other examples, the value-based payment incentives for physicians contained in the Medicare Access and CHIP Reauthorization Act (MACRA),[79] an important recent piece of bipartisan health care legislation. While there has been some Republican questioning as to the value and continued funding of CMMI and definite objection to the notion of mandatory payment change requirements, such as those put forth by CMS related to bundled services, no major attack on the thrust of Title III of the ACA has been proposed or is expected.

That said, there is uncertainty as to how a Republican administration's health care reform strategy might impact value-based payment. Would all such programs be continued as is, be rewritten, or get lost in a replacement effort? While private sector value-based payment initiatives will not be directly affected and many state-based innovations are expected to continue, a lessening of the federal "foot on the pedal" of payment and delivery reform would necessarily slow overall momentum. In addition, Tom Price, Secretary of Health and Human Services, had this to say about value-based payment and quality at a private sector conference in November of 2016:

> The nation has kind of bought into this in a superficial way, and there are folks in Washington who are pushing this; that all of health care, for all of us, needs to be run through this massive process of integrated care, value-based purchasing, or whatever the latest buzzword is so that every single incident of care must go through the federal government in some way. This is so they can make those numbers add up and control it. This is a very very dangerous place to be. I believe strongly in fee for service medicine—the ability for one free American to identify

79 Medicare Access and CHIP Reauthorization Act of 2015, Pub. L. No. 114-10, 129 Stat. 87 (2015), *available at* www.congress.gov/114/plaws/publ10/PLAW-114publ10.pdf.

> another free American who has a service or a product that they desire, and to contract independently, outside the realm of government control. This is absolutely vital for quality health care in this country. In fact, I think it's the only thinking that is going to save quality health care in this country.[80]

Adding to this concern across a variety of sectors is the potential for a higher level of disregard for science in the Trump administration. Certainty that the respect for evidence and the spirit of testing that we have experienced since 2001 will continue is not guaranteed.

Uncertainty can lead to progress and innovation or it can lead to loss of momentum or even retrenchment. In the author's opinion, the changes being wrought by the end of the Obama era and the beginning of the Trump administration, in health care and elsewhere, effectively constitute the close of 15 years in health care quality improvement that began with the Chasm Report in 2001. Once again, there should be no obstacle to continued progress on quality unless intentional obstruction for private gain or a collective failure of will prevails. If the federal government slows its support for value-based care, states and the private sector will need to push even harder. As former HHS Secretary Mike Leavitt stated recently:

> [P]olicy should continue to fund evidence-based demonstrations of new [alternative payment models] so that providers, payers and patients can learn how they work in the real-world and improve and scale these models to work effectively in clinical settings. []Now is not the time to walk away from these investments.[81]

80 Greg Thompson, *Cautious Optimism Reigns as Tom Price is Confirmed New HHS Secretary,* Medtrade, Feb. 13, 2017, *available at* www.medtrade.com/news/legislative-advocacy/Cautious-Optimism-Reigns-as-Tom-Price-is-Confirmed-New-HHS-Secretary-3216.shtml.

81 Michael O. Leavitt, *Alternative Payment Models in Healthcare are a Must,* The Hill, Jan. 25, 2017, *available at* http://thehill.com/blogs/pundits-blog/healthcare/315999-alternative-payment-models-in-healthcare-are-a-must.

It is up to those committed to the principles of the six aims to keep fighting to preserve them in this new era.

As always, health law and health lawyers will play an important role in sustaining the momentum of quality improvement in health care—whether writing or advising on laws and regulations, guiding clients on collaborative and quality-enhancing relationships that will hold up over time, teaching health law classes, or in many other ways. As the former governor for New York Mario Cuomo stated in a speech at an AHLA Annual Meeting in 1998 that still resonates: "We, the lawyers who are familiar with health care and its problems, should be making the case for change right now. Nothing is more important to the nation than people's health."[82] As AHLA celebrates its 50th birthday, let us all recommit to another 50 years of advancement in health care quality in our great country. J

82 *Annual Meeting Special Session*, Health Lawyers News, at 12 (Aug. 1998).

Doug Hastings has been a health care lawyer for more than 30 years. His national practice has focused on health care transactions and he is recognized as an advisor on health care change. In addition, Doug has been actively engaged at the national level in efforts to improve the quality and cost efficiency of the U.S. health care system. He has made significant impact in both the public and private sectors through his active roles with accountable care organizations and population health initiatives.

Doug's leadership and service to the profession include being a Past President and Fellow of the American Health Lawyers Association, a frequent and sought after health care lecturer and author, a former member of the Board of the Health Care Services of the Institute of Medicine (IOM), and a former member of the IOM Committee on Geographic Variation in Health Care Spending and Promotion of High-Value Care. He is the Chair Emeritus of Epstein Becker and Green, having been named the first chair in 2006 and serving in the capacity until 2014.

Doug is a member of the Board of Directors of the Guthrie Clinic and the Quality and Community Benefit Committee of Riverside Health System. He also serves on the advisory boards of *Accountable Care News* and BNA's *Health Law Reporter*. As a member of the Healthcare Executives Study Society, he uses his extensive health care and leadership experiences to advance the state and art of executive leadership and positively affect health care public policy.

Doug's colleagues, clients, friends, and family value him not only because of his exemplary professional career but also because of his personal warmth, intellectual curiosity, vision, and integrity. Contact him via email at dhastings@ebglaw.com.

—**Almeta E. Cooper** *contributed this author profile.*

Mr. Hastings thanks Regina M. Faulkenberry, Associate General Counsel/ Compliance Officer for SoutheastHEALTH, for her assistance with the citations for this Comment.

The Government's Golden Rule: America's Attempts to Control Health Care Payment

J.D. Epstein

What is the issue? Medicare has transformed American health care from a cottage industry into an industrial giant. Over the past 50 years, efforts to control health care costs have struggled against the system's explosive growth, fueled by the demands of both patients and providers.

What is at stake? The debate over how to pay for health care has divided the country as legislative initiatives targeting various constituencies' concerns are pushed out, only to be pulled back by later proposals addressing others' concerns. At times, this process seems to lack forward momentum toward a sustainable health care delivery and payment system.

What do you need to know? America need not necessarily choose between public and private health care. Even as public health care coverage has expanded, private innovation has flourished. As Britain's example demonstrates, government-run health care could operate next to a thriving and profitable private system.

J.D. Epstein, *The Government's Golden Rule: America's Attempts to Control Health Care Payment*, J. Health & Life Sci. L., June 2017 at 34.

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Introduction

The sentinel event spawning growth in the provision and cost of health care, and health law and the practice thereof, was Public Law 89-97, signed by President Lyndon Baines Johnson on July 30, 1965.[1] This law created the Medicare and Medicaid Programs (Titles 18 and 19 amending the Social Security Act). Prior to this time, health care was a cottage industry dominated by tax-exempt hospitals, nursing homes, and trade associations. The primary third-party payers were Blue Cross Plans, which were often times also tax-exempt organizations. The boards of directors of these organizations often included local attorneys and accountants who performed many routine functions pro bono (exceptions being litigation and audits, which were not frequent or required aside from public financing issuances).

The federal government's involvement infused billions of dollars into the health care industry and morphed it into an industrial giant accounting for 18% of the economy.[2] The government's involvement also increased professionalism. Health care providers now needed (among other disciplines) advanced educated administrators, causing an increase in Masters in Health Administration programs; certified public accountants to perform government-mandated audits, resulting in accounting firms hiring thousands of new accountants from within and outside the U.S.; appraisal experts to produce asset values not previously required, creating a boutique health care appraisal industry; and, most importantly for purposes of this Comment, attorneys to deal with the consequences of thousands of pages of a new and vast regulatory scheme, resulting in the creation of health law specialties in both boutique and large firms alike, as well as organizations preceding the American Health Lawyers Association.

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1 Social Security Amendments of 1965, Pub. L. No. 89-97, 79 Stat. 286 (1965), *available at* www.gpo.gov/fdsys/pkg/STATUTE-79/pdf/STATUTE-79-Pg286.pdf [hereinafter *Social Security Amendments of 1965*].

2 *See* Ctrs. for Medicare & Medicaid Servs. (CMS), U.S. Dep't of Health & Human Servs. (DHHS), National Health Expenditure Accounts Methodology Paper, 2015 5 (2015), *available at* www.cms.gov/Research-Statistics-Data-and-Systems/Statistics-Trends-and-Reports/NationalHealthExpendData/Downloads/DSM-15.pdf.

Prior to the Medicare program, the Blue Cross/Shield Systems (BC/BS) attempted to influence the cost of health care through contracts with hospitals and physicians. The attempt was marginally successful only locally or regionally. The system was fragmented due to the high number of BC/BS plans[3] and differences in payment models (cost reimbursement versus charge) and market penetration (i.e., control of the local market). One of the effects of such fragmentation of coverage and payment methods is that this country has never formulated a national health care policy.

Contrary to this environment, the sheer size and oneness of the Medicare program makes it a force for dictating health care delivery and payment policy. In the U.S., Medicare payment rates are established by Congressional fiat through the federal appropriations and budget reconciliation process (which also begat the Affordable Care Act). If nothing else, recent experience demonstrates that the use of the federal appropriations process to effect Medicare reform is, at best, a deeply flawed approach to making national health care policy and, at worst, an irresponsible one. Having said that, Medicare payment reform and rates paid to providers dictate the cost of health care, including new drugs and technology, because most other non-governmental payers eventually follow.

The three branches of government, from the Nixon presidency through Obama's administration, have all attempted to constrain the growth of health care costs. This Comment will provide an overview of those efforts and their impact from 1965 forward, starting with passage of the Medicare Law in 1965; the rapid expansion of health care services during the 1970s and the federal government's initial attempts to contain costs; the government's ongoing efforts in the 1980s to address rapidly rising costs through alternative delivery arrangements and by changing the financial incentives for providers; followed by a decade of new laws and regulations regarding provider compliance and efforts to improve health insurance portability and continuity; and finally, the impact of the Affordable Care Act and the financial viability of the trust funds

3 The author recalls that at one time there were over 150 BC/BS plans, with some states divided by trade agreements into as many as nine separate plans.

that have been funding Medicare for the past 50+ years. Major laws and regulations are presented in chronological order of their original passage to provide the reader with a sense of the rich and complex evolution of health law, as well as society's growing demands for more medical care and the government's efforts to curb rising health care costs—bifurcated goals that may ultimately lead us to a bifurcated health care payment model.

Medicare and Medicaid: Government Provides the Gold

The Medicare Law was enacted in 1965.[4] The Medicare program is a social health insurance program that provides universal hospital coverage for Americans who are 65 years or older.[5] Originally established as "a health insurance program for aged persons to complement the retirement, survivors, and disability insurance benefits under Title II of the Social Security Act,"[6] Medicare now also insures the long-term disabled and those who require renal dialysis.[7] Four separate components or "Parts" comprise the Medicare program: Part A, Part B, Part C, and, later on, Part D.

Medicare Part A

Borrowing from the Blue Cross model, **Medicare Part A** covers inpatient hospital, skilled nursing facility care, hospice, and home health care.[8] In adopting one of the Blue Cross models, Congress chose the cost reimbursement model based on Blue Cross of Alabama, which required providers to file an annual cost report, similar to a corporate tax return. In the cost report, the provider claims as cost all of its business expenses (i.e., labor, depreciation, interest expense, contract payments, etc.). Medicare pays the provider a

4 *Social Security Amendments of 1965.*
5 *See* 42 U.S.C. §§ 1395-1395lll.
6 Barbara S. Klees et al., Office of the Actuary, CMS, DHHS, Brief Summaries of Medicare & Medicaid: Title XVIII and Title XIX of The Social Security Act 6 (2009), *available at* www.cms.gov/Research-Statistics-Data-and-Systems/Statistics-Trends-and-Reports/MedicareProgramRatesStats/downloads/MedicareMedicaidSummaries2009.pdf.
7 Medicare was expanded in 1973 to include certain non-covered persons who may buy into the program under specific circumstances. *Id.* at 3.
8 *Id.* at 4.

percentage of the provider's cost represented by the Medicare usage (Medicaid does the same). This creates a financial incentive to spend because more spending means more Medicare/Medicaid reimbursement. Medicare Part A is financed through the Hospital Insurance (HI) Trust Fund, established at the inception of the Medicare program, and payroll (FICA) taxes. The interest income that accumulates over time is used to defray program costs; however, the HI Trust Fund has hovered near bankruptcy since 1970.[9]

Medicare Part B

Borrowing from the Blue Shield model, **Medicare Part B** covers physician and outpatient ambulatory services, speech and physical therapy, rehabilitation, diagnostic, and home health care (after 2002).[10] Medicare adopted the Blue Shield payment model of paying physicians 80% of their "reasonable" charge, defined as the lessor of the actual charge, the physician's customary charge, or the usual charge in the community. The patient was responsible for the remaining 20%.

Part B, also known as Supplementary Medical Insurance, is a voluntary program and beneficiaries may elect to purchase Part B coverage through monthly premiums deducted from their Social Security checks. The remainder of Part B is financed primarily through general tax revenues and earned interest income. The Medicare Part B or Supplementary Medical Insurance (SMI) Trust Fund is used to pay expenses for Part B beneficiaries. Because the majority of Part B coverage is financed by general revenue from the federal government, bankruptcy of the SMI Trust Fund has not been a concern.

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9 Patricia A. Davis, Cong. Research Serv., Medicare: Insolvency Projections 3 (2016), *available at* www.fas.org/sgp/crs/misc/RS20946.pdf.

10 Home Health Agency (HHA) services are covered under Medicare Parts A and B. The first 100 home health care visits following a beneficiary's three-day hospital stay are covered under Part A. 42 U.S.C. § 1395d. Under the Balanced Budget Act, Medicare payment for post-institutional HHA services furnished on or after January 1, 1998 for beneficiaries enrolled in both Parts A and B (other than the first 100 visits) are covered under Part B. *Id.* § 1395k. Such services, however, will continue to be covered under Part A for qualifying beneficiaries enrolled only in Part A. *Id.* § 1395d.

Medicare Part C

The Balanced Budget Act (BBA) of 1997 established a private health plan coverage option for Medicare beneficiaries by adding a new **Medicare Part C** to the Social Security Act.[11] Formerly known as "Medicare+Choice" or "M+C," the "MedicareAdvantage" or "MA" program offers Medicare beneficiaries a choice of coverage options.[12] Beneficiaries who have Medicare Part A and Part B coverage may elect coverage through the "original Medicare plan" or through a Medicare-approved private managed care or fee-for-service (FFS) plan for a monthly premium. MA plans may offer lower out-of-pocket costs and additional benefits. At a minimum, however, every MA plan must provide beneficiaries all of the items and services offered by Parts A and B with limited exceptions. Payments to MA organizations are financed through the HI and SMI Trust Funds. Funding is proportional and based on the actuarial value of total benefits paid under Medicare Parts A and B.[13]

The Medicare program, despite all of its complexities, would not exist and could not survive if not for the federal government's commitment to "providing the gold" by which the programs are funded. The Department of Treasury manages the two Medicare Trust Funds (the HI Trust Fund for Part A and the SMI Trust Fund for Part B) through the Medicare Board of Trustees. The Social Security Administration determines Medicare eligibility. The U.S.

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11 Balanced Budget Act of 1997, Pub. L. No. 105-33, 111 Stat. 251 (1997), *available at* www.gpo.gov/fdsys/pkg/PLAW-105publ33/pdf/PLAW-105publ33.pdf [hereinafter BBA]. The BBA added §§1851–59 to the Social Security Act establishing the M+C [now MA] program. As discussed in more detail later, the BBA was amended in 1999 by the Medicare, Medicaid & SCHIP Balanced Budget Refinement Act of 1999, Pub. L. No. 106-113, 113 Stat. 1501 (1999), *available at* www.gpo.gov/fdsys/pkg/PLAW-106publ113/pdf/PLAW-106publ113.pdf [hereinafter BBRA] and the following year by the Medicare, Medicaid and SCHIP Benefits Improvement and Protection Act of 2000, Pub. L. No. 106-554, 114 Stat. 2763 (2000), *available at* www.gpo.gov/fdsys/pkg/PLAW-106publ554/pdf/PLAW-106publ554.pdf [hereinafter BIPA].

12 The Medicare Prescription Drug, Improvement, and Modernization Act of 2003, Pub. L. No. 108-173, 117 Stat. 2066 (2003), *available at* www.gpo.gov/fdsys/pkg/PLAW-108publ173/pdf/PLAW-108publ173.pdf [hereinafter MMA]. The MMA, Title II effected a number of substantive changes to Medicare Part C, including changing the name to "Medicare Advantage." Numerous economic improvements included a significant rate increase for managed care plans as well as the creation of a $10 billion plan entry and retention stabilization fund.

13 42 U.S.C. § 1395w-24.

Department of Health and Human Services (HHS) oversees the Medicare program and issues regulations.[14] The Centers for Medicare and Medicaid Services (CMS) implements the HHS regulations and manages the operation of the program. The HHS Office of Inspector General (OIG) is responsible for the audit and evaluation of the Medicare program. To that end, the OIG conducts comprehensive financial and management evaluation audits and inspections to identify, document, and provide recommendations for the efficient and effective operation of the program. As the enforcement arm of HHS, the OIG also conducts criminal and civil investigations into Medicare fraud and abuse.

Medicaid

Enacted as a means-tested assistance program the same year Medicare was created, **Medicaid** provides medical, nursing home, and catastrophic insurance coverage to low income and medically indigent persons.[15] Medicaid is a federal/state cost-sharing program that is administered by the states and financed through general revenue funds. Federal Medicaid outlay is determined annually by a formula that compares each state's average per capita income level with the national average. The regular average federal contribution varies by state based on criteria such as per capita income, from 50% up to 75%.[16]

CMS is the federal agency charged with overseeing and approving the state administration of the Medicaid program within broad federal guidelines. States are given considerable flexibility in their organization of the program. States may select the locus of program administration (e.g., state or county); the coverage (insurance) mechanism for program enrollees (e.g., traditional indemnity vs. managed care); the scope of program eligibility, duration, and

14 *See* 42 C.F.R. pts. 405–26, 482–98.
15 *See* 42 U.S.C. §§ 1396–96w-5.
16 *See* Medicaid.gov, Financing & Reimbursement, www.medicaid.gov/medicaid/financing-and-reimbursement/ (last visited Mar. 28, 2017). The regular average contribution is distinguished from increased rates available beginning in 2014 for individuals newly eligible under the Affordable Care Act.

benefit options (where not mandated by federal law); and provider reimbursement rates.

Medicaid is an open-ended entitlement, which means that benefits must be provided by the states to everyone who qualifies. Historically linked to state welfare assistance criteria, there is wide variation as to when Medicaid entitlement begins. Poverty alone will not automatically qualify an individual for Medicaid. Traditionally, applicants must fall into one or more special population groups: (i) those who are eligible, as of July 16, 1996, under the Aid to Families with Dependent Children (AFDC) federal assistance program, (ii) pregnant women and children under 6 years with incomes up to 133% of the federal poverty line (FPL), (iii) children under 19 years below 100% FPL, (iv) Supplemental Security Income (SSI) recipients, (v) individuals who receive foster care and adoption assistance under Title IV-E of the Social Security Act, and (vi) qualifying low-income Medicare beneficiaries. Certain additional population groups may be covered by the states at their option, including pregnant women and children with income levels above 133% FPL, the medically needy as defined by the state, state SSI recipients, low-income persons receiving long-term care, and working individuals who are disabled.

Further Medicaid expansion occurred in 2010 under the Affordable Care Act (ACA).[17] All non-elderly under 138% of FPL were mandated full Medicaid coverage. All non-elderly between 138 and 400% of FPL were provided federal premium credits. The Supreme Court in 2012 ruled that such expansion was at state option.[18] As of January 1, 2017, 31 states and the District of Columbia have opted to expand.[19]

17 Patient Protection and Affordable Care Act, Pub. L. No. 111-148, 124 Stat. 119 (2010), *available at* www.gpo.gov/fdsys/pkg/PLAW-111publ148/pdf/PLAW-111publ148.pdf.

18 Nat'l Fed'n of Indep. Bus. v. Sebelius, 567 U.S. 519 (2012).

19 *Status of State Action on the Medicaid Expansion Decision–Timeframe: as of January 1, 2017*, The Henry J. Kaiser Fam. Found., http://kff.org/health-reform/state-indicator/state-activity-around-expanding-medicaid-under-the-affordable-care-act/?currentTimeframe=0&sortModel=%7B%22colId%22:%22Location%22,%22sort%22:%22asc%22%7D (last visited Mar. 14, 2017).

With or without expansion, the costs of Medicaid are a major financial stress in every state and territory's budget. Such stress often leads to reductions in payment to providers and physicians, which can reduce access to care. In fact, a 2014 study found that, from the 15 major metropolitan areas surveyed, the average overall rate of Medicaid acceptance was 45.7% and that cardiologists averaged the highest rate of acceptance.[20] According to a 2015 Kaiser Family Foundation article, an estimated 67% of primary care physicians accept Medicaid but are not taking new Medicaid patients.[21]

States are continually looking for ways to reduce their share of the Medicaid costs. One of the favored options is reducing choice by forcing Medicaid recipients into capitated managed care plans.

Point Counterpoint: Explosive Growth and Cost Containment

The 1970s experienced a tug-of-war of sorts: As the cost of Medicare and Medicaid continued to outgrow all actuarial predictions, the government sought ways to both constrain the outlays for the programs and expand coverage to more Americans. Although President Nixon achieved a consensus with the Democratic Congressional leadership on a national health insurance plan, the agreement subsequently unraveled under the weight of added demands by Congressman Wilbur Mills and the Watergate scandal.

Congress did, however, amend the Hospital Survey and Construction Act, known as the **Hill-Burton Act**, which required hospitals that received federal construction funding to provide uncompensated care to indigent patients for a period of 20 years after receipt of funds.[22] Under the 1976 amendments,

20 *See* Tammy Worth, *Treating Medicaid Patients*, Medical Economics (Feb. 18, 2015), *available at* http://medicaleconomics.modernmedicine.com/managed-healthcare-executive/news/treating-medicaid-patients?page=full.

21 *See* Christina Boccuti et al., *Primary Care Physicians Accepting Medicare: A Snapshot* (Figure 1), The Henry J. Kaiser Fam. Found., (Oct. 30, 2015), *available at* http://kff.org/medicare/issue-brief/primary-care-physicians-accepting-medicare-a-snapshot/.

22 Title VI of the Public Health Service Act (Hospital Survey and Construction Act), Pub. L. No. 79-725, 60 Stat. 1040 (1946).

Hill-Burton funded hospitals are required to provide uncompensated services and participate in the federal Medicare/Medicaid programs in perpetuity.[23]

The Nixon administration did manage to implement in four phases between 1971 and 1974 the **Economic Stabilization Program** (ESP). The program enacted a 90-day national wage and price freeze in 1971 and imposed wage and price controls on physician fees and hospital charges between November 1971 and April 1974.[24] The ESP also included controls on hospital admissions and stays, but these were never implemented.

During this time, the **Social Security Act Amendments of 1972** (i) expanded coverage by adding individuals with disabilities and those on renal dialysis as Medicare-eligible groups, (ii) authorized the states to establish planning agencies at the state's option for reviewing capital expenditures greater than $100,000 (Section 1122 Review), and (iii) established the first anti-kickback provisions applicable to the Medicare and Medicaid programs.[25]

In 1973, unable to reach a consensus on health care reform, Congress enacted the federal **Health Maintenance Organization Act of 1973** to foster market-oriented competition in health care.[26]

The following year, the **National Health Resources Planning and Development Act** (NHRPDA) provided for the regulatory approval of health-related capital expenditures in excess of $150,000 to constrain supply.[27] Under the NHRPDA, providers were required to apply to the state health planning and development agency (SHPDA) for "certificate of need" (CON) approval. The

23 Title XVI of the National Health Planning and Resources Development Act of 1974, Pub. L. No. 93-641, 88 Stat. 2258 (1976); 42 C.F.R. § 124.603.

24 Ronald J. Ozminkowski et al., *Hospital Wage and Price Controls: Lessons from the Economic Stabilization Program*, 16 Health Care Financing Rev. 13 (1994), *available at* www.ncbi.nlm.nih.gov/pmc/articles/PMC4193497/pdf/hcfr-16-2-13.pdf.

25 Social Security Amendments of 1972, Pub. L. No. 92-603, 86 Stat. 1329 (1972), *available at* www.gpo.gov/fdsys/pkg/STATUTE-86/pdf/STATUTE-86-Pg1329.pdf.

26 Health Maintenance Organization Act of 1973, Pub. L. No. 93-222, 87 Stat. 914, § 2 (1973), *available at* http://uscode.house.gov/statutes/pl/93/222.pdf; 42 U.S.C. § 300e–300e-17.

27 National Health Planning and Resources Development Act of 1974, Pub. L. No. 93-641, 88 Stat. 2225 (1975), *available at* www.gpo.gov/fdsys/pkg/STATUTE-88/pdf/STATUTE-88-Pg2225.pdf (formerly codified at 42 U.S.C. §§ 300k–n-6), *repealed by* Pub. L. No. 99-660, 100 Stat. 3743, tit. VII, § 701(a) (1986), *available at* www.gpo.gov/fdsys/pkg/STATUTE-100/pdf/STATUTE-100-Pg3743.pdf.

SHPDA would then review the appropriateness of existing health services, analyze the "need" for additional beds, equipment and technology (within the parameters dictated by the law), and make CON determinations on the basis of this assessment. Congress repealed the NHRPDA in 1986.[28]

In 1974, the **Employee Retirement Income Security Act** (ERISA) established a statutory scheme for the regulation of self-funded employee health benefit plans.[29] ERISA preemption of state insurance laws sparked an explosion of court cases involving medical negligence claims under managed care.

Two years later in 1976, Congress passed the **HEW Inspector General Act**,[30] which mandated the creation of an Office of Inspector General within the Department of Health, Education, and Welfare (HEW). Charged with auditing and investigating HEW programs, Congress vested the OIG with full functional autonomy to carry out its internal monitoring functions.

In 1977, Congressional hearings concluded that existing penalties were insufficient to deter Medicare and Medicaid fraud and abuse, so Congress passed the **Medicare/Medicaid Anti-Fraud and Abuse Amendments**, which elevated fraud and abuse violations to felony status subject to a five-year imprisonment term, a $25,000 fine, or both.[31] This increase from misdemeanor to felony is one of the most significant cost control measures enacted in the 50-year history of the Medicare program. It completely changed the fiscal mentality of "Just claim/bill it because if the auditors disagree, they will just disallow it." Now, this type of payment/reimbursement dispute is subject to years in prison and tens of thousands of dollars in fines and penalties. By a

28 *Id.*

29 Employee Retirement Income Security Act, 29 U.S.C. §§ 1001–1461.

30 Health, Education, and Welfare Inspector General Act, Pub. L. No. 94-505, 90 Stat. 2429 (1976), *available at* http://uscode.house.gov/statutes/pl/94/505.pdf. The result of the 1976 creation of the OIG, combined with the 1977 increase in penalties for violations of the Anti-Kickback Law, and then the 1983 Stark Law, is the position of Health Care Compliance Officer. This then occasioned the creation of the Health Care Compliance Association (HCCA).

31 Medicare-Medicaid Anti-Fraud and Abuse Amendments, Pub. L. No. 95-142, 91 Stat. 1175 (1977), *available at* www.gpo.gov/fdsys/pkg/STATUTE-91/pdf/STATUTE-91-Pg1175.pdf; 42 U.S.C. § 1320a-7b.

mere stroke of the pen, Congress turned old-fashioned payment disputes into criminal allegations.

President Carter's proposed **Hospital Cost Containment Act** of 1977, which is viewed as the precursor to a national health insurance plan, tied hospital rate increases to the growth rate in the consumer price index and capped them at nine percent per year.[32] The hospital industry responded with a nationwide "voluntary" rate control effort that lasted less than two years.

That same year, HEW reorganized and established the **Health Care Financing Administration** (HCFA), which transferred the responsibility for the administration of the Medicare and Medicaid programs from HEW to HCFA (now CMS).[33] As the 1970s came to a close, Congress created in 1979 a separate cabinet-level department for education and renamed HEW to reflect this change.[34] The newly named **Department of Health and Human Services** (HHS) became effective May 4, 1980.

Changing Focus: Outpatient Services and Alternative Delivery Arrangements

The 1980s brought new attempts to improve the cost-containing measures of previous years by changing the financial incentives that drove providers to provide more treatment for more payment. Creation of a prospective payment system, the revival of a 19th century statute, and the development and application of a resource-based relative value of a physician's medical care all worked towards reducing payments for services provided to Medicare and Medicaid beneficiaries.

Drawing on principles developed under Nixon's Economic Stabilization Program, the **Tax Equity and Fiscal Responsibility Act of 1982** (TEFRA)

32 Hospital Cost Containment Act of 1977, H.R. Res. 9717, 95th Cong. (1977), *available at* www.congress.gov/bill/95th-congress/house-bill/9717.

33 CMS, Medicare & Medicaid: Milestones 1937-2015 3 (2015), *available at* www.cms.gov/About-CMS/Agency-Information/History/Downloads/Medicare-and-Medicaid-Milestones-1937-2015.pdf.

34 Department of Education Organization Act, Pub. L. No. 96-88, 93 Stat. 668 (1979), *available at* www.gpo.gov/fdsys/pkg/STATUTE-93/pdf/STATUTE-93-Pg668.pdf; 20 U.S.C. § 3508.

required Medicare to pay hospitals for "reasonable costs" subject to a limit established by the Act (i.e., the "TEFRA limit") and set the stage for the enactment of a DRG-based payment system by Congress the following year.[35]

In 1983, after more than a decade of failing to control governmental outlays by reducing the payments for services provided and attacking the financial incentives that encouraged the mentality of providing more services, increasing days, and ordering more tests, Congress acted to impact the volume of services provided by changing the financial incentives. Under the **Medicare Prospective Payment System** (PPS), hospitals are paid a predetermined flat rate for inpatient care that is based on the patient's diagnosis at discharge.[36] The full PPS amount is paid for each stay during which there is at least one Medicare payable "day of care." Inpatient hospital PPS uses diagnosis related groups (DRGs) to calculate the inpatient hospital payment rate. Developed by Yale University as a patient care management system in 1969, the DRG method groups diseases by diagnosis and assigns them into case types that consider, among other things, the amount of resources needed to treat the condition. Costs incurred in excess of the PPS amount are absorbed by the hospital.

The impact of the PPS initiative cannot be overstated. It changed the cost and payment narrative forever.[37] While the 1983 Act "only" applied to inpatient hospital care, it would eventually become the base of virtually all Medicare provider payments as we know them today. In short, the provider mindset of "do more, get paid more" changed to "do less, do it quickly, and make more!"

In 1986, Congress dusted off and significantly amended a Civil War era statute, the **False Claims Act** (FCA) to combat all forms of government procurement and contracting fraud, including Medicare and Medicaid fraud.[38]

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35 Tax Equity and Fiscal Responsibility Act of 1982, Pub. L. No. 97-248, 96 Stat. 324 (1982), *available at* https://history.nih.gov/research/downloads/PL97-248.pdf (codified as amended at 42 U.S.C. § 1395x(v)(1)). The "cost with TEFRA limit" reimbursement scenario is set out in 42 C.F.R. §§ 412.22, 413.40.

36 Social Security Amendments of 1983, Pub. L. No. 98-21, 97 Stat. 65 (1983), *available at* www.gpo.gov/fdsys/pkg/STATUTE-97/pdf/STATUTE-97-Pg65.pdf (codified as amended at 42 U.S.C. § 1395ww(d)); 42 C.F.R. pt. 412.

37 It also led to an explosion in the growth of outpatient care and a new outpatient care industry.

38 31 U.S.C. § 3729.

The FCA imposes civil liability on persons or corporations who "knowingly" present a false or fraudulent claim for payment to the United States. Violations of the statute are subject to civil monetary penalties of $5,000 to $10,000 for each false claim filed plus treble damages and can result in exclusion from the Medicare and Medicaid programs. Under the FCA, a private individual (known as a "qui tam" plaintiff, "relator," or "whistle-blower") may initiate an FCA action on behalf of the federal government and receive a percentage of the recovery. If the government declines to intervene, the qui tam relator may pursue the FCA action on his or her own. As a result, qui tams proliferated. The expansion of the FCA together with the 1977 expansion of the Anti-Kickback Statute to felony status provided the basis of significant cost controls, enabling the OIG, Federal Bureau of Investigation (FBI) and the U.S. Department of Justice (DOJ) with enforcement hammers never before seen by any industry.

In 1987, Congress directed the OIG to establish **Safe Harbors under the Anti-Kickback Law** in the Medicare and Medicaid Patient and Program Protection Act of 1987.[39] This statute directed the HHS OIG to issue regulations that describe permissible activities under the Anti-Kickback Law and provided the OIG with administrative sanction authority.

Later in 1988, Congress passed the **Medicare Catastrophic Coverage Act**,[40] which required the OIG to study financial arrangements between physicians and health care entities. The Act also expanded Medicare coverage of inpatient hospital care and provided payment for outpatient prescription drugs and home intravenous (IV) therapy. In response to intense outrage by seniors who objected to paying an income-related premium for Part B services, Congress repealed the Act one year later.[41]

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39 Medicare and Medicaid Patient and Program Protection Act of 1987, Pub. L. No. 100-93, 101 Stat. 680 (1987), *available at* www.gpo.gov/fdsys/pkg/STATUTE-101/pdf/STATUTE-101-Pg680.pdf.

40 Medicare Catastrophic Coverage Act of 1988, Pub. L. No. 100-360, 102 Stat. 683 (1988), *available at* www.gpo.gov/fdsys/pkg/STATUTE-102/pdf/STATUTE-102-Pg683.pdf, *repealed by* Medicare Catastrophic Coverage Repeal Act of 1989, Pub. L. No. 101-234; 103 Stat. 1979 (1989), *available at* www.gpo.gov/fdsys/pkg/STATUTE-103/pdf/STATUTE-103-Pg1979.pdf.

41 *Id.*

As in 1983 when Congress sought to control costs and volume in the hospitals, in 1989 Congress turned its attention to the escalating costs of physician services. Congress established a new payment system under the **Omnibus Reconciliation Act of 1989** (OBRA) that paid physicians the lesser of the actual charge, or the amount determined from a **resource-based relative value scale (RBRVS)** fee schedule.[42] Developed by the Harvard School of Public Health under the direction of William Hsiao, the fee schedule is based on the relative value of a physician's work (i.e., intensity of effort, skill, and medical judgment) as adjusted for geographic, practice, and malpractice expense variations.

In compliance with the Medicare Catastrophic Coverage Act mandate to study physician financial arrangements, the OIG recommended that CMS require **disclosure of physician ownership** interest in health care businesses and/or prohibit selfreferrals.[43] The OIG also issued the first **Special Fraud Alert** identifying fraudulent and abusive practices within the health care industry, printing and distributing the alert directly to all Medicare providers.[44] The Ethics in Patient Referrals Act or physician self-referral statute (also known as the **Stark Law** or Stark I) was enacted as part of OBRA '89, and it prohibited a physician from referring Medicare/Medicaid patients to a clinical laboratory in which the physician (or immediate family member) has a financial relationship.[45]

Reform Redux: Coverage, Cuts, Contraction, and Compliance

The 1990s brought a redux of reforms through the issuance of several new safe harbors under the federal Anti-Kickback Law and the Health Insurance

42 Omnibus Budget Reconciliation Act of 1989, Pub. L. No. 101-239, 103 Stat. 2106 (1989), *available at* www.gpo.gov/fdsys/pkg/STATUTE-103/pdf/STATUTE-103-Pg2106.pdf [hereinafter *Omnibus Budget Reconciliation Act of 1989*]; 42 U.S.C. § 1395w-4(a)-(j); 42 C.F.R. pt. 414.

43 OIG, Financial Arrangements Between Physicians and Health Care Businesses: Report to Congress (1989), *available at* https://oig.hhs.gov/oei/reports/oai-12-88-01410.pdf.

44 OIG, Special Fraud Alert: Joint Venture Arrangements (1989), *available at* https://oig.hhs.gov/fraud/docs/alertsandbulletins/121994.html.

45 *Omnibus Budget Reconciliation Act of 1989*; 42 U.S.C. § 1395nn.

Portability and Accountability Act, to name a few. Not all efforts at new reforms succeeded, however, such as the Boren Amendment.

In 1990, the U.S. Supreme Court ruled that the **Boren Amendment** created a right to adequate payment.[46] Congress had enacted the Boren Amendment in 1980 to provide states with greater flexibility in structuring provider payment rates.[47] The Boren Amendment required Medicaid payments to be reasonable, adequate, and sufficient to attract providers and maintain adequate levels of services and care commensurate with the general population in a given geographic area. According to the Supreme Court, the Boren Amendment "created a substantive federal right to adequate reimbursement" that could be enforced by health care providers. The high court's decision produced an onslaught of state Medicaid payment litigation. Congress repealed the Boren Amendment in 1997.[48]

The OIG issued the **first safe harbors** on July 29, 1991, delineating 13 activities that would not be subject to prosecution or exclusion under the federal Anti-Kickback Law.[49] OBRA of 1993 expanded the Stark I Physician Self-Referral Law in an amendment commonly referred to as **Stark II** by including the following "designated health services:" (i) clinical laboratory services, (ii) radiology services, (iii) occupational therapy services, (iv) durable medical equipment (DME), (v) radiation therapy services, (vi) outpatient prescription drugs, (vii) parenteral and enteral nutrients, equipment and supplies, (viii) home health services, (ix) prosthetics, orthotics and prosthetic devices, and (x) inpatient and outpatient hospital services.[50]

In 1994, the Clinton Administration granted an unprecedented number of statewide **Medicaid demonstration waivers**, more than any previous adminis-

46 Wilder v. Va. Hosp. Ass'n, 496 U.S. 498, 524 (1990).

47 Omnibus Reconciliation Act of 1980, Pub. L. No. 96-499, 94 Stat. 2599 § 962(a) (1980), *available at* www.govtrack.us/congress/bills/96/hr7765/text/enr, *repealed by* Balanced Budget Act of 1997, Pub. L. No. 105–33, 111 Stat. 251 (1997), *available at* www.gpo.gov/fdsys/pkg/PLAW-105publ33/pdf/PLAW-105publ33.pdf [hereinafter *BBA*]; formerly codified at 42 U.S.C. § 1396a(a)(13)(E).

48 *Id.*

49 42 C.F.R. § 1001.952.

50 Omnibus Budget Reconciliation Act of 1993, Pub. L. No. 103-66, 107 Stat. 312 (1993); 42 U.S.C.A. § 1395nn(h)(6).

tration. As a result, more than half of the states are now operating under Medicaid waivers.[51]

In 1995, HHS published the final **Stark I regulations** in the Federal Register, which interpreted the billing and referral restrictions relating to clinical laboratory services.[52] A year later in 1996, Congress implemented the **Health Insurance Portability and Accountability Act** (HIPAA), a series of reforms to improve health insurance portability and continuity, control fraud and abuse in federal health programs, and initiate administrative simplification.[53] As with most statutory schemes, the Act had a cost to the industry. HIPAA created large increases in costs of compliance.[54] Those costs are passed on to the consumer through increased charges and ultimately to the payers. Specifically, HIPAA requires insurance companies to make individual policies available to persons who lose their group coverage and to ensure that an individual beneficiary is not denied enrollment or other benefits because of health status. Health insurers are also required to renew group health coverage, subject to certain exceptions, including, among other things, nonpayment of premiums, fraud, and violation of participation or contribution rules. According to the OIG, HIPAA "was the portal through which the HHS OIG moved into a new era. The Act not only guaranteed a stable funding source for the OIG, but also provided for funding increases."[55]

HIPAA also (i) created a new criminal code provision for federal health care related offenses, (ii) established new criminal penalties for the disposing of assets to qualify for Medicaid, (iii) extended the application of health care

51 *See* www.medicaid.gov/medicaid/section-1115-demo/demonstration-and-waiver-list/waivers_faceted.html.

52 Medicare Program; Physician Financial Relationships With, and Referrals to, Health Care Entities That Furnish Clinical Laboratory Services and Financial Relationship Reporting Requirements, 60 Fed. Reg. 41914 (Aug. 14, 1995) (codified at 42 C.F.R. pt. 411).

53 Health Insurance Portability and Accountability Act of 1996, Pub. L. No. 104-191, 110 Stat. 1936 (1996), *available at* www.gpo.gov/fdsys/pkg/PLAW-104publ191/pdf/PLAW-104publ191.pdf.

54 Deeb Salem, *HIPAA's Privacy Regulations: Increased Privacy Comes at a Cost*, Medscape (Sept. 24, 2003).

55 OIG, A Brief History of the HHS OIG (2001), *available at* www.kinneyassoc.com/MedEdHistory/historyhhsoig.pdf.

anti-fraud and abuse sanctions to all federal and state health care programs,[56] (iv) revised Medicare and Medicaid fraud and abuse sanctions and program exclusions, (v) established new civil monetary penalties for certain fraud and abuse activities, and (vi) established a new intent threshold for the imposition of civil monetary penalties.

Medicare Part A Trust Fund on the Brink of Bankruptcy—Again

The late 1990s and early 2000s saw efforts by the Clinton, Bush, and Obama administrations to address the impossible task of neutralizing tensions created by constant demands for both more health care and lower costs, ranging from the Balanced Budget Act to the Affordable Care Act. At some point, we may face the sobering possibility that the federal government and insurers may no longer effectively cover the full range of health care services we have come to expect. In fact, many argue that Medicare has not been able to do so for decades, relying on general tax revenues.

President Clinton signed the **Balanced Budget Act** (BBA) into law on August 7, 1997, making deep funding cuts to providers.[57] The product of two and one-half years of political wrangling between the President and Congress, the BBA was projected to produce a net savings of $115 billion for Medicare and $13 billion for Medicaid over five years.[58] Government forecasters predicted that the BBA would slow the growth rate in Medicare spending to 6% per year. What actually occurred, however, was a rapid reversal in spending growth that culminated with an unprecedented -1% decline in 1999.[59]

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56 HIPAA excluded the Federal Health Benefit Program from this provision; however, this omission was corrected by the Balanced Budget Act.

57 *BBA*.

58 It is important to note that the BBA actually reduced Medicaid spending by an additional 40% since the states did not have to match their share of the $13 billion federal reduction.

59 *See generally* Cathy A. Cowan et al., *National Health Expenditures, 1998,* 21 Health Care Financing Rev. 165 (1999), *available at* www.ncbi.nlm.nih.gov/pmc/articles/PMC4194653/pdf/hcfr-21-2-165.pdf; Cathy A. Cowan et al., *National Health Expenditures, 1999,* 22 Health Care Financing Rev. 77 (2001), *available at* www.ncbi.nlm.nih.gov/pmc/articles/PMC4194743/pdf/hcfr-22-4-077.pdf.

Although the BBA established a new children's health care initiative and provided $24 billion in coverage benefits for uninsured children over five years, a more common theme that emerged from its enactment is the reduced spending growth through provider payment cuts, diminishing federal payments to the states, and greater state freedom to set Medicaid payment and reduce provider rates. The BBA also eliminated certain federal requirements for enrolling Medicaid recipients in managed care, repealed the controversial Boren Amendment, and reduced disproportionate share hospital (DSH) payments so as to "avoid undue hardship" on any state.

The BBA substantially overhauled Medicare managed care. It restructured the payment methodology for Medicare risk contracts and established new managed care coverage options under Medicare Part C. The BBA also called for an unprecedented expansion of PPS to other facility types by requiring the concurrent phase-in of multiple payment systems for skilled nursing facilities, home health care agencies, outpatient departments, ambulatory surgical centers, rehabilitation hospitals, psychiatric hospitals, and long term care hospitals. More amazing is the fact that the BBA did all of this within five years!

A number of the President's proposed anti-fraud and abuse initiatives, including new civil monetary penalties for Anti-Kickback Law violations and program exclusion of convicted felons, were included within the BBA. Other fraud and abuse provisions called for the issuance of Stark Law advisory opinions, the posting of substantial surety bonds by certain providers, and the tracking of referrals to post-acute care facilities.

The BBA's economic impact on the health care industry is both staggering and immediate. Some statistics from 1998–99:

- 26% of hospitals suffered a negative profit margin.[60]
- 42 hospitals closed.[61]

60 Deanna Bellandi & Ann Saphir, *Location, Location, Location,* Modern Healthcare, Dec. 20–27, 1999, at 8.

61 Am. Hosp. Ass'n, *Trend Watch,* AHA News, Nov. 22, 1999, at 4.

- Nearly 120 nonprofit hospitals suffered downgrades on their bond ratings; bond upgrades declined by more than 50%.[62]
- The average share price of health industry stocks (all sectors) plunged 20%.[63]
- Over 2,500 home health agencies (out of 8,500 total) closed.[64]
- Medicare spending growth by sector plunged: 2.5% for hospitals, -11% for skilled nursing facilities, and -15% for home health agencies.[65]

In 1998, CMS began issuing and posting **advisory opinions on Stark Law** to the agency's website. Also in 1998, United States **Deputy Attorney General Eric H. Holder, Jr. issued a memorandum** containing guidance for U.S. Attorneys regarding the use of the False Claims Act in civil health care matters.[66] The memo, which emphasized the importance of pursuing civil FCA actions against health care providers in a fair, even-handed, and consistent manner, instructed DOJ attorneys to (i) first inquire if a false claim exists, (ii) verify the accuracy of the data upon which the DOJ is relying, and (iii) use contact letters before a specific demand is made.

On October 17, 2000, President Clinton signed into law the **Children's Health Act of 2000**, expanding funding for children's health care.[67] The bill

62 Am. Hosp. Ass'n, *Moody's Forecasts Tough Times Ahead for Hospitals,* AHA News Now; Deanna Bellandi, *Moody's Forecast: Stormy, Then Sunny,* Modern Healthcare, Jan. 10, 2000, at 6.

63 *Healthcare Stocks Plunged in 1999, Jenks List Survey Reveals,* Healthcare Intelligence Network.

64 In 1997, three-fifths of all home health agencies operating in the U.S. were hospital-based. Harris Meyer, *Home (Care) Improvement: Medicare has Fueled a Boom in Home Health. But the President's Reforms May Change All That,* Hosps. & Health Networks, Apr. 20, 1997, at 40. Ann Saphir, *Portrait of an Industry in Turmoil*, Modern Healthcare, Dec. 20-27, 1999, at 58.

65 Cong. Budget Office, An Analysis of the President's Budgetary Proposals for Fiscal Year 2000: A Preliminary Report (1999), *available at* www.cbo.gov/sites/default/files/106th-congress-1999-2000/reports/ppb03-99.pdf.

66 Memorandum from Eric H. Holder, Jr., Deputy Attorney Gen. to All U.S. Attorneys, All First Assistant U.S. Attorneys, All Civil Health Care Fraud Coordinators in the Offices of U.S. Attorneys, & All Trial Attorneys in the Civil Div. Commercial Litig. Section, Guidance on the Use of the False Claims Act in Civil Health Care Matters (June 3, 1998), *available at* www.justice.gov/archives/dag/memo-guidance-use-false-claims-act-civil-health-care-matters-june-3-1998.

67 Children's Health Act of 2000, Pub. L. No. 106-310, 114 Stat. 1101 (2000), *available at* www.gpo.gov/fdsys/pkg/PLAW-106publ310/pdf/PLAW-106publ310.pdf.

authorized, among other things, increased appropriations to children's hospitals for direct expenses associated with operating approved graduate medical residency training programs.

Later that same year on December 21, President Clinton signed into law The **Medicare, Medicaid and SCHIP Benefits Improvement and Protection Act** (BIPA), which represented a second attempt by Congress to moderate the financial blows dealt to providers by the BBA.[68] Estimated to restore approximately $35 billion in funding cuts to providers and Medicaid managed care plans over five years, the new law (i) expanded preventative health care benefits for Medicare beneficiaries, (ii) increased reimbursement for participating hospitals, skilled nursing facilities, home health agencies, hospice and rural providers, (iii) raised the annual capitation rate for M+C HMOs, (iv) increased the Medicaid DSH allotment, and (v) enhanced funding for state children's health insurance programs (SCHIP) under certain circumstances. The vast majority of rate increases provided by BIPA, however, did not carry forward in federal fiscal year 2002 and beyond.

In 2000, the U.S. Department of Justice released its civil fraud recovery statistics for the federal fiscal year, which was hailed by the Attorney General for collecting a record **$1.5 billion from settlements and judgments under the civil False Claims Act**, almost 50% higher than any previous year.[69] Of the total recovery amount, health care fraud represented $932 million.[70]

In 2001, HHS published the long-awaited **Stark II final rules** implementing additional provisions of the physician self-referral law.[71] The regulations, Phase I of a two part publication process, addressed the general referral and billing prohibition set forth in Stark II; the definitions establishing the scope of

68 Medicare, Medicaid and SCHIP Benefits Improvement and Protection Act of 2000, Pub. L. No. 106-554, 114 Stat. 2763 (2000), *available at* www.gpo.gov/fdsys/pkg/PLAW-106publ554/pdf/PLAW-106publ554.pdf.

69 *See* Civil Div., U.S. Dep't of Justice, Fraud Statistics–Overview (2016), *available at* www.justice.gov/opa/press-release/file/918361/download. DOJ has since routinely announced $1B plus annual recoveries.

70 *Id.*

71 Medicare and Medicaid Programs; Physicians' Referrals to Health Care Entities With Which They Have Financial Relationships, 66 Fed. Reg. 856 (Jan. 4, 2001) (codified at 42 C.F.R. pts. 411 & 424) [Phase I].

the restrictions, including the group practice definition; exceptions relating to both ownership and compensation relationships, including the in-office ancillary services exception; and three new exceptions.

Two years later in 2003, the U.S. Supreme Court held that two state "**any willing provider" (AWP) statutes were not federally preempted** and may be enforced against HMOs that offer qualified ERISA employee benefit plans in Kentucky.[72]

That same year, CMS issued a **final rule revising its outlier payment policies**[73] after an OIG audit of hospitals owned by Tenet Healthcare Corporation found that the company's cost outliers had comprised an escalating percentage of total inpatient payments (22% in FY 2003), believing that some hospitals may have been attempting to game the current payment systems for purposes of maximizing reimbursement.

In December 2003, President Bush signed the **Medicare Prescription Drug, Improvement and Modernization Act** (MMA) into law.[74] The hefty 678-page Act represented the largest single transformation of the Medicare program since its inception in 1965. Most notably, the MMA added a prescription drug benefit (Part D) for Medicare beneficiaries that would be administered through private insurance plans or pharmacy benefit managers. It also established a transitional drug discount card program that would remain in effect until the drug benefit became operational in 2006. The importation of drugs from Canada also was authorized subject to certification by the HHS Secretary regarding safety and cost.

Many substantive changes were made to the Medicare+Choice program, including a change of name to "MedicareAdvantage." A new regional preferred provider organization (PPO) option, available to beneficiaries in 2006, oper-

72 Ky. Ass'n of Health Plans v. Miller, 538 U.S. 329, 334 (2003).

73 Medicare Program; Change in Methodology for Determining Payment for Extraordinarily High-Cost Cases (Cost Outliers) Under the Acute Care Hospital Inpatient and Long-Term Care Hospital Prospective Payment Systems, 68 Fed. Reg. 34494 (June 9, 2003) (codified at 42 C.F.R. pt. 412).

74 Medicare Prescription Drug, Improvement, and Modernization Act of 2003, Pub. L. No. 108-173, 117 Stat. 2066 (2003), *available at* www.gpo.gov/fdsys/pkg/PLAW-108publ173/pdf/PLAW-108publ173.pdf.

ated using competitive bidding and benchmark rates. Numerous economic improvements were also made to Medicare Part C, including a significant rate increase for managed care plans as well as a new $10 billion stabilization fund.

Other notable changes included institutionalizing Medicare Medical Savings Accounts as a permanent option for seniors, establishing new tax-favored Health Savings Accounts for individuals not of retirement age, and creating new federal subsidies for employment-based retiree health insurance coverage.

Estimated by the Congressional Budget Office to cost nearly $395 billion over 10 years, the MMA increased payments to providers, physicians, and suppliers by some $11 billion over 5 years.[75] The new largess was not, however, spread evenly among this group. Home health, clinical laboratory, and DME suppliers were all subject to significant cuts and freezes under the MMA.

Hospitals were the clear dollar winners in the MMA sweepstakes, especially those in rural areas. The new law sweetened payment for critical access hospitals, rural referral centers, low-volume hospitals, and disproportionate share hospitals. Physicians did not fare too badly either. The MMA eliminated the budget neutrality adjustment from the physician fee schedule for 2004 and 2005, which would have resulted in a 4.5% decrease in payments to physicians.[76] As a result, physicians saw a 1.5% increase in payment from Medicare for 2004.[77] The new law also attempted to address some of the volatility in payment updates to the physician fee schedule by incorporating a 10-year rolling average factor in the sustainable growth rate. Other changes beneficial for physicians included a modified payment for drug administration costs.

Starting in FY 2005, eligible hospitals, physicians, and ambulance suppliers began receiving payment for emergency health services to undocumented aliens. The MMA appropriated $250 million per year for this purpose through FY 2008. Of the $250 million, $167 million was used to pay eligible providers.

75 *See* The Henry J. Kaiser Family Found., Fact Sheet: Medicare Advantage (2016), *available at* http://files.kff.org/attachment/Fact-Sheet-Medicare-Advantage.

76 Jennifer O'Sullivan, Cong. Research Serv., Medicare: Payments to Physicians CRS-10 (May 13, 2005).

77 *Id.*

The remaining $83 million was allotted to the six states with the highest number of undocumented alien apprehensions in a given year.

On March 26, 2004, HHS published the long awaited **Stark II, Phase II regulations**, the second phase of the final regulations addressing the physician self-referral statute.[78] Phase II addresses the categories of physician ownership exceptions, including the whole hospital ownership exception as modified by Congress for ownership in specialty hospitals,[79] and compensation exceptions, including the exceptions for space and equipment rental, personal service and employment relationships, and physician recruitment. New regulatory exceptions were established, including one for professional courtesy discounts offered by hospitals to medical staff members. Other noteworthy items included a new exception to enable participation by physicians in community-wide health information systems, restrictions in the physician recruitment exception relating to recruitment of physicians to existing groups, and guidelines on establishing fair market value compensation.

The number of **pay for performance programs** more than doubled between 2003–2005, totaling more than 100.[80] In March 2005, the Medicare Payment Advisory Commission (MedPAC) endorsed establishing a quality incentive payment policy for hospitals in Medicare.[81] The three-year Medicare pay-for-performance demonstration project, which began in October 2003, released preliminary reports from the more than 270 participating hospitals showing a significant improvement in quality of care.

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78 Medicare Program; Physicians' Referrals to Health Care Entities With Which They Have Financial Relationships (Phase II), 69 Fed. Reg. 16054 (Mar. 26, 2004) (codified at 42 C.F.R. pts. 411 & 424).

79 Medicare Prescription Drug, Improvement, and Modernization Act of 2003, Pub. L. No. 108-173. 117 Stat. 2066 § 507 (2003), *available at* www.gpo.gov/fdsys/pkg/PLAW-108publ173/pdf/PLAW-108publ173.pdf (specialty hospitals).

80 *Examining Pay-for Performance Measures and Other Trends in Employer Sponsored Health Care: Hearing Before the H. Subcomm. on Employer-Employee Relations* (2005) (statement of Meredith B. Rosenthal, Assistant Professor of Health Econ. & Policy, Harvard Sch. of Pub. Health), *available at* www.commonwealthfund.org/~/media/files/publications/testimony/2005/may/examining-pay-for-performance-measures-and-other-trends-in-employer-sponsored-health-care/rosenthal_testimony_05-17-2005-pdf.pdf.

81 Medicare Payment Advisory Comm'n, Report to the Congress: Medicare Payment Policy (2005) *available at* www.medpac.gov/docs/default-source/reports/Mar05_EntireReport.pdf.

In February 2005, the OIG approved six advisory opinions permitting limited cardiology and cardiovascular **gainsharing arrangements**.[82] The OIG concluded that the gainsharing arrangements reviewed violated the rules against inducing physicians to limit or reduce care to federal health program beneficiaries as well as the Anti-Kickback Statute (assuming presence of the requisite wrongful intent). Nonetheless, due to safeguards built into each of the programs, the OIG concluded it would not take enforcement action against the respective parties. The OIG rulings suggested that the agency was becoming increasingly comfortable with respect to gainsharing arrangements; however, the scope of permissible gainsharing arrangements under the advisory opinions remained extremely narrow.

On January 1, 2006, Medicare began full implementation of the **Part D prescription drug benefit**.[83] The ten-year projected cost of the program was roughly $720 billion.[84] Part D enrollment was substantial, despite a rocky enrollment process. According to an HHS news release, as of Summer 2006, over 38 million people or 90% of Medicare beneficiaries received at least the standard prescription drug coverage through Part D.[85]

For beneficiaries and the states, the transition from Medicaid drug benefits to Part D was challenging. CMS, having identified potential problems for "dual eligibles" (Medicaid beneficiaries who are also eligible for Medicare) whose Medicaid drug coverage would end on December 31, 2005, released transition guidelines for the roughly six million people affected by this change.[86] Some states challenged the "clawback" provision, which required state payments to

82 HHS-OIG Advisory Opinions 05-01–05-06 (Feb. 2005).

83 *See* The Henry J. Kaiser Family Found., Fact Sheet: The Medicare Part D Prescription Drug Benefit (2016), *available at* http://files.kff.org/attachment/Fact-Sheet-The-Medicare-Part-D-Prescription-Drug-Benefit.

84 Press Release, CMS, Medicare Part D Spending Projections Down Again, Part A and Part B Increases Highlight Need for Further Reforms (July 11, 2006), www.cms.gov/Newsroom/MediaReleaseDatabase/Fact-sheets/2006-Fact-sheets-items/2006-07-11.html (last visited Mar. 25, 2017).

85 Press Release, HHS, Over 38 Million People with Medicare Now Receiving Prescription Drug Coverage (June 14, 2006), https://archive.hhs.gov/news/press/2006pres/20060614.html (last visited Mar. 25, 2017).

86 Press Release, CMS, Ensuring an Effective Transition of Dual Eligibles from Medicaid to Medicare Part D (Dec. 1, 2005), www.cms.gov/Newsroom/MediaReleaseDatabase/Fact-sheets/2005-Fact-sheets-items/2005-12-01.html (last visited Mar. 25, 2017).

the federal government for Medicaid drug cost saving due to Part D drug coverage.[87]

Many Part D beneficiaries discovered an unfortunate gap in coverage, the so-called "doughnut hole." The standard Part D plan had a $250 deductible and 25% beneficiary coinsurance for the first $2,250 in drug costs. After that, the beneficiary would be responsible for the next $2,850 toward prescription drug costs, as well as plan premiums. After spending that amount, the beneficiary would pay 5% of drug costs.[88] One proposed solution would require Medicare to bargain for lower drug prices, freeing up funds to fill in the coverage gap.

To address looming fraud issues within Part D, CMS issued in April 2006 fraud guidance for Part D drug plans, citing ways to prevent, detect, and correct potential fraud and abuse.[89] Part D sponsors were expected to incorporate recommendations by 2007. The OIG also approved several advisory opinions permitting some non-profit subsidization of part D premiums owed by financially needy patients.[90]

Signed into law on February 8, 2006, the **Deficit Reduction Act of 2005** (DRA) contains significant changes for the future of mandatory government spending on Social Security, Medicare, and Medicaid.[91] Upon passage, the

87 *See, e.g.*, Motion for Leave to File Bill of Complaint, Supporting Brief, and Bill of Complaint, Texas v. Leavitt, 547 U.S. 1204 (2006), *available at* www.oag.state.tx.us/newspubs/releases/2006/030306medicare_complaint.pdf.

88 *See generally* Medicare.gov, Costs in the Coverage Gap, www.medicare.gov/part-d/costs/coverage-gap/part-d-coverage-gap.html (last visited Mar. 27, 2017). In 2017, the coverage gap begins at $3,700.

89 CMS, Prescription Drug Benefit Manual: Chapter 9- Part D Program to Control Fraud, Waste, and Abuse (2006), *available at* www.cms.hhs.gov/PrescriptionDrugCovContra/Downloads/PDBManual_Chapter9_FWA.pdf.

90 HHS-OIG, Advisory Opinions 06-03, -04, -08, -09, -10, -13, and -14 (Apr. through Sept. 2006).

91 Deficit Reduction Act of 2005, Pub. L. No. 109-171, 120 Stat. 4 (2006), *available at* www.gpo.gov/fdsys/pkg/PLAW-109publ171/html/PLAW-109publ171.htm [hereinafter *Deficit Reduction Act of 2005*]. For an in-depth discussion on the health law provisions of the DRA, *see* Nat'l Conference of State Legislatures, Deficit Reduction Act of 2005: Summary of Medicaid/Medicare/Health Provisions (2006) *available at* www.ncsl.org/print/health/SumS1932Jan3106.pdf. For a summary of Medicare-related provisions that went into effect in 2006, *see* Press Release, CMS, Payment Provisions in the Original Medicare Program Immediately Affected by the Deficit Reduction Act (Feb. 10, 2006), www.cms.gov/Newsroom/MediaReleaseDatabase/Fact-sheets/2006-Fact-sheets-items/2006-02-102.html (last visited Mar. 25, 2017).

DRA was projected to save taxpayers nearly $40 billion over the next five years by slowing program growth and increasing program efficiency.[92] The DRA provides financial incentives for states to enact laws that establish liability to the state for individuals or entities that submit false or fraudulent claims to the state's Medicaid program.[93] The HHS OIG released guidelines for evaluating whether a state false claims law meets requirements imposed by the DRA, including liability provisions for false or fraudulent claims and provisions that reward and facilitate qui tam (whistleblower) actions.[94] If a state meets these requirements as of the effective date of January 1, 2007, any state recovery from a state action brought under a qualifying law will be increased by ten percentage points. Although a state is not required to enact a law meeting these requirements, it will not be eligible for the additional recovery if the enumerated requirements are not met.

On September 5, 2007, CMS published the **Stark Phase III Final Regulations**, expanding the reach of the Stark Law.[95] These final rules, posted on August 27, 2007, include clarifications and relatively minor modifications to the Phase II Interim Final Regulations that were issued in March 2004. Phase III focuses primarily on closing perceived loopholes, clarifying potentially confusing points, and taking a few baby steps toward giving health care entities some flexibility in uncontroversial areas.

Specifically, the rule eliminates the compensation safe harbors within the definition of Fair Market Value, provides greater flexibility in physician recruitment and retention for rural hospitals, expands the Non-Monetary Compensation exception to address circumstances of noncompliance, and allows an entity with a formal medical staff to provide one local medical staff appreciation event each year.

92 Press Release, The White House, Office of the Press Secretary, Fact Sheet: President Bush Signs the Deficit Reduction Act (Feb. 8, 2006), https://georgewbush-whitehouse.archives.gov/news/releases/2006/02/20060208-9.html (last visited Mar. 25, 2017).

93 *Deficit Reduction Act of 2005*.

94 Reimbursement Rates for Calendar Year 2006, 71 Fed. Reg. 48552 (Aug. 21, 2006).

95 Medicare Program; Physicians' Referrals to Health Care Entities with Which They Have Financial Relationships (Phase III), 72 Fed. Reg. 51012 (Sept. 5, 2007) (codified at 42 C.F.R. pts. 411 & 424).

In 2010, the **Patient Protection and Affordable Care Act** (ACA)[96] had a significant impact on private insurers and their interactions with the government, individuals, and providers. This fulfilled a long-held dream, at least temporarily. The Democrats—seeking a major change that would impact rising health care cost and health care delivery—had control of Congress and the White House, and the ACA was enacted without a single Republican vote. (Nancy Pelosi famously quipped, "We have to pass the bill so you can find out what is in it."[97]) The ACA intended to provide an umbrella of coverage to all Americans and was the attempted fulfillment of the dream for universal health coverage, first proposed by Teddy Roosevelt in his unsuccessful 1912 campaign for president and passionately championed by Ted Kennedy beginning in 1971 with the introduction of SB1. Virtually every Congressional session from 1971 to his death, Kennedy (at the urging of the AFL/CIO) introduced SB1 in hopes of bringing universal health care coverage to all Americans and reducing health care costs to the individual.

Unable to pass such legislation then and even now, the population of this country has been covered by a patchwork of coverage unlike any other nation. Beginning with union workers during the wage freezes of the WWII era, most workers receive health care coverage through their employers. Medicare provides coverage for Americans not employed over 65, disabled, or suffering end stage renal disease (ESRD), and Medicaid provides coverage for the poor, unemployed, or underemployed. All are coverage gap fillers that the Democrats sought to complete through coverage by the ACA. (Although through the ACA, most newly insured are forced into Medicaid, not private insurance.) While universal coverage was the goal of the ACA,[98] it remains elusive for many reasons. One of the most salient reasons is that a large portion of

96 Patient Protection and Affordable Care Act, Pub. L. No. 111-148, 124 Stat. 119 (2010), *available at* www.gpo.gov/fdsys/pkg/PLAW-111publ148/pdf/PLAW-111publ148.pdf.

97 Peter Roff, Opinion, *Pelosi: Pass Health Reform So You Can Find Out What's In It*, U.S. News, Mar. 9, 2010, *available at* www.usnews.com/opinion/blogs/peter-roff/2010/03/09/pelosi-pass-health-reform-so-you-can-find-out-whats-in-it.

98 The ACA also advanced value-based payment through Medicare cost-control experiments (including bundled payments for surgical procedures and follow-up care) as well as demonstration projects for Accountable Care Organizations (ACOs).

Americans (mostly young and healthy) simply do not want coverage at the price offered and will not be forced into buying it.[99]

Conclusion: Is Our Health Care System Becoming More British Than Canadian?

While the progressive left desires a Canadian style single payer system (there is almost no private medical care in Canada, resulting in 50,000 Canadians a year seeking care in the U.S.[100]) and points to the failures of the ACA as proof that private/public partnership does not work, this author does not believe the country is ready for the elimination of private medical care. Rather, the result of unintended consequences from the failed ACA will be more privatization, not less: A direct effect of the ACA's push towards universal coverage under one or more government programs has been the growth in privatization of the health care industry. We are seeing a surge in physicians refusing Medicaid and Medicare patients, turning exclusively to privately insured or cash-paying patients. Likewise, there is a significant growth in ancillary service providers not participating in government programs. The next step to a stand-alone private system will be full-service hospitals cutting ties to government programs. This move towards privatization could result in a national system similar to the British system where government-run health care exists and operates next to a thriving and profitable private system for those who want and can afford to pay for private health care.

While I am not suggesting, nor recommending, that the U.S. have a government-run, government-employed, Veterans Administration-like system, I am postulating that as the percentage of health care is paid for by the government

99 As an aside, the ACA reduced payment to Medicare by over $700 billion over 10 years.

100 Randi Druzin, *Crossing the Border for Care*, U.S. News, Aug. 3, 2016, *available at* www.usnews.com/news/best-countries/articles/2016-08-03/canadians-increasingly-come-to-us-for-health-care; *see also* Daniel Katz, *More Than 52,000 Canadians Travelled Abroad for Health Care Last Year, Study Finds*, Nat'l Post, Mar. 17, 2015, *available at* http://news.nationalpost.com/news/canada/number-of-canadian-patients-travelling-abroad-for-treatment-increased-by-25-study-finds.

(currently in excess of 50%[101]) continues to increase, most providers will become dependent upon government payment and will function as in a government-run system. Individuals with means will seek alternatives to this system, resulting in the creation of a uniquely private system of physicians, ancillary providers, and hospitals. Finally, insurance markets will develop complementary private insurance products for these individuals willing to spend to obtain more, if not better care. J

101 Everette James and Meredith Hughes, *Government-Sponsored Programs Make Up 52% of What We Spend on Healthcare*, Forbes Opinion, July 29 2015, https://www.forbes.com/sites/realspin/2015/07/29/for-the-first-time-government-programs-make-up-the-majority-of-u-s-health-spending/#12ff2c09137f (last visited Apr. 5, 2017).

J.D. Epstein's involvement with the Medicare program began in the late 1960s when he advised on both Medicare policy and implementation at the Blue Cross Association. When a formal provider payment appeal process was created at the Blue Cross Association in the late 1960s, J.D. served as counsel to the Appeals Board. J.D. moved to private practice in 1974 and, in 1975, handled the seventh case heard by the Provider Reimbursement Review Board (PRRB) and handled the first group appeal heard by the PRRB.

In the ensuing years, J.D. represented thousands of hospitals and other providers in hundreds of appeals before the agency and in the federal courts. His involvement continues to the present—through the nearly annual legislative changes designed to reduce program expenditures, through the revolutionary change from cost reimbursement to DRGs, and through coercive application of fraud and false claims statutes. J.D. not only understands the "big picture" of Medicare, but also is familiar with the minutiae and can cite little known Manual provisions, Federal Register commentary, or decisions.

J.D. has been active in multiple health care organizations, including the Catholic Healthcare Association, the Healthcare Financial Management Association, the Federation of American Hospitals, and the American Hospital Association. J.D. was also very much involved with Bar organizations, including serving as President of the American Academy of Hospital Attorneys and working with Len Homer for 21 years in creating and chairing the annual Institute on Medicare and Medicaid, an annual program that continues to this day under the sponsorship of the American Health Lawyers Association. J.D. remains an active Fellow with AHLA. Contact him via email at jepstein@greerherz.com.

—Dennis M. Barry *contributed this author profile.*

The author has used prior iterations of portions of this work for educational purposes. He thanks Kathleen P. Rubinstein of BakerHostetler and Jillian A. Sparks of Bradley Arant Boult Cummings for their contributions to the research for this Comment.

The Evolution of Patient Rights: Individual Benefits and Provider Burdens

S. Allan Adelman

What is the issue? Patients' rights have evolved significantly during the past 50 years, affording patients greater autonomy over treatment options and end-of-life decisions, as well as new rights concerning access to treatment, access to medical records, and privacy protections. The expansion of those rights, however, are not without costs and risks.

What is at stake? As patients' rights continue to expand, the provider community has experienced increased costs, sometimes substantial, as a result of efforts to comply with numerous laws and regulations. In addition, constant advances in medical research and genomics present ethical, legal, and privacy issues that the courts and/or Congress have yet to resolve, leaving providers and their advisors wondering what legal and operational burdens they might face in the future.

What do you need to know? In an ideal world, advances in patient rights could be achieved while simultaneously recognizing the stress and expense these advances impose on health care providers. Perhaps the requisite balance can only be achieved if funding is made available to cover the true costs associated with the development and implementation of policies relating to patient rights, as well as the training and oversight required to ensure those rights are routinely afforded and protected.

S. Allan Adelman, *The Evolution of Patient Rights: Individual Benefits and Provider Burdens*, J. Health & Life Sci. L., June 2017 at 66.

Adelman: Patient Rights

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Introduction

The evolution of patient rights and medical ethics over the last 50 years has been significant but not surprising, especially in light of changes that have occurred in other areas affecting the delivery of health care, including technology and reimbursement. In fact, many of the shifts in patient rights and ethics have been related to developments in such other areas. Key areas that have experienced significant changes in patient rights—and which are the focus of this Comment—are patient autonomy and decision making, the right to refuse treatment (including the right to die), the right to treatment regardless of ability to pay, rights related to privacy and medical records, rights addressed by Medicare, rights in connection with clinical research, and rights related to genetic information. This Comment examines the continuing evolution of these patient rights and ultimately questions the extent to which the commensurate provider burdens have been effectively recognized and addressed.

Increases in Patient Autonomy and Decision Making

A foundational principal of patient autonomy is the right of each individual to control decisions about what happens to his or her body. The concept of an unauthorized or unlawful touching in the course of providing health care treatment has been recognized since the early 20th Century.[1] Initially labeled as straightforward battery, it did not take long for the concept to be expanded beyond simple unlawful touching to include treatment that was considered to be negligently provided because the patient was not fully informed about the nature and expected consequences of the proposed treatment.

Obtaining informed consent has long been considered the treating physician's primary responsibility because the physician best understood the patient's condition and the potential risks and benefits of a given medical treatment for that particular patient. Obtaining informed consent involves the physician advising the patient of the nature of the proposed treatment and,

1 *See* Schloendorff v. Soc'y of N.Y. Hosp., 105 N.E. 92 (N.Y. 1914).

more importantly, any alternatives, including non-treatment and the common risks, potential complications, and anticipated benefits of each alternative. By the 1960s, the concept of "informed consent" was well formed, although differences in the application of the principle remained.

Courts have been divided between applying a physician-centered standard of informed consent and a patient-centered approach. The physician-centered standard holds that a physician must inform patients about the material risks, expected benefits, and reasonable alternatives associated with a proposed treatment consistent with what would be expected of a reasonably prudent physician—essentially, a negligence approach to informed consent.[2] The patient-centered approach, on the other hand, is further broken down into two different standards. The first standard requires disclosure of the risks, benefits, and alternatives that a reasonable patient would consider to be material to making an informed decision.[3] The second patient-centered standard allows for consideration of the particular fears and prejudices of each specific patient.[4] The latter, more subjective standard has largely been disfavored by the courts because physicians cannot possibly know each individual patient's relevant education, experiences, and biases to gauge what information a particular patient would consider material to his or her choices.[5] Even under the first patient-centered standard, however, establishing what a hypothetical reasonable patient would consider material is often a daunting task at trial because, in the absence of objective criteria, each individual juror invariably interprets "reasonable" based on his or her own personal experiences and expectations.

The uncertainty as to how much information should be communicated has led to the creation of increasingly long and complex informed consent notices,

2 *See, e.g.*, Curran v. Buser, 711 N.W.2d 562, 568 (Neb. 2006) (the standard of care in medical malpractice cases for informed consent is not determined by the doctor's personal or customary routine, but on the information doctors ordinarily supply to patients in similar circumstances and locations).

3 *See* Canterbury v. Spence, 464 F.2d 772, 787 (D.C. Cir. 1972).

4 *See* Ashe v. Radiation Oncology Assocs., 9 S.W.3d 119, 122 (Tenn. 1999) (explaining that under the subjective standard, patients must testify and prove that they would not have consented to the procedures had they been advised of the particular risk in question).

5 *Id.*

likely predicated on the belief that telling a patient absolutely everything about a proposed treatment and putting it in writing is the best defense to a lawsuit alleging a lack of informed consent. If, however, the intended purpose of this data dump is to help the patient make an informed decision regarding treatment, it is more often than not counterproductive.

Overwhelmed by a plethora of information, much of which addresses low probability risks and rare complications, patients have an increasingly difficult time effectively evaluating their options and understanding the impact of their choices. This is compounded by the fact that patients now obtain information about their condition and treatment alternatives from the internet.[6] Today, it is the rare patient who, after being diagnosed with a significant medical condition, does not immediately conduct an exhaustive internet search. Understandably, information relayed by the patient's physician can easily be diluted or even contradicted by the background noise of internet information, much of which may be entirely incorrect or inapplicable. The ability of physicians to adequately inform and guide their patients by prioritizing the materiality of information may be lost in the haze of fear and anxiety patients feel about their condition, uncertainty about the treatment(s) being proposed, and the fog of information from other sources.

The evolution of the concept of informed consent has, to date, largely overlooked the fact that the movement toward a more informed patient has focused almost entirely on aggregated statistical clinical data relating to the likely outcomes of treatment. That is to say, the information given to patients is based on statistical data regarding how often a particular treatment is successful and what the percentage chances are for an adverse outcome or an undesirable side effect. Patients are not typically provided with data related to other

6 Pamela Hartzband & Jerome Groopman, *Untangling the Web—Patients, Doctors, and the Internet*, 362 New Eng. J. Med. 1063 (2010), *available at* www.nejm.org/doi/pdf/10.1056/NEJMp0911938.

critical variables affecting treatment outcomes, such as the abilities and competency of the specific practitioner who will be providing the treatment.[7]

Information that could be equally, if not more, important to an informed decision may include: (i) the training and experience the treating physician has with the patient's condition and proposed treatment; (ii) how much of the procedure the physician will actually be performing versus a resident or other assistant; (iii) how often the physician has performed the proposed procedure and the physician's outcomes; (iv) the individual physician's complication or infection rate; and (v) patient satisfaction with the treatment provided by that specific physician. Even information about the physician's mental and physical ability to perform a procedure successfully, such as how much sleep the physician has had in the last 24 hours, how much alcohol was consumed in the last 12 hours, and any stressors in the physician's life, could be meaningful. Few patients, however, would be comfortable questioning a physician about such matters, and it would be most unusual for a physician, particularly one with lesser qualifications, to volunteer such information as part of the discussion of anticipated risks and benefits.

At least one study has suggested it is difficult to obtain accurate data regarding individual physicians' outcomes and more importantly, whether patients desire such information and would use it as part of their informed decision making process.[8] At the same time, others have argued that effective informed consent necessarily includes disclosure of information about the comparative clinical performance of available surgeons.[9] Meanwhile, the courts

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7 It is significant that The 2017 Joint Commission Hospital Accreditation Standards do not address providing information about individual practitioners' experience or outcomes. *See* The Joint Comm'n, Standard RI.01.03.01 ("The hospital honors the patient's right to give or withhold informed consent."); Element of Performance 9 ("The informed consent process includes a discussion about potential benefits, risks, and side effects of the patient's proposed care, treatment, and services; the likelihood of the patient achieving his or her goals; and any potential problems that might occur during recuperation.").

8 Ingrid Burger et al., *Disclosure of Individual Surgeon's Performance Rates During Informed Consent: Ethical and Epistemological Considerations*, 245 Annals Surgery 507 (2007), *available at* www.ncbi.nlm.nih.gov/pmc/articles/PMC1877054/pdf/20070400s00002p507.pdf.

9 Steve Clarke & Justin Oakley, *Informed Consent and Surgeons' Performance*, 29 J. Med. & Phil. 11 (2004).

have been divided regarding whether individual performance data is a required part of the informed consent process.[10]

Further complicating matters is the fact that obtaining informed consent is often treated only as the formality of obtaining the patient's signature on a form, rather than as an opportunity to help the patient understand the potential consequences of his or her decision. This author spoke to a physician who described the futility of discussing possible treatment options with a patient immediately after informing the patient that he has cancer. The trauma of the diagnosis would undoubtedly overwhelm the patient's ability to have a meaningful discussion about treatment options at that time. That is not to say that options should not be discussed, but there should be no expectation the patient will be able to truly understand and internalize treatment options during such a traumatic moment. For the same reason, there should be no expectation that a patient will fully comprehend a detailed consent form when it is presented to her for the first time on the morning of surgery. We must recognize that true informed consent is a state of mind such that when a surgeon reports, "Things did not go as we had hoped," the patient or family's reaction is not, "How could that happen?!," but rather, "OK, we knew that was a risk."

Despite these shortcomings or difficulties in implementing meaningful informed consent practices, the basic concept that patients have the right to make informed decisions about their treatment is now universally accepted and has led to a much greater awareness of patients' rights. Health care providers are shifting away from a paternalistic approach to patient care and moving towards a partnership approach. They are starting to focus less on the pure science of medicine and the statistical probability of a particular outcome. The need for meaningful discussions with patients about risks and alternatives associated with various treatments has prompted physicians to become more sensitive to the individual patient's personal goals or desires regarding quality of life and happiness.

10 *See* Johnson by Adler v. Kokemoor, 545 N.W.2d 495 (Wis. 1996) (information about a physician's risk statistics would facilitate awareness of viable alternatives); Duttry v. Patterson, 741 A.2d 199 (Pa. 1999) (personal information about physicians is outside the scope of informed consent).

The Right to Refuse Treatment and the Right to Die

Issues related to an individual's right to refuse treatment and, ultimately, the right to die came into sharp focus in 1975 in the Karen Ann Quinlan case.[11] Karen Quinlan lapsed into a coma after consuming drugs and alcohol. Her father sought to remove her from a ventilator after it was determined she was in a persistent vegetative state. The New Jersey Supreme Court agreed, citing Karen's right to privacy and right to refuse treatment through her father. That decision sparked the enactment of various state laws defining brain death and recognizing living wills and the right to die.[12]

The rights of patients recognized in the *Quinlan* case were later constrained in the case of *Cruzan v. Director, Missouri Department of Health*.[13] *Cruzan* addressed the issue of whether the family of an incompetent individual has a right to decide whether to withhold or withdraw lifesaving treatment. In a 5–4 decision, the U.S. Supreme Court upheld a Missouri law that required clear and convincing evidence of the patient's wishes before removal of life support. That decision was followed by the federal Patient Self-Determination Act,[14] which requires hospitals and nursing homes receiving federal funding to give patients information about advance directives and right-to-die options.

As a result of *Quinlan*, *Cruzan,* and other similar cases, patients have been afforded greater authority to control their treatment, and the use of living wills and advance directives became common. On the other hand, the natural expansion of the right to refuse treatment, particularly at the end of life, has evolved into a discussion of assisted suicide. The United States Supreme Court

11 *See In re* Quinlan, 355 A.2d 647 (N.J. 1976).

12 Charity Scott, *Why Law Prevades Medicine: An Essay on Ethics in Health Care*, 14 Notre Dame J.L., Ethics & Pub. Pol'y 245, 269 (2000), *available at* http://scholarship.law.nd.edu/cgi/viewcontent.cgi?article=1334&context=ndjlepp ("Over the past few decades, all state legislatures have [passed] legislation recognizing the right of patients to express their wishes, and to have them honored, through advance directives like living wills or durable powers of attorney.").

13 *See* Cruzan v. Dir., Mo. Dep't of Health, 497 U.S. 261 (1990).

14 Patient Self-Determination Act of 1990, H.R. Res. 4449, 101st Cong. (1990) (enacted), *available at* www.congress.gov/bill/101st-congress/house-bill/4449/text; Omnibus Budget Reconciliation Act of 1990, Pub. L. No. 101-508, 104 Stat. 1388 §§ 4206, 4751 (1990), *available at* www.gpo.gov/fdsys/pkg/STATUTE-104/pdf/STATUTE-104-Pg1388.pdf.

has held there is no constitutional right to commit suicide and, correspondingly, that state laws prohibiting physician-assisted suicide are not unconstitutional.[15] Accordingly, the vast majority of states currently prohibit physician-assisted suicide and only six states have enacted "death with dignity" laws (one by court decision[16]) that permit assisted suicide. As of April 1, 2017, 25 other states are considering such legislation.[17]

One cannot ignore the poignant and powerful essay by one of the great leaders in health care law, Nathan Hershey, who as a result of Alzheimer's disease and the effects of a stroke became completely dependent on others. He wrote, "As I assess my life, I feel fulfilled. I am prepared to conclude my life now. . . . but [] am unable to do so without help. . . . [If you] [l]ive too long, [you will] lose your right to make a decision that will be honored."[18] So for now, it seems that considerable limits stand in the way of one of the most important rights a patient can have—the right to exercise ultimate control over how and when to die.

The Right to Treatment Regardless of Ability to Pay

Hospitals, especially tax-exempt hospitals, have a tradition of providing uncompensated care. Hospitals and other health care facilities that received federal funds under the Hill-Burton Act[19] are required to provide emergency services (but not non-emergency services) regardless of one's ability to pay. This obligation came to the forefront in 1986 when Congress passed the

15 *See* Washington v. Glucksberg, 521 U.S. 702 (1997).

16 While Montana does not have a statute protecting physician-assisted suicide, Montana's Supreme Court has held there is nothing in state law prohibiting physicians from honoring a terminally ill, mentally competent patient's request to die by prescribed medication. *See* Baxter v. State, 224 P.3d 1211 (Mont. 2009).

17 *Take Action: Death with Dignity Around the U.S.*, Death with Dignity, www.deathwithdignity.org/take-action/ (last visited Apr. 1, 2017).

18 Nathan Hershey, Opinion, *I Cannot Manage To Die*, Pittsburgh Post-Gazette, Aug. 17, 2014, *available at* www.post-gazette.com/opinion/2014/08/17/I-cannot-manage-to-die-NATHAN-HERSHEY-explains-why-he-wishes-to-die/stories/201408170060.

19 Title VI of the Public Health Service Act (Hospital Survey and Construction Act), Pub. L. No. 79-725, 60 Stat. 1040 (1946); Title XVI of the National Health Planning and Resources Development Act of 1974, Pub. L. No. 93-641, 88 Stat. 2258 (1976).

Emergency Medical Treatment and Labor Act (EMTALA).[20] EMTALA requires all hospitals receiving Medicare funds to provide medical screening and treatment to anyone coming to the hospital's emergency department seeking treatment for an emergency medical condition. Unlike most legislative requirements related to Medicare, the law applies to all presenting patients regardless of their ability to pay, not just Medicare beneficiaries.

The law had its origin in Congress's desire to stop hospitals from refusing emergency treatment to patients who did not have the ability to pay or had insufficient insurance coverage, a practice termed "patient dumping." EMTALA requires a hospital to provide a medical screening examination to determine whether a patient has an emergency medical condition and, if so, to either (i) treat the patient within the hospital's capabilities and, if necessary, admit the patient or (ii) stabilize the patient and transfer or discharge the patient as appropriate.

EMTALA is a classic example of the principle that one's right is another's burden. While EMTALA has expanded patients' rights to receive emergency medical treatment, the trade-off is the burden placed on hospitals to provide uncompensated care and comply with EMTALA's administrative requirements. Already financially stressed, safety net hospitals are disproportionately impacted by these burdens by virtue of their location in areas where a greater percentage of impoverished patients reside.

The most recent legislative enactment of patient rights relating to payment for health care services is the Patient Protection and Affordable Care Act, (commonly known as the Affordable Care Act, ACA, or more colloquially, "Obamacare"[21]). The ACA aims to increase health insurance quality and affordability, expand coverage to uninsured individuals, and lower health care costs. While the provisions of the ACA relate primarily to insurance coverage, they reverberate with health care providers because they affect payment for

20 Emergency Medical Treatment and Labor Act, 42 U.S.C. § 1395dd.

21 Patient Protection and Affordable Care Act, Pub. L. No. 111-148, 124 Stat. 119 (2010), *available at* www.congress.gov/111/plaws/publ148/PLAW-111publ148.pdf, *amended by* Health Care and Education Reconciliation Act of 2010, Pub. L. No. 111-152, 124 Stat. 1029 (2010), *available at* www.gpo.gov/fdsys/pkg/PLAW-111publ152/pdf/PLAW-111publ152.pdf.

health care services and therefore access to health care.[22] Among the more significant patients' rights created by the ACA are:

- a prohibition on annual and lifetime limits on coverage of essential benefits;
- the right to health care insurance coverage regardless of pre-existing conditions;
- the right of young adults to remain covered on their parents' policy until age 26 if certain conditions are met; and
- notice requirements related to certain matters, such as denial of coverage, premium increases, and cancellation of coverage.

While these are not fundamental rights such as informed consent, the right to die, and privacy rights, they are nevertheless important rights that have a direct impact on the ability to pay for medical care and, therefore, access to care.

Right to Privacy and Access to Medical Records

Although all states have had laws protecting the privacy of patient records for many years,[23] the advent of electronic medical records and the ease with which electronic information can be lost, stolen, or inappropriately disclosed gave rise to the enactment of the Health Insurance Portability and Accountability Act of 1996 (HIPAA).[24] HIPAA and the implementing regulations known as the Privacy Rule[25] established various rights related to privacy of

22 Peter Cunningham et al., The Henry J. Kaiser Family Found., The Kaiser Comm'n on Medicaid & the Uninsured, Issue Brief: Understanding Medicaid Hospital Payments and the Impact of Recent Policy Changes (2016), *available at* http://kff.org/report-section/understanding-medicaid-hospital-payments-and-the-impact-of-recent-policy-changes-issue-brief/.

23 A 50-state statutory survey on the privacy of medical records is available on Westlaw by searching 0020 SURVEYS 24. George Washington University and the Robert Wood Johnson Foundation maintain resources on health information, including state medical information confidentiality laws, at www.healthinfolaw.org/topics/63.

24 Health Insurance Portability and Accountability Act of 1996, Pub. L. No. 104–191, 110 Stat. 1936 (1996), *available at* www.gpo.gov/fdsys/pkg/PLAW-104publ191/pdf/PLAW-104publ191.pdf.

25 45 C.F.R. pts. 160, 164, subpts. A & E.

electronic medical records (known as Protected Health Information or PHI) and patients' rights to access their medical records.

Before HIPAA, it was not uncommon for health care providers to discourage patients and their families from easily accessing medical records. This was in large part attributed to a misguided sense of paternalism and the concept that patients could not understand, and might even be disturbed by, the contents of their medical records. HIPAA has been a major force in changing health care providers' attitudes about patients' rights to their medical records and it has resulted in a heightened awareness of the importance of protecting patient information.

The key elements of HIPAA involve the establishment of privacy programs by covered entities, limitations on the use and disclosure of PHI, and enumeration of various patient rights and security safeguards. HIPAA generally prohibits the use or disclosure of PHI without a patient's consent unless a specific regulatory exception applies. The exceptions permitting use and release of PHI without patient consent are designed to preserve the smooth delivery of health care and other lawful activities without infringing on essential privacy protections imposed by HIPAA. Embedded in the restriction on use and disclosure is the concept of "minimum necessary," which requires that even when it is permissible to disclose PHI, only the minimum amount of information necessary to accomplish the immediate purpose should be released.

Other rights codified by HIPAA include the rights of patients to (i) obtain copies of their medical records, (ii) request that incorrect PHI be changed or supplemented (although health care providers are not required to make the changes), (iii) file complaints about perceived violations of HIPAA, (iv) receive notices of health care providers' privacy practices and patients' rights under HIPAA, and (v) receive an accounting of everyone who has accessed their electronic medical records. HIPAA provides additional protections for sensitive information, such as psychotherapy notes.

While some of those rights were already protected by state laws, the enactment of HIPAA resulted in a nationwide set of patient privacy rules.

These advances, however, did not come without cost to health care providers, who must expend additional time and resources to comply with HIPAA's requirements or face potentially costly enforcement actions by patients or governmental agencies. In 2016 alone, the federal agency that enforces HIPAA, the Office of Civil Rights for the U.S. Department of Health and Human Services (HHS), collected more than $23.5 million in penalties from HIPAA enforcement actions.[26]

Rights Addressed by Medicare Conditions of Participation

State and federal laws and regulations have established numerous other patient rights, including those applicable beyond the health care setting, such as civil rights laws.[27] One of the most significant codifications of patient rights can be found in the Medicare Conditions of Participation[28] (CoPs), which identify patient rights that must be recognized by hospitals, home health agencies, and other Medicare providers. The CoPs protect, among other things, the rights to:

- participate in the development and implementation of the patient's plan of care,
- have a family member or representative of choice notified of admission to the hospital,
- be free from all forms of abuse or harassment,
- be free from restraints and seclusion (this right alone required over 50 pages of regulations to implement),
- receive notice of all the other rights,
- have access to a grievance process,

26 *2016 OCR HIPAA Settlements Target Risk Analyses, Total $23.5M*, HealthIT Security, http://healthitsecurity.com/news/2016-ocr-hipaa-settlements-target-risk-analyses-total-23.5m (last visited Mar. 30, 2017).

27 Individuals seeking health care treatment are entitled to all the protections afforded by the Civil Rights Act of 1964 and its progeny. These include freedom from discrimination by payers and providers based on race, color, national origin, age, gender, disability, and religion. While it is important to acknowledge the existence of these general civil rights, their evolution and application is beyond the scope of this Comment.

28 Conditions of Participation for Hospitals, 42 C.F. R. pt. 482.

- make advanced directives and have them followed,
- have personal privacy, and
- have visitors of their choosing.

Although the rights set forth in the Medicare Conditions of Participation were promulgated to apply only to Medicare beneficiaries, hospitals and other health care facilities, including ambulatory health care settings, have almost universally adopted them for all patients.

Rights and Ethics in Clinical Research

The past 50 years have been a period of significant reform in the area of human subject research. Compared to other areas of medicine, the ethics of human experimentation did not become a major focus of the scientific community until after World War II when Congress implemented policy reforms on human subjects research. Public concerns over the adequacy of protections continued to rise during the 1960s and 1970s, as human subjects violations by the United States government during the Tuskegee Study became public.

The Tuskegee Study, conducted by the Public Health Service, was intended to observe the progression of untreated syphilis in African-American men.[29] None of the men who were infected with the syphilis bacterium were ever told they had the disease, and none were treated.[30] The ethical concerns raised by the Tuskegee Study led to significant regulatory reform. In 1974, the Nixon Administration passed the National Research Act,[31] which created the National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research (the Commission). In 1979, the Commission published the Belmont Report,[32] which underlined three basic guiding principles in clinical

29 *U.S. Public Health Service Syphilis Study at Tuskegee: The Tuskegee Timeline*, Cntrs. for Disease Control & Prevention, www.cdc.gov/tuskegee/timeline.htm (last visited Mar. 30, 2017).

30 *Id.*

31 National Research Service Award Act of 1974, Pub. L. No. 93-348, 88 Stat. 342 (1974), *available at* www.gpo.gov/fdsys/pkg/STATUTE-88/pdf/STATUTE-88-Pg342.pdf.

32 Office of the Sec'y, Ethical Principles and Guidelines for the Protection of Human Subjects Research, The Nat'l Comm'n for the Protection of Human Subjects of Biomedical and Behavioral Research, The Belmont Report (1979), *available at* www.hhs.gov/ohrp/regulations-and-policy/belmont-report/.

and biomedical research: (i) respect for persons, (ii) beneficence, and (iii) justice. The Belmont Report served as a foundation for future federal policy for the protection of human subjects. The first major piece of legislation derived from the Belmont Report was the Federal Policy for the Protection of Human Subjects, also known as the "Common Rule," which was enacted in 1991.[33] The Common Rule requires research institutions to assure compliance with research-related regulations, requires researchers to obtain and document informed consent, and requires Institutional Review Board (IRB) review of human subjects research. The Common Rule also imposes special protections for vulnerable populations, including pregnant women, prisoners, and children.[34]

Following enactment of the Common Rule, the research community turned to the ethical implications of technology and information sharing. In the last two decades, much of the ethics discussion in research has centered on patient privacy and the use of biospecimens: materials taken from the human body, such as blood, saliva, tissue, or plasma. The collection, storage, and research use of biospecimens raises concerns about informed consent, research oversight, data sharing, privacy and confidentiality, and the right of human research subjects to withdraw from research.[35]

The Common Rule was developed to protect human subjects from physical risks involved in experimental research; it did not contemplate research on biospecimens. Under the Common Rule, when an investigator uses biospecimens that have already been collected for another purpose, no human subject is involved and therefore informed consent is not required.[36] This means the patient is not informed of subsequent research conducted on his or her

33 *Federal Policy for the Protection of Human Subjects ('Common Rule')*, HHS.GOV, www.hhs.gov/ohrp/regulations-and-policy/regulations/common-rule/ (last visited Mar. 30, 2017).

34 Protection of Human Subjects, 45 C.F.R. pt. 46.

35 Laura M. Beskow, *Lessons from HeLa Cells: The Ethics and Policy of Biospecimens*, ANN. REV. GENOMICS & HUM. GENETICS 395 (2016), *available at* www.ncbi.nlm.nih.gov/pmc/articles/PMC5072843/pdf/nihms821852.pdf. *See also* Jennifer S. Geetter, *Another Man's Treasure: The Promise and Pitfalls of Leveraging Existing Biomedical Assets for Future Use*, J. HEALTH & LIFE SCI. L., June 2011 at 1, *available at* www.healthlawyers.org/Publications/Documents/Journal-June2011-final-article1-abstract.pdf.

36 *Id.*

biospecimens and is denied the opportunity to either consent to or withdraw from participation in that research.

In an attempt to address some of the concerns surrounding biospecimens, the federal government published a Notice of Proposed Rulemaking (NPRM) to overhaul the Common Rule in 2015.[37] Specifically, the NPRM proposed the following revisions related to biospecimen research:

- modification of the definition of "human subject" to include biospecimens;
- requirement of consent for research use of all biospecimens, regardless of whether they were originally collected for research, clinical, or other purposes;
- addressing the circumstances under which researchers may obtain broad consent for future unspecified research; and
- addition of new elements of informed consent, including information about commercial use, profit, and the return of individual research results.

Following the NPRM, industry stakeholders expressed concerns that the changes would hinder human subjects research and the advancement of science and medicine. HHS received over 2,100 public comments on the NPRM. In particular, the proposal to include biospecimens in the definition of "human subject" triggered significant backlash, with some commenters suggesting that the NPRM represented "a lack of balance among the ethical principles articulated in the Belmont Report" by inappropriately emphasizing the principle of autonomy and the individual's right to consent to the use of his or her biospecimens, with little regard for beneficence and justice.[38]

37 Federal Policy for the Protection of Human Subjects: Part II, 80 Fed. Reg. 53933 (proposed Sept. 8, 2015).

38 Letter from Anthony De Crappeo, President, Council on Governmental Relations, to Jerry Menikoff, Office for Human Research Prots., Dep't of Health & Human Servs. (Dec. 8, 2015), *available at* www.regulations.gov/contentStreamer?documentId=HHS-OPHS-2015-0008-0456&attachmentNumber=1&contentType=pdf.

Due to the large number of proposed changes in the NPRM and the number of public comments received, it took HHS nearly a year to issue the final Common Rule regulations (the Final Rule). The Final Rule was released January 18, 2017, just days before the end of President Barack Obama's second term. Many in the research community believe the Obama administration hastened the release of the Final Rule and removed several controversial portions in an effort to issue the regulations before the Trump administration took office.[39] As a result, the Final Rule deviated greatly from the NPRM and failed to include many of the biospecimen and other controversial provisions. The Final Rule did, however, adopt some of the NPRM's new informed consent requirements.[40] Specifically, the Final Rule requires that informed consent documents begin with a "concise and focused presentation of the key information that is most likely to assist a prospective subject . . . in understanding the reasons why one might or might not want to participate in the research."[41] In addition, research subjects must be informed of the following:

- whether their identity can be removed from collected data or specimens and whether that non-identified data can be used for secondary research studies without further consent;
- if their biospecimens may be used for commercial profit and whether or not the subject will share in that profit;
- whether they will be informed of clinically relevant research results, including individual research results and under what conditions; and
- whether the research will (if known) or might include whole genome sequencing.

39 Jeannie Baumann, *Obama Administration Still Wants to Release New Common Rule*, Life Sci. L. & Industry Rep., Nov. 18, 2016, *available at* www.bna.com/obama-administration-wants-n57982082973/.

40 Federal Policy for the Protection of Human Subjects: Part IX, 82 Fed. Reg. 7149 (Jan. 19, 2017).

41 *Id.* at 7213.

The changes outlined in the Final Rule will become effective January 19, 2018.[42] It is anticipated that ethical issues concerning biospecimens will continue to challenge the research industry, especially as science advances. As new waves of information-sharing practices continue to be a key component in the development of new and efficient medical therapies in this country, privacy and confidentiality issues will be at the forefront of patient rights and ethics for the next several decades.

Rights Related to Genetic Information

Advances in genomic research have provided an entirely new source of information about individuals and their health, but that knowledge has also given rise to innumerable questions about how genetic information can and should be used. The most immediate and obvious concerns—that genetic information may be used to discriminate against individuals—has been dealt with to some extent by the Genetic Information Nondiscrimination Act of 2008 (GINA).[43] GINA prohibits health plans and insurers from making coverage decisions based on genetic predisposition to developing disease in the future. GINA also prohibits employers from using genetic information when making employment-related decisions; however, myriad other patient rights issues related to genetic information still need to be addressed.

While many patient rights issues that arise in genetics research are familiar and similar to those confronted in other areas of research (e.g., issues of informed consent and non-discriminatory inclusion of subjects), other issues are unique to genetic research or have unique genetic implications. For example, the question of how to respond to incidental findings arises in all research, but what should a researcher do when, in the course of research, a genetic anomaly associated with an increased chance for a given illness that is

42 *Id.* at 7152.
43 The Genetic Information Nondiscrimination Act of 2008, 42 U.S.C. § 2000ff, *available at* www.eeoc.gov/laws/statutes/gina.cfm.

not the focus of the research is discovered? Should the study subject be advised? What if the researcher is not qualified to advise the study subject as to the potential impact of the discovery? What are the necessary levels of certainty and risk to trigger a need to disclose? The mere presence of a genetic anomaly does not necessarily mean that the genetic trait will be expressed. If the subject can take no action to minimize the risk or address the threat of the illness, is the subject better served by knowing or not knowing of the genetic anomaly?

Under the concept of autonomy, the individual has the right to make decisions about whether to receive testing and treatment. In the context of research, however, autonomy is partially suspended. Study participants agree to comply with the limitations of the study design in return for the opportunity to participate in the study and possibly obtain access to a (potentially) effective new drug or device. Does it follow then that the participant has similarly surrendered his or her right to be advised of unrelated incidental findings, even if they are possibly significant? These questions take on additional challenges in the context of genetics research. In short, the more we know, the more ethical issues providers will have to address.

Another area in which genetic research participants' rights are difficult to determine concerns ownership of genetic materials collected for study. In many cases, study sponsors seek to own all biological samples collected pursuant to the study protocol. This is particularly true in genetics studies, where sponsors often seek not only to evaluate the genes in question for purposes of one study, but also to build large libraries of genetics data. These repositories of genetic data, both preserved biological specimens and results of genetic sequencing, are valuable to researchers but also present unique issues related to the preservation of privacy for study participants. Unlike other forms of research, genetics research can reveal intensely personal information, which can call into question core perceptions of the participant. For example, genetics research can bring into question paternity, as well as fundamental beliefs about a person's history and religion. Despite efforts to de-identify information, it is still possible to re-identify a genome given access to the proper

ancillary databases.[44] Genetic information, when associated with identifiers, is considered PHI under HIPAA, but de-identified data loses that protection. Nonetheless, the removal of listed identifiers is no guarantee that an individual's privacy will be sufficiently protected. As big data continues to grow and data analytics is better able to support cross-linkages between databases, the ability of the de-identification standard set forth in HIPAA becomes less effective in protecting privacy. Thus, more than any other type of research, genetics research can invade individual privacy and impact the autonomy of research participants directly and invidiously.

The rights of research participants have evolved significantly since the issuance of the Belmont Report, but the unique challenges presented by genetics research suggest that further consideration of ethical principles and research participant protections may be necessary. As it becomes easier to identify individuals by genome and as incidental findings in genetic studies become more meaningful, the appropriate legal and ethical approach to these issues will require further consideration. This creates significant tension as the focus on wellness, precision medicine, and population health increases the emphasis on development of mega-datasets that permit population-wide analysis of the interplay of genetics, environment, and social and behavioral variables to further scientific and clinical understanding of disease.

Conclusion

The evolution and advancement of patient rights have generated material improvements in recognition of the importance of patient dignity and the ability of patients to be active participants in the care they receive. In many circumstances, however, those advances illustrate one of the fundamental laws of physics: For every action, there is an equal and opposite reaction. For example, when considering the advances in informed consent, one cannot ignore the corresponding increase in the demands placed on health care providers to provide comprehensive information about common risks, ben-

44 Melissa Gymrek et al., *Identifying Personal Genomes by Surname Inference*, 339 Sci. 321 (2013).

efits, and alternatives, as well as a corresponding increase in the lack of informed consent claims. It seems whenever there is an untoward outcome of treatment, patients now routinely resort to claims of lack of informed consent, which avoids the need to prove that the health care provider was negligent.[45]

Legislatively created patient rights have also resulted in administrative and recordkeeping burdens, as well as mandated procedures that present clinical and operational challenges, such as those associated with Medicare Outpatient Observation Notice (MOON), Advance Beneficiary Notice of Noncoverage (ABN), EMTALA, HIPAA, and the prohibitions on the use of restraints and seclusion. Health care providers are required to inform patients about their rights, document that the rights have been afforded, train health care providers regarding those rights, assure the procedural and operational infrastructure necessary to implement these protections are in place, bear the cost of internal and external audits and investigations regarding whether such rights have been violated, and defend against claims of violation of rights. All of these requirements impose cost and time burdens on health care providers that require additional resources and/or redirection of existing resources that could otherwise be devoted to direct patient care.

None of this is intended to denigrate the advances that have occurred in patient rights, but it would be better still if patient rights could be achieved while simultaneously recognizing the stress and expense these advances impose on health care providers. It is submitted that the requisite balance can only be achieved if funding is made available to cover the costs associated with the development of required policies relating to patient rights and the training and oversight required to ensure those rights are afforded and protected. J

45 *See, e.g.*, the web presence of many attorneys from the plaintiffs' bar advertising the availability of informed consent civil claims: *Lack of Informed Consent*, Joye Law Firm, www.joyelawfirm.com/medical-malpractice-lawyer/lack-of-informed-consent/ (last visited Apr. 1, 2017); David Goguen, *What is "Informed Consent" in a Medical Malpractice Case*, Lawyers.com, http://medical-malpractice.lawyers.com/professional-duty-of-care/lack-of-informed-consent.html (last visited Apr. 1, 2017); Coulter Boeschen, *Medical Malpractice: Informed Consent*, Nolo, www.nolo.com/legal-encyclopedia/medical-malpractice-informed-consent-29872.html; *Medical Malpractice Cases: Lack of Informed Consent*, The Law Office of Alan H. Crede, www.bostonmainjurylawyer.com/medical-malpractice-informed-consent.php (last visited Apr. 1, 2017).

S. Allan (Al) Adelman has defended hospitals and health care providers before judges and juries for over 40 years. His litigation experience is a superb foundation for the review and analysis of patient rights and ethics found in this Comment. Through his representation of health care providers as defense counsel, he has a deep understanding of how the health care system wrestles with the ever-evolving rights of patients who receive care and the ethical standards of professionals who provide care. As his litigation reputation grew, Al broadened his practice to serve as outside general counsel to hospitals, particularly on issues involving the medical staff and hospital-physician relationships, governance, and compliance.

A member of the Board of Directors of the American Health Lawyers Association (AHLA) from 1997–2007, Al became a member of the Executive Committee in 1999 and was elected President in 2005. He furthered his contributions to AHLA in his area of expertise as Chair of the Credentialing and Peer Review Practice Group. In 2016, he received the David J. Greenburg Award in recognition of his long-standing contributions to the Association and the health law bar. Also in 2016, Al opened the Annapolis, MD office of the national health law practice of Hall Render Killian Heath & Lyman PC where he proudly practices with his sons Tim and Chris. He continues to focus his professional activities on the myriad patient, ethical, corporate and compliance issues facing hospitals and physicians. Contact him via email at aadelman@hallrender.com.

—Marilou King *contributed this author profile.*

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Access to Health Care: 50 Years of Growth, but an Uncertain Future

Thomas K. Hyatt

What is the issue? Meaningful access to health care has both a financial component (the ability to pay for the cost of available care) and a personal component (the availability of health care information and physical and virtual points of care). Although access to health care has expanded in the past 50 years, problems remain and proposed federal legislative changes threaten to reduce access.

What is at stake? Without adequate access to care, our comprehensive medical facilities, state-of-the-art technology, exceptional caregivers, community health needs assessments, and carefully crafted health insurance programs will be of limited value. Health care is not care at all unless there is adequate and appropriate access to it.

What do you need to know? Access to health care in the United States has expanded dramatically over the last 50 years, not only due to federal legislation expanding coverage and shaping the role of providers through tax policy and other laws, but also through innovation. Although the legislative outlook is uncertain, new technologies and care settings will continue to improve financial access through reduced costs and personal access through evolving delivery mechanisms.

Thomas K. Hyatt, *Access to Health Care: 50 Years of Growth, but an Uncertain Future*, J. Health & Life Sci, L., June 2017 at 88.

Hyatt: Access to Health Care

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Introduction

As we look back at the first 50 years of the American Health Lawyers Association (AHLA) and its forebears, the issues surrounding access to health care tell us a great deal about the state of the American health care system. Without adequate access to care, all of the comprehensive medical facilities, state-of-the-art technology, exceptional caregivers, community health needs assessments, and carefully crafted health insurance programs will be of limited value. Health care is not care at all unless there is adequate and appropriate access to it.

As explained by the Agency for Healthcare Research and Quality (AHRQ) and defined by the Institute of Medicine (IOM), access to health care means having "the timely use of personal health services to achieve the best health outcomes."[1] Attaining good access to care involves three steps:

1. Entry into the health care system
2. Access to sites of care where patients can receive needed services
3. Identifying providers who meet the needs of patients and with whom patients can establish mutual communication and trust.[2]

Access, then, has both a financial component (the ability to pay for the cost of available care at an affordable price) and a personal component (the availability and use of information to make informed health care decisions and the availability of physical and virtual points of care).

This Comment will review and assess the debate, raging for centuries, over whether health care is an American right or a privilege; the expansion of government programs that pay for or subsidize the cost of care through reimbursement, payment, and the use of tax policy to effect operational change; the shift to alternatives to inpatient care to expand access; and the

1 Inst. of Med., Comm. on Monitoring Access to Personal Health Care Servs., Access to Health Care in America 4 (Nat'l Acad. Press 1993), as quoted in AHRQ, National Healthcare Quality Report, ch. 9, Access to Healthcare (2011), *available at* www.ahrq.gov/research/findings/nhqrdr/nhqr11/chap9.html.

2 AHRQ, National Healthcare Quality Report, ch. 9, Access to Healthcare (2011), *available at* www.ahrq.gov/research/findings/nhqrdr/nhqr11/chap9.html.

dramatic expansion of information and devices to enable greater personal involvement in health care decision making.

Right or Privilege?

Determining how to achieve desired access, and ordaining who is responsible to do so, is predicated on a fundamental debate, ongoing for as long as we have been a nation, as to whether health care is a right for all American citizens, or a privilege. Proponents of the "right" philosophy include the United Methodist Church, which posits: "Health care is a basic human right. Providing the care needed to maintain health, prevent disease, and restore health after injury or illness is a responsibility each person owes others and government owes to all, a responsibility government ignores at its peril."[3] President Franklin Delano Roosevelt, in his 1944 State of the Union Address, envisioned a "Second Bill of Rights" for Americans that included the "Freedom from Want," as well as the right to adequate medical care and the opportunity to achieve and enjoy good health.[4] Put into current context, President Obama has stated that health care should be a right for every American and that "[i]n a country as wealthy as ours, for us to have people who are going bankrupt because they can't pay their medical bills . . . there's something fundamentally wrong about that."[5]

Proponents of the "privilege" school of thought decry the notion that providers of care should somehow have to be conscripted against their will to provide health care to others, and instead argue that our founders established the right to pursue happiness, but with no guarantee of physical comfort. As one business executive asserted:

> Health care is a service that we all need, but just like food and shelter it is best provided through voluntary and mutually beneficial market exchanges. A careful reading of both the Declaration of Independence and the Constitu-

3 *Social Principles: The Social Community,* UMC.ORG, www.umc.org/what-we-believe/the-social-community (last visited Apr. 3, 2017).

4 President Franklin D. Roosevelt, State of the Union Message to Congress (Jan. 11, 1944), *available at* www.fdrlibrary.marist.edu/archives/address_text.html.

5 *October 7, 2008 Debate Transcript*, COMM'N ON PRESIDENTIAL DEBATES, *available at* www.debates.org/index.php?page=october-7-2008-debate-transcrip.

> tion will not reveal any intrinsic right to health care, food or shelter.[6]

Or as one Congressman put it: "Nowhere does [the Declaration of Independence] mention anything about free MRIs."[7]

Financial Access and Personal Access to Care

When considering the current status of access to health care in the United States, it is perhaps best broken down into two elements: financial access and personal access. Of these, financial access is the more critical of the two. It matters not how comprehensive nor how physically available providers of care are if the patient cannot afford the cost of care, whether by direct payment through an insurer, through charity or uncompensated care, or through the government (as reimbursement or forgone tax revenue). The last 50 years, give or take, have seen a huge leap in the growth of financial access to care, most notably through the game-changing passage of the Medicare and Medicaid Acts in 1965[8] and the Affordable Care Act (ACA) in 2010.[9] Notwithstanding the continuing lack of health care insurance coverage for millions of Americans, it is estimated that only 4.5% of persons in the U.S. failed to obtain needed medical care due to cost.[10]

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6 John Mackey, *The Whole Foods Alternative to ObamaCare*, Wall St. J., Aug. 11, 2009.

7 John Campbell, Opinion, *A Right to Health Care?*, The Orange County Reg., July 13, 2009, *available at* www.ocregister.com/articles/care-26474-right-health.html.

8 Social Security Amendments of 1965, Pub. L. No. 89-97, 79 Stat. 286 (1965) (codified as amended at 42 U.S.C. § 426a), *available at* www.gpo.gov/fdsys/pkg/STATUTE-79/pdf/STATUTE-79-Pg286.pdf [hereinafter *Social Security Amendments of 1965*].

9 Patient Protection & Affordable Care Act of 2010, Pub. L. No. 111-148, 124 Stat. 119 (2010), *available at* www.gpo.gov/fdsys/pkg/PLAW-111publ148/pdf/PLAW-111publ148.pdf [hereinafter *Patient Protection & Affordable Care Act of 2010*].

10 Brian W. Ward et al., Div. of Health Interview Statistics, Nat'l Ctr. for Health Statistics, National Health Interview Survey Early Release Program: Early Release of Selected Estimates Based on Data From the 2015 National Health Interview Survey, Figure 3.2. Percentage of Persons of All Ages Who Failed to Obtain Needed Medical Care Due to Cost at Some Time During the Past 12 Months, by Age Group and Sex: United States, 2015, at 19 (2016), *available at* www.cdc.gov/nchs/data/nhis/earlyrelease/earlyrelease201605.pdf.

The Role of Government: Enabling Financial and Physical Access to Care

Medicare, Medicaid, the State Children's Health Insurance Programs, and the Affordable Care Act have been the most significant legislative efforts by the federal government to expand access to quality health care for the uninsured and underinsured. Requirements associated with federal charitable tax exemption have increased patients' financial access to necessary medical care, while federal laws such as the Emergency Medical Treatment and Labor Act and the Hill-Burton Act promote both financial and physical access to health care.

Financial access through health insurance

Whether right or privilege, access is essential to health care, and access has expanded remarkably over the last 50 or so years. A fair conclusion is that most of the heavy lifting in providing affordable coverage to enable financial access to care has been done by government. The passage of the Medicare legislation in 1965 provided health insurance (and thereby, access to hospital, skilled-nursing facility, home health, hospice, outpatient, and physician care) to those over 65 without regard to their income or medical history, as well as to certain individuals with disabilities and those with End-Stage Renal Disease.[11] Over time, coverage has expanded to extend access to care provided by health maintenance organizations and prescription drug coverage.

The Medicaid Act, also enacted in 1965, was intended as a social program for those with limited means.[12] It directed the federal government to provide matching funds to states so that the states could provide medical assistance programs to lower-income residents, including families and children, pregnant women, the elderly, and people with disabilities.

Another highly successful expansion of government health care insurance coverage came in the bipartisan creation of the State Children's Health Insur-

11 *Social Security Amendments of 1965*.
12 *Id.*

ance Program (SCHIP) in 1997.[13] This program provides matching funds to states that provide health insurance to families with children that have low incomes still considered too high to qualify for Medicaid. Filling that gap required the largest expansion of government-funded health insurance for children since Medicaid, extending coverage to an additional 4 million children and pregnant women in 2009, including legal immigrants. SCHIP covered 7.6 million children in 2010 and is available in every state.[14]

The greatest expansion of the federal government's role in providing health care coverage after Medicare and Medicaid came in 2010 when the Affordable Care Act, also known as "ObamaCare," became law.[15] The ACA expanded access to care by instituting far-reaching health insurance reforms designed to expand Medicaid coverage, lower health care costs, provide greater choice in insurance carriers and providers, and improve the quality of care. It is estimated that an additional 20 million people have obtained health insurance coverage through the ACA.[16]

The ACA also tackled two vexing access problems that affect many Americans, and that are perhaps its most popular features, with bi-partisan support. First, it ensured that health insurance coverage would extend to health conditions that existed at the time the insurance was secured. The practice of commercial health insurers excluding pre-existing conditions had been widely panned, giving support to the complaint that only healthy people could get health insurance. Second, the ACA permitted parents to maintain health insurance coverage for their children as dependents until age 26. In a difficult job market and an era where many millennials return home after college, this has provided key financial access to care to a segment of the population that often would have otherwise gone without insurance.

13 Medicare, Medicaid & SCHIP Balanced Budget Refinement Act of 1999, Pub. L. No. 106-113–Appendix F, 113 Stat. 1501A-321 (1999), *available at* www.gpo.gov/fdsys/pkg/PLAW-106publ113/pdf/PLAW-106publ113.pdf.

14 *See generally Children's Health Insurance Program Overview,* NCSL, www.ncsl.org/research/health/childrens-health-insurance-program-overview.aspx (last visited Apr. 4, 2017).

15 *Patient Protection & Affordable Care Act of 2010.*

16 *See* Press Release, The White House, Office of the Press Sec'y, Statement by the President on the Sixth Anniversary of the Affordable Care Act (Mar. 22, 2016), *available at* https://obamawhitehouse.archives.gov/the-press-office/2016/03/22/statement-president-sixth-anniversary-affordable-care-act.

Notwithstanding these governmental efforts to expand access to care, it is estimated that over 29 million Americans, about 10% of the population, did not have financial access to care through health insurance as of 2016.[17]

Still, challenges to the extent and manner of Medicare and Medicaid coverage, largely stemming from their cost, have continued since they were established. In 2017, a new administration and Congress have started anew, trying to determine whether to repeal, replace, repair, or return to the ACA for ensuring access to care. At the core of that debate is whether government-sponsored health insurance is more effective than the free market in promoting access to care and, evidently, whether access to health care is a serious problem. As President George W. Bush stated in a 2007 speech, "The immediate goal is to make sure there are more people on private insurance plans. I mean, people have access to health care in America. After all, you just go to an emergency room."[18]

Financial access through tax policy

Over the last 50 years, Congress and the Internal Revenue Service (IRS) have regularly used federal tax law to achieve the health policy of enhanced access to health care through the recognition of tax-exempt status for nonprofit health care providers and health-related entities. This tax policy began with a focus on the provision of charity care, but pivoted in 1969 toward a broader concept of community benefit and the promotion of health, opening the doors to greater financial and personal access to care in the years to follow. Congress grants tax-exempt status through the Internal Revenue Code to nonprofit organizations organized and operated exclusively in furtherance of charitable purposes. Prior to 1969, the IRS's primary basis for recognizing charitable status for health care providers was that they were dedicated to the relief of poverty—the most basic and historically founded form of charitable activity.

17 Jessica C. Barnett & Marina S. Vornovitsky, U.S. Census Bureau, U.S. Dep't of Commerce, Econ. & Statistics Admin., Health Insurance Coverage in the United States: Current Populate Reports (2016), *available at* www.census.gov/content/dam/Census/library/publications/2016/demo/p60-257.pdf; *see also* Lara Cooper, *Even With Obamacare, 29 Million People Are Uninsured: Here's Why*, The Fiscal Times, May 10, 2016.

18 Press Release, Office of the Press Sec'y, President Bush Visits Cleveland, Ohio, July 10, 2007, *available at* https://georgewbush-whitehouse.archives.gov/news/releases/2007/07/20070710-6.html.

Federal tax regulations define the term "charitable" as including "[r]elief of the poor and distressed or of the underprivileged[.]"[19]

Indeed, the Internal Revenue Code does not expressly state that the provision of hospital services constitutes operation as a charitable organization. If this were true, investor-owned hospitals would also qualify for tax-exempt status as charitable organizations. It was not until 1956 that the IRS established administrative standards for recognizing hospitals as charitable entities.[20] Under the "financial ability standard" established at that time, hospitals were required to provide health care services to patients to the extent of their financial ability to do so, and not exclusively to those patients able and expected to pay. Charitable hospitals could not refuse to accept patients in need of hospital care who could not pay for such services.

In 1969, however, the IRS modified its position by issuing another revenue ruling that forever changed the landscape with regard to the basis for recognizing charitable tax-exempt status for health care providers. It ostensibly eliminated the financial ability criterion and established the community benefit standard as the contemporary rationale for recognizing federal tax exemption for nonprofit hospitals and other health care providers.[21] This standard is predicated on the theory that one of the elements of the term charitable is the promotion of health. Thus, to be tax-exempt under this standard, a provider must promote the health of a class of persons broadly enough to benefit a community and must be operated to serve a public, rather than a private, interest. It is not necessary that the provider base its tax exemption on some other rationale, such as relief of the poor.[22]

19 Treas. Reg. § 1.501(c)(3)–(d)(2).

20 Rev. Rul. 56-185, 1956-1 C.B. 202, *available at* www.irs.gov/pub/irs-tege/rr56-185.pdf.

21 Rev. Rul. 69-545, 1969-2 C.B. 119, *available at* www.irs.gov/pub/irs-tege/rr69-545.pdf. Notwithstanding its 1969 ruling, the IRS frequently has asked hospitals to detail amounts and manner of charity care when a hospital requests IRS advice on transactions such as joint ventures, during field audits, and in reporting on IRS Form 990 to justify continued recognition of tax-exempt charitable status.

22 Indeed, the IRS at the time concluded that the 1965 establishment of the Medicare and Medicaid programs would largely eliminate the problem of access to care for the poor and, accordingly, a basis for exemption other than the relief of poverty would be warranted to justify recognition of exemption. Clearly, that conclusion would prove premature, at best. *See generally* John D. Colombo, *The Role of Access in Charitable Tax Exemption*, 82 Wash. U. L. Q. 343, 348–349 (2004), *available at* http://openscholarship.wustl.edu/law_lawreview/vol82/iss2/2.

The 1969 revenue ruling took the position that providing hospital care on a nonprofit basis for members of the community, operating an open emergency room that does not deny treatment to any person requiring emergency care, and providing hospital care to all persons in the community able to pay the cost of the services collectively constituted the promotion of health of a class of persons broad enough to benefit the community, which is a charitable purpose in the generally accepted legal sense of the term. Factors also deemed relevant include:

- The hospital uses its surplus operating revenue to improve the quality of patient care, advance its medical training, education, and research programs, and expand its facilities.
- The hospital's board of trustees, consisting of independent civic leaders, controls the hospital.
- That the hospital maintains an open medical staff with privileges available for all qualified physicians consistent with the size and nature of its facilities.

Each of these criteria is an essential ingredient of expanding financial and personal access to health care.

The promotion of health as a charitable purpose, as interpreted by the IRS and the courts, includes the establishment or maintenance of hospitals, clinics, homes for the aged, and the like; advancement of medical and similar knowledge through research; and the maintenance of conditions conducive to health. Some of the various health care entities recognized as tax-exempt on this basis include those that engage in the following activities: assistance in securing a private room at a hospital; facilitation of visits to hospital patients by family and friends; operation of a health club in a community; operation of a mobile cancer screening program; sale of hearing aids by a hospital; interpretation of diagnostic tests by one hospital for another that lacks the necessary resources; sale of pharmaceuticals to a hospital's patients; operation of a gift shop or cafeteria and coffee shop by a hospital; and operation of a parking lot

by a hospital.[23] Each of these activities also contributes to expanding access to care (especially being able to find a parking space).

The parameters of "community benefit" and "promotion of health" as a basis for qualification for charitable tax-exempt status continue to be debated, with some arguing that the concepts have become so malleable as to have little meaning for identifying charitable activity, notwithstanding good intent behind the approach. In 2008, following a pitched battle between investor-owned hospitals, the American Hospital Association, the Catholic Health Association, and others as to what should constitute community benefit, the IRS implemented a major overhaul of Form 990 as a reporting tool, adding a new Schedule H for charitable hospital reporting of provision of financial assistance, community benefit, community building activities, bad debt and Medicare shortfalls, and other activities.[24]

Subsequently, in response to frequent complaints received by Congress that charitable hospitals were not living up to their full obligations to provide expanded access to care, several oft-proposed requirements for charitable hospitals were grafted onto the Affordable Care Act, adding a new section to the Internal Revenue Code.[25]

CHNAs and financial assistance policies

Under these new rules, hospitals must undertake a community health needs assessment (CHNA) at least every three years.[26] A CHNA must generally include:

- a description of the community served by the hospital facility;
- a description of the process and methods used to conduct the assessment;

23 *See* Thomas K. Hyatt & Bruce R. Hopkins, The Law of Tax-Exempt Healthcare Organizations, §1.8 Promotion of Health (Wiley, 4th ed. 2013).
24 *Schedule H (Form 990), Hospitals*, IRS, www.irs.gov/uac/about-schedule-h-form-990 (last visited Apr. 5, 2017).
25 IRC § 501(r).
26 *Id.*

- a description of how input was taken from persons who represent the broad interests of the community served by the hospital facility;
- a prioritized description of all community health needs identified through the CHNA; and
- a description of existing health care facilities and other resources within the community available to meet the community health needs identified through the CHNA.

The organization must also adopt an implementation strategy to meet the community health needs identified by the assessment. In other words, as a condition of continued recognition by the IRS of qualification as a charitable, tax-exempt hospital, such organizations must detail in regular reports how they identify impediments to access to care and how they plan to remedy those problems.

Further, the new ACA rules require that a charitable hospital organization ensure appropriate financial access to care by meeting certain financial assistance policy requirements.[27] Hospitals must have a written financial assistance policy that includes:

1. eligibility criteria for financial assistance;
2. a statement as to whether the assistance includes free or discounted care;
3. the basis for calculating amounts charged to patients;
4. the method for applying for the assistance;
5. in the case of an organization that does not have a separate billing and collections policy, the actions the organization may take in the event of nonpayment, including collections action and reporting to credit agencies; and
6. measures to widely publicize the policy within the community served.

27 *Id.*

Also under the ACA, charitable hospital organizations must establish a written emergency medical care policy that requires it to provide, without discrimination, care for emergency medical conditions to individuals regardless of their eligibility under the financial assistance policy. Further, the hospital must limit amounts charged for emergency or other medically necessary care provided to individuals eligible for assistance under the financial assistance policy to not more than the amounts generally billed to individuals who have insurance coverage, and the hospital must prohibit the use of gross charges. A charitable hospital may not engage in extraordinary collection actions before it has made reasonable efforts to determine whether the individual is eligible for assistance under the financial assistance policy.[28]

It should be noted that charity care, or uncompensated care, is not the sole province of nonprofit hospitals. Investor-owned hospitals assert that they provide comparable amounts of uncompensated care without the benefit of tax exemption and General Accountability Office studies indicate that the difference is small.[29] Indeed, the Internal Revenue Commissioner once famously asked in 2005, "What's the difference between a profit making hospital and a not-for-profit hospital these days? Not a lot."[30] Congress, and Senator Chuck Grassley in particular, have persistently inquired whether the activities of nonprofit hospitals are sufficiently different from those of investor-owned hospitals to warrant continued tax exemption.[31] This aspect of the government vs. free market debate has continued for decades. The conclusion need not be binary; financial access through charity care is derived most effectively from both.

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28 *Id.*

29 *Nonprofit, For-Profit, and Government Hospitals: Uncompensated Care and Other Community Benefits: Hearing Before the H. Comm. on Ways & Means* (2005) (statement of David M. Walker, Comptroller General of the United States, United States Government Accountability Office), *available at* www.gao.gov/assets/120/111707.pdf.

30 *Remarks of IRS Commissioner Mark Everson at Representing and Managing Tax-Exempt Organizations Conference*, BNA Daily Tax Report, Apr. 29, 2005, at G-9.

31 *See e.g.*, Letter from Charles E. Grassley, Chairman, Comm. on the Judiciary, to The Honorable John Koskinen, Comm'r, Internal Revenue Serv. (June 9, 2016), *available at* www.grassley.senate.gov/sites/default/files/constituents/2016-06-09%20CEG%20to%20IRS%20(Mosaic%20Non-Profit).pdf.

Government programs promoting both financial and physical access: EMTALA and Hill-Burton

Another important government initiative to ensure access to care came in response to a concern that some hospitals, including nonprofit charitable hospitals, "economically triaged" patients by transferring them to public hospitals if it seemed likely they would be unable to pay for the cost of their care, a practice known as "patient dumping." This led to the passage in 1986 of the Emergency Medical Treatment and Labor Act (EMTALA).[32] EMTALA requires hospitals that participate in Medicare (which is most all of them) and that offer emergency services to provide a medical screening examination when a patient requests examination or treatment for an emergency medical condition or active labor, without regard to the individual's ability to pay. Hospitals must then provide stabilizing treatment, and only if the hospital is unable to stabilize the patient (or upon patient request) is the hospital permitted to make an appropriate transfer. Substantial penalties apply for failure to comply with EMTALA, and patient dumping has largely been curtailed in this manner.

EMTALA was and remains an unfunded mandate, and yet it is regarded as largely successful in achieving its aims. It is credited with changing how emergency departments, administrators, and caregivers think about providing emergency care for those without the means to pay for it, and changing how they respond.[33]

Another government program, the Hill-Burton program, provided hospitals, nursing homes, and other health facilities with grants and loans to be used for construction and modernization of their facilities.[34] In exchange, these providers were required to offer a reasonable amount of health care services to

32 42 U.S.C. § 1395dd; 42 C.F.R. §§ 489.20, .24. *See also Emergency Medical Treatment & Labor Act (EMTALA)*, CMS.GOV, www.cms.gov/regulations-and-guidance/legislation/emtala/ (last visited Apr. 5, 2017).

33 *See, e.g.*, Emily Friedman, *The Law That Changed Everything—and It Isn't the One You Think*, HOSPS. & HEALTH NETWORKS ONLINE, Apr. 5, 2011.

34 *Hill-Burton Free and Reduced-Cost Health Care*, HRSA, www.hrsa.gov/gethealthcare/affordable/hillburton/ (last visited Apr. 5, 2017).

patients with incomes below established federal poverty guidelines and to make their services available to all residents in their service area. The program was established in 1946 and continued providing funds through 1997. Approximately 140 health care facilities nationwide remain obligated to provide free or discounted care to indigent patients. It is estimated that, since 1980, more than $6 billion in uncompensated services have been provided through the Hill-Burton program; many of the facilities constructed with these funds continue to provide expanded access to care.[35]

The Role of the Free Market

As government programs expanded financial access to care and promoted a greater variety of more cost-efficient (and often more therapeutically effective) treatment venues, the free market has likewise had a substantial impact on improving financial access to care, particularly through employer-sponsored health benefits. While federal and state law requires employers to provide certain employee benefits, such as workers' compensation benefits, Social Security and Medicare contributions, and family and medical leave, it generally does not require employers to provide health insurance (although failure to do so may subject employers to fees under the ACA). Employers have provided such benefits to secure a competitive workforce and in response, in part, to long-time collective bargaining with employee unions.

More Americans, about 60% of the population, obtain health insurance through an employer-sponsored benefit than from any other source, although that number has declined steadily since 2000.[36] In recent years, however, employees have been responsible for paying a larger share of the premium and increased deductibles and co-pays due to the rising cost of medical care. The percentage of employers that provide the full cost of employees' family health care coverage has fallen below 10%, according to some reports.[37] Increasingly,

35 *Id.*

36 Julie Sonier et al., State Health Access Data Assistance Ctr., State-Level Trends in Employer-Sponsored Health Insurance: A State-by-State Analysis (2013), *available at* www.rwjf.org/content/dam/farm/reports/reports/2013/rwjf405434.

37 *See generally* The Kaiser Family Found. & Health Research & Educ. Trust, Employer Health Benefits: 2016 Annual Survey, Exhibit C (2016), *available at* http://files.kff.org/attachment/Report-Employer-Health-Benefits-2016-Annual-Survey.

employers have taken a lead role in seeking to reduce the cost of medical care and thereby expand access to it through bargaining and direct contracting, as well as expanding physical access by directly providing care to employees at the worksite.

The Dramatic Growth in Personal Access to Care

Personal access to care has also been greatly expanded thanks to the above-described government initiatives, the evolution of payment reimbursement systems, technological advancements, changes in health insurance mechanisms, and personal empowerment. A somewhat surprising statistic is that an estimated 87.8% of Americans have a usual place to go for medical care.[38]

Until 1983, the Medicare reimbursement system was a cost-based reimbursement system. Simply put, hospitals were paid more if they spent more and there were limited incentives to save. Accordingly, inpatients had longer lengths of stay and hospitals invested in bricks and mortar through the building of additional hospitals and clinics, physician office buildings, and other care sites. They also made substantial investments in major medical equipment.

In addition, starting as early as 1929 in Oklahoma, health cooperatives were set up to offer physician and hospital services on a pre-paid basis.[39] Others established later were The Group Health Association in Washington, D.C., Kaiser-Permanente in California, and the Health Cooperatives of Puget Sound in Seattle. These were the predecessors to the health maintenance organizations that bloomed in the 1970s and thereafter, to what we broadly refer to as "managed care." In an effort to lower the costs of insurance and care, employ-

38 Brian W. Ward et al., Div. of Health Interview Statistics, Nat'l Ctr. for Health Statistics, National Health Interview Survey Early Release Program: Early Release of Selected Estimates Based on Data From the 2015 National Health Interview Survey, Figure 2.2. Percentage of Persons of All Ages With a Usual Place to Go for Medical Care, By Age Group and Sex: United States, 2015, at 14 (2016), *available at* www.cdc.gov/nchs/data/nhis/earlyrelease/earlyrelease201605.pdf.

39 Nat'l Council on Disability, Medicaid Managed Care for People with Disabilities: Policy and Implementation Considerations for State and Federal Policymakers, Appendix B. A Brief History of Managed Care (2013), *available at* http://ncd.gov/publications/2013/20130315/20130513_AppendixB.

ers began favoring the use of managed care providers to treat employees. Managed care is typically provided by health maintenance organizations, preferred provider organizations, accountable care organizations, and similar organizations, and is focused on collaborative care and cost containment. Managed care providers were among the first to focus on preventive and wellness care, for which previously there had been little financial incentive for either providers or patients to pay attention to. The shift to managed care gave a larger group of patients access to a greater range of health care services, albeit with diminished individual choice of physician or institution.

Also occurring during this 50-year period was a seismic shift from inpatient care to outpatient care. While primarily driven by the desire to reduce the cost of inpatient care, the shift was partly driven by studies showing that care in most cases could be just as efficacious in an outpatient setting, if not more so. This led to an increase in the number of physician clinics, including urgent care centers staffed by physicians and other care providers (dubbed a "doc in the box"). The embedding of walk-in clinics in pharmacies and grocery stores for the treatment of basic primary care needs, staffed by physician assistants and nurse practitioners, also saw an increase.[40]

Home health and hospice care was another significant outgrowth of the shift to outpatient care. The expansion and development of home care is somewhat ironic when one considers the origination of hospitals in America. The first hospital in United States was the Pennsylvania Hospital, founded by Benjamin Franklin and Dr. Thomas Bond in Philadelphia in 1751.[41] The first hospitals were largely considered almshouses for the treatment of the poor and destitute, who had chronic rather than acute medical conditions. Poor sanitary conditions led to the spread of deadly infections and caused most individuals

40 There has been an almost 20 percent growth in the number of urgent care clinics in the U.S. in the past four years, with the total number exceeding 9,000. *See* Scott Becker et al., *Private Equity Investment in Healthcare: 15 Healthcare Investment Niches–A Review of Key Sectors for 2015*, Becker's Hospital CFO, Aug. 3, 2015, *available at* www.beckershospitalreview.com/finance/private-equity-investment-in-healthcare-15-healthcare-investment-niches-a-review-of-key-sectors-for-2015.html.

41 *In the Beginning: The Story of the Creation of the Nation's First Hospital*, Penn Med., www.uphs.upenn.edu/paharc/features/creation.html (last visited Apr. 5, 2017).

to avoid hospitals. Individuals who could afford the cost of care didn't go to the hospital. They received care at home. Those of a certain age recall the days when physicians made house calls. The pendulum has swung back again, and home health care is now a booming segment of the health care sector that has expanded access to care, much of which is covered by health insurance.

Also during this time, we witnessed exponential growth and improvements in the ability to treat illness and injury through the use of pharmaceuticals. Illness that once would have required clinical care and even surgical intervention can now often be treated with a pill, a modern illustration of the oft-repeated medical advice: "Take two aspirin and call me in the morning." The ability to treat patients of all income levels and in all care settings through effective pharmaceutical use has resulted in dramatic improvements regarding access and quality of care. Indeed, illnesses that may have been debilitating or even fatal 50 years ago can now be cured, or at least managed, through medicinal care. Through a robust vaccination program, some diseases have been substantially controlled or even virtually eradicated in the U.S., including diphtheria, hepatitis A and B, measles, mumps, polio, rubella, and smallpox.

With the enactment of the Hatch-Waxman Act in 1984,[42] recognition and prescription of generic drugs greatly expanded. Access to most medicines was greatly improved by lowering their cost. As of 2016, generic drugs accounted for 89% of the 4.4 billion prescriptions dispensed in the United States, while accounting for only 27% of total drug spending.[43] Availability does not always mean access, however; some pharmaceutical treatments for orphan drugs now require annual outlays exceeding $100,000. Further, drugs that come off patent and could be produced as lower cost generics drugs are not necessarily less expensive than the original brand-name drug, due in large part to the government's failure to successfully negotiate prices, coverage policies in the insurance market, and the economics of pharmaceutical manufacturing (the price of Daraprim® (Pyrimethamine), a 63-year old toxoplasmosis drug that costs $1

42 Drug Price Competition and Patent Term Restoration Act of 1984, Pub. L. No. 98-417, 98 Stat. 1585 (1984), *available at* www.gpo.gov/fdsys/pkg/STATUTE-98/pdf/STATUTE-98-Pg1585.pdf.

43 Generic Pharm. Ass'n, 2016 Generic Drug Savings & Access in the United States Report, *available at* http://www.gphaonline.org/media/generic-drug-savings-2016/html5forwebkit.html.

in Australia and Britain, was raised to $750/pill in 2016,[44] and the charge for a single Epipen®, which are dispensed two at a time, increased from $165 in 2011 to about $608 in 2016).[45]

Access to rural care has also been significantly enhanced.[46] Medicare and Medicaid reimbursement has been revised over the years to add incentives to promote and expand rural health care. This includes geographic wage index reclassification, additional reimbursement available for sole community hospitals and critical access hospitals, and support for hospitals that serve a disproportionate share of indigent patients. Academic medical centers have also made it a focal point to collaborate with rural facilities as a means of improving access.

Technological advances, particularly the use of telemedicine, have substantially expanded the ability of physicians to reach rural facilities and patients, and have improved access in urban facilities as well. The highest quality health care professionals and resources are now often only a digital connection away. It has been estimated that telehealth will grow from reaching fewer than 350,000 patients in 2013 to 7 million by 2018.[47]

The dawning of the Information Age in the early 1990s led to a sea change in personal access to health care. Health and fitness publishers used books, magazines, videos, and other media to share information, research, alternative medicine strategies, and diet plans too numerous to count. Through the advent of personal computers and the internet, patients were empowered to take control of their own health care regimens. Thanks to the likes of WebMD, MayoClinic, Healthgrades, Drugs.com, and other similar websites, they did so,

44 Kenneth L. Davis, *Price Gougers Like Valeant Pharmaceuticals Must be Tamed*, Forbes, June 3, 2016, *available at* www.forbes.com/sites/kennethdavis/2016/06/03/a-market-fix-for-generic-drug-price-gouging/#2aad78106f21.

45 Dan Mangan, *This Chart Shows Why Everyone's Angry About Soaring Price of Lifesaving EpiPen*, CNBC, Aug. 23, 2016, *available at* www.cnbc.com/2016/08/23/this-chart-shows-you-why-a-lot-of-people-are-angry-about-the-price-of-epipen.html.

46 *See generally Federal Office of Rural Health Policy*, HRSA, www.hrsa.gov/ruralhealth/index.html (last visited Apr. 7, 2017).

47 Press Release, IHS Markit, Global Telehealth Market Set to Expand Tenfold by 2018 (Jan. 17, 2014), *available at* http://news.ihsmarkit.com/press-release/design-supply-chain-media/global-telehealth-market-set-expand-tenfold-2018.

armed with a greater understanding of their personal health status and better information from which to choose appropriate treatment modalities and providers. Insurers have seized upon this phenomenon and have been among the leaders in disseminating health care and wellness information as a means of directing patients to the right treatment portal and reducing cost. And now, a smartphone or watch can measure your heart rate, monitor your weight and exercise, and connect you with a physician in a video call. Fitness wearables that track activity challenge us to stay on our exercise plans and even tell us whether we had a good night's sleep.

The Uncertain Future

For all the advances that have been made in financial and personal access to care over AHLA's 50 years of existence, the path ahead is not likely to be linear, nor even necessarily forward. At this writing, a new president has been elected, and both the House and the Senate are controlled by the same political party. The political position of both the new president and the party in power has unmistakably been to repeal the Affordable Care Act in its entirety. This call has, at various times, been combined with a pledge to replace or repair the ACA; however, the legislation first proposed by the majority party to repeal and replace the ACA, the American Health Care Act, failed to earn enough votes for passage and was pulled back. If the ACA is repealed, the threat to financial access to care is substantial and readily apparent. It has been estimated that over 24 million individuals, and potentially far more, could find themselves without health insurance coverage and thereby without financial access to the full menu of health care services they had been eligible to receive.[48] This would, of necessity, cause us to return to a time in which much primary care was provided in emergency rooms already stretched to the limit, or in which care was deferred or not provided at all.

48 Cong. Budget Office, Cost Estimate: American Health Care Act: Budget Reconciliation Recommendations of the House Committees on Ways and Means and Energy and Commerce, March 9, 2017 (2017), *available at* www.cbo.gov/system/files/115th-congress-2017-2018/costestimate/americanhealthcareact.pdf.

Restrictions on the growth of Medicare and Medicaid, as well as cuts in those programs, are a common talking point in political campaigns. For example, it has been proposed that eligibility for Medicare coverage be pushed back from age 65 to the full Social Security retirement age as a means of protecting the Medicare trust fund.[49] The focus is already shifting, however, from political campaign rhetoric to the actuality of governing the provision of health care services and health insurance. There has been rising opposition by those at risk of losing their financial access to care, while the far-right of the Republican party asserts that proposed cutbacks have not gone far enough. At this writing, the political dialogue includes talk of repairing the ACA, and even returning to it in some fashion. For all of the rhetoric—and for logistical reasons as well as policy reasons—it seems unlikely there will be substantial rollbacks of the ACA's health insurance coverage within the next 2 to 3 years. Private health insurers would then continue to pursue reasonable cost methods for providing affordable health insurance for individuals and families under a free market system and greater latitude would apparently be given to the states to frame health insurance coverage obligations.

Meanwhile, personal access to health care services continues to evolve and expand, particularly through technological advances spurred on by the cost-savings to employers and insurers, as well as the innovations of pioneering software and hardware manufacturers. On a positive note, the mega-telehealth company Teladoc reports that it now has 17.1 million members, to whom physician care is available 24/7, anytime, anywhere.[50] Doctors, it seems, are making house calls again. J

49 House Speaker Paul Ryan (R-Wis) has stated that "because of Obamacare, Medicare is going broke;" however, the Medicare Trustees' report indicates that it will be solvent at least until 2028, an improvement over prior forecasts, due in part to Medicare changes in the ACA. Alison Kodjak, *Paul Ryan's Plan to Change Medicare Looks A Lot Like Obamacare*, NPR, Nov. 26, 2016, www.npr.org/sections/health-shots/2016/11/26/503158039/paul-ryans-plan-to-change-medicare-looks-a-lot-like-obamacare.

50 Teladoc, www.teladoc.com/ (last visited Apr. 6, 2017).

AHLA members, health lawyers, accountants, compliance officers, and tax managers all should know **Thomas K. Hyatt.** If for no other reason, you should know him because he (along with his former colleague Bruce Hopkins) wrote the book on the law of tax-exempt health care organizations, now in its fourth edition. I keep it on my credenza, right next to the Code. Professionally speaking, Tom is a Partner at Dentons US LLP in Washington, D.C., and was named to the inaugural class of AHLA Fellows.

Tom goes back a long way in health care tax law. He began speaking at the AHLA Tax Issues in Health Care Organizations conference in the late 1980s and soon joined founder and long-time Chair Robert S. Bromberg on the Program Planning Committee, eventually succeeding him as Program Chair. Bromberg had pioneered the hospital tax field in the 1970s, and Tom would readily admit that he (as many others of us) learned a lot from Bob in those early years and benefitted from Bob's legendary epicurean sensibilities as well. I had the honor of serving on the Planning Committee with Tom and eventually succeeded him as Chair. Tom encouraged me to lean in but never encouraged me to try the eel or the deep-fried jellyfish, for which I remain eternally grateful.

Tom served on the Board of AHLA from 1992 to 1998, during the all-important merger between the National Health Lawyers Association and the American Academy of Hospital Attorneys. His leadership and contributions to AHLA were honored with the David J. Greenburg Award in 2004. Contact him via email at tom.hyatt@dentons.com.

—T.J. Sullivan *contributed this author profile.*

Brief Insight

Health IT and Patient Safety: A Paradigm Shift to Shared Responsibility

Elisabeth Belmont

In 2003, I co-authored an article with Adele A. Waller, *The Role of Information Technology in Reducing Medical Errors.*[1] We explored the role that information technology (IT) could play in reducing medical errors in the wake of the Institute of Medicine (IOM) Report, *Crossing the Quality Chasm: A New System for the 21st Century.*[2] While health IT has been demonstrated to improve the efficacy of patient care, it also can introduce new risks and potential sources of harm into the health care delivery system, particularly as technology continues to evolve. The importance of minimizing health IT-related safety events has been recognized by regulatory agencies,[3] accrediting organizations,[4] the National Quality Forum,[5] in patient safety-related best

1 Elisabeth Belmont & Adele A. Waller, *The Role of Information Technology in Reducing Medical Errors,* J. Health L. 615 (Fall 2003).

2 Inst. of Med., Crossing the Quality Chasm: A New Health System for the 21st Century (Nat'l Acads. Press 2001), *available at* www.nap.edu/read/10027/chapter/1.

3 *See* 42 C.F.R. § 482.12(a)(5) (The governing body must ensure that the medical staff is accountable to the governing body for the quality of care provided to patients.).

4 *See* The Joint Comm'n, Sentinel Event Alert: Safely Implementing Health Information and Converging Technologies (2008), *available at* www.jointcommission.org/assets/1/18/SEA_42.pdf. *See also* The Joint Comm'n, Sentinel Event Alert: Safe Use of Health Information Technology (2015) *available at* www.jointcommission.org/assets/1/18/SEA_54.pdf.

5 *See, e.g.,* Nat'l Quality Forum, Identification and Prioritization of Health IT Patient Safety Measures 13 (2016), *available at* www.qualityforum.org/Publications/2016/02/Identification_and_Prioritization_of_HIT_Patient_Safety_Measures.aspx [hereinafter Identification and Prioritization of Health IT Patient Safety Measures].

practices,[6] and in additional IOM recommendations.[7] The 2012 IOM Report, *Health IT and Patient Safety: Building Safer Systems for Better Care,* concluded that ensuring health IT is used safely to improve patient care is a shared responsibility among many stakeholders, including provider organizations and their practitioners and IT professionals; health IT developers and vendors; and public and private agencies that focus on quality of care.[8]

This Brief Insight advocates for shared responsibility in the design, implementation, and use of health IT among involved stakeholders through contractual allocation of responsibility to ensure that the party who has the most control over the factors giving rise to a particular health IT patient safety risk takes appropriate steps to prevent and mitigate the risk, with corresponding liability for damages apportioned accordingly.

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6 *See, e.g.,* The Office of the Nat'l Coordinator for Health Info. Tech., Safety Assurance Factors for EHR Resilience, Self-Assessment: Organizational Responsibilities (2016), *available at* www.healthit.gov/safer/sites/safer/files/guides/safer_organizational_responsibilities.pdf; The Office of the Nat'l Coordinator for Health Info. Tech., EHR Contracts Untangled: Selecting Wisely, Negotiating Terms, and Understanding the Fine Print (2016), *available at* www.healthit.gov/sites/default/files/EHR_Contracts_Untangled.pdf. *See also* guidance of the National Institute of Standards and Technology (NIST) *available at* www.nist.gov. *See also* Identification and Prioritization of Health IT Patient Safety Measures. The National Quality Forum Committee reviewed a set of health IT safety-related measure concepts developed specifically for consideration in a shared risk environment and incorporated aspects of these concepts into their recommendations.

7 *See* IOM (Inst. of Med.), Comm. on Patient Safety & Health Info. Tech., Bd. on Health Care Servs., Health IT and Patient Safety: Building Safer Systems for Better Care (Nat'l Acads. Press 2011), *available at* www.nap.edu/read/13269/chapter/1 [hereinafter Health IT and Patient Safety: Building Safer Systems for Better Care].

8 *See id.* at 111. The concept of shared responsibility also appears in the IOM report on *Improving Diagnosis in Health Care,* which recommended "the Secretary of HHS should establish a mechanism for both vendors and users to report health IT-related deaths, serious injuries, or unsafe conditions." *See* Nat'l Acads. of Scis., Eng'g, & Med., *Improving Diagnosis in Health Care*, Recommendation 7 (Nat'l Acads. Press 2015).

Health IT-Related Safety Events

Myriad risks to patient safety may be associated with the design, implementation, and use of health IT.[9] A health IT-related safety event, referred to by some commentators as e-iatrogenesis, has been defined as "patient harm caused at least in part by the application of health information technology."[10] Eminent health IT researchers Sittig and Singh have described health IT-related patient safety errors as occurring "anytime the [health IT] system is unavailable for use, malfunctions during use, is used incorrectly, or when [health IT] interacts with another system component incorrectly, resulting in data being lost or incorrectly entered, displayed, or transmitted."[11] Various factors across the spectrum of design, implementation, and use of health IT systems contribute to safety hazards and conditions that may induce or facilitate errors.[12]

The National Quality Forum (NQF) report on the *Identification and Prioritization of Health IT Patient Safety Measures* noted that health IT-related errors often initially manifest as medication errors, wrong site surgeries, or delays in treatment, being reclassified as health IT errors at a later time.[13] The NQF Report further indicates that root cause investigation and analysis often is required to understand fully a health IT-related event, and that many

9 *See* Dean F. Sittig & Hardeep Singh, *Defining Health Information Technology-Related Errors: New Developments Since To Err Is Human*, 171 Archives Internal Med. 1281 (2011) [hereinafter *Defining Health Information Technology-Related Errors: New Developments Since To Err Is Human*]; Farah Magrabi et al., *Patient Safety Problems Associated with Heathcare Information Technology: An Analysis of Adverse Events Reported to the US Food and Drug Administration,* AMIA Ann. Symp. Proc. 853 (2011), *available at* www.ncbi.nlm.nih.gov/pmc/articles/PMC3243129/pdf/0853_amia_2011_proc.pdf.

10 *See* Jonathan P. Weiner et al., *"e-iatrogenesis": The Most Critical Unintended Consequence of CPOE and Other HIT*, 14 J. Am. Med. Informatics Ass'n 387, 387 (2007), *available at* www.ncbi.nlm.nih.gov/pmc/articles/PMC2244888/pdf/387.S1067502707000552.main.pdf.

11 *See Defining Health Information Technology-Related Errors: New Developments Since To Err Is Human*.

12 *See* Dean F. Sittig & Hardeep Singh, *Electronic Health Records and National Patient-Safety Goals*, 367 New Eng. J. Med. 1854 (2012) [hereinafter *Electronic Health Records and National Patient-Safety Goals*]; Derek W. Meeks et al., *Exploring the Sociotechnical Intersection of Patient Safety and Electronic Health Record Implementation*, 21 J. Am. Med. Informatics Ass'n e28 (2014); Health IT and Patient Safety: Building Safer Systems for Better Care.

13 *See* Identification and Prioritization of Health IT Patient Safety Measures, at 13.

providers do not have the requisite expertise (e.g., informatics, human factors, ergonomics) to correctly identify such errors.[14]

Sittig and colleagues have developed a categorization of health IT-related safety events:

1. The health IT fails during use or does not work as designed. In other words, the safety concern is directly attributable to the health IT;
2. The health IT works as designed, but the design does not meet user needs or expectations (i.e., poor design). The health IT is a contributing factor to the safety concern;
3. The health IT is well-designed and works correctly, but was not configured, implemented, or used in a manner anticipated by system designers and developers. Such events are related to use of health IT, rather than the health IT itself, and may be referred to as configuration errors, "workarounds," or incorrect usage;
4. The health IT works as designed and was configured and used correctly, but interacts with external systems (e.g., via hardware or software interfaces) such that data were lost or incorrectly transmitted or displayed. Certain of these events may be inevitable due to the interactive complexity of tightly coupled systems and often are referred to as health IT system interface safety concerns; and
5. Specific health IT safety features or functions were not implemented or not available.[15]

The authors suggest that these categories could form the basis for a nationwide health IT-related patient safety surveillance system that could be incorporated into the AHRQ Common Formats for Patient Safety Reporting.[16]

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14 *Id.*

15 *See* Dean F. Sittig, *Patient Safety Goals for the Proposed Federal Health Information Technology Safety Center*, 22 J. Am. Med. Informatics Ass'n 472 (2015).

16 *See Patient safety organization (PSO) program common formats*, Agency for Healthcare Research & Quality (AHRQ), www.pso.ahrq.gov/common (last visited Mar. 26, 2017); *Electronic Health Records and National Patient-Safety Goals*. Established by the Patient Safety and Quality Improvement Act of 2005, the Common Formats for Patient Safety Reporting is a program administered by the Agency for Healthcare Research and Quality (AHRQ) to enable reporting of patient safety events, hazards, and near-misses in standardized formats and with confidentiality protections.

Sittig and Singh also have proposed a three-phase approach for the development of EHR-specific patient safety goals.[17] This formed the basis for the Office of the National Coordinator for Health Information Technology of the Department of Health and Human Service's *SAFER Guides for EHRs*,[18] and subsequently served as the underpinning for the Health IT Safety (HITS) framework, a methodology to provide a conceptual foundation for health IT-related patient safety measurement, monitoring, and improvement.[19] Sittig and Singh's proposed model is instructive with respect to the safety and safe use of health IT. An overview of this model includes the following "domains":

- Domain 1: Safe health IT addresses concerns unique to EHR technology, including data integrity, data confidentiality, data availability, and information transfer;
- Domain 2: Using health IT safely addresses concerns arising from failure to use EHRs appropriately (*e.g.*, alert fatigue and override) and from unsafe changes in workflow triggered by health IT (*e.g.*, workarounds); and
- Domain 3: Using health IT to improve safety addresses efforts to optimize the use of EHRs to improve quality and safety and to proactively monitor and report on the safety and safe use of EHRs.[20]

The authors further opine that the three domains of health IT safety could be used as a framework for measurement and benchmarking of health IT-related safety performance.[21] The adoption of the framework proposed by Sittig and Singh serves to facilitate stakeholder understanding of the incidence and nature of health IT-related errors as well as the causes of these errors and interventions to improve health IT safety.

17 *See Electronic Health Records and National Patient-Safety Goals*.
18 *See SAFER Guides*, HealthIT.gov., www.healthit.gov/safer/safer-guides (last visited Mar. 26, 2017).
19 *See* Hardeep Singh & Dean F. Sittig, *Measuring and Improving Patient Safety Through Health Information Technology: The Health IT Safety Framework*, 0 BMJ Quality & Safety Online First 1 (2016), *available at* http://qualitysafety.bmj.com/content/qhc/early/2015/09/13/bmjqs-2015-004486.full.pdf.
20 *See Electronic Health Records and National Patient-Safety Goals*.
21 *Id.*

Ensuring Safe Implementation and Use of Health IT

Health IT typically is deployed with other third-party hardware and software and interacts in complex ways with clinicians and workflow processes within the local environment. Consequently, the safe use of health IT is affected by the following factors: (i) the design, development, and configuration of hardware and software components; (ii) the manner in which these components are implemented and used; and (iii) the extent to which effective processes are in place to monitor and improve the use of the health IT and associated outcomes.

Health IT developers and vendors typically use standard form agreements where the terms and conditions are prepared by the developer or vendor and the health care organization has limited ability to negotiate more favorable provisions. Historically, health IT developers and vendors have shifted responsibility for the safety of health IT to the purchasers of hardware and software through the inclusion of indemnity and limitation of liability provisions in these form agreements. Such agreements, however, should fairly allocate responsibility for acts and omissions to the party who is primarily responsible for the conduct that leads to the acts or omissions and resulting damages. The party who has the most control over the factors giving rise to a health IT patient safety risk is in the best position to prevent and mitigate such a risk.

Thus, to promote the safe use of health IT and fairly allocate accountability for minimizing the associated risks, developer and vendor agreements should clearly identify responsibilities within the control of each party:

Responsibilities of Health Care Organization:

1. Defining and documenting the roles and responsibilities of the health IT developer or vendor and the health care organization (along with administrative and clinical personnel) toward ensuring the safe design, implementation, and use of the health IT, including ongoing maintenance, upgrades, performance monitoring, and optimization;
2. Ensuring adequate education and training of organizational users; appropriate resourcing; customization; and use of health IT in accordance with risk assessment, developer or vendor recommendations, and applicable institutional policies; and

3. Conducting risk assessments to optimize the safety and safe use of health IT in the areas of system configuration, system interfaces, patient identification, EHR and computerized provider order entry with decision support, test results reporting and follow-up, internet-enabled medical devices, clinician communication, and contingency planning.

Responsibilities of Health IT Developer or Vendor:

1. Maintaining appropriate internal controls and processes to ensure the quality and safety of the information technology hardware, software, and related upgrades;
2. Cooperating with and assisting in the investigation of technology-related deaths, serious injuries, or unsafe conditions, including reasonable cooperation with obligations to report health IT safety issues to government agencies, where applicable;
3. Sharing real-time comparative user experiences and notifying the health care organization in a timely manner whenever the developer or vendor identifies or becomes aware of software deficiencies, hardware defects, implementation errors, poor design or usability, misinterpreted user-technology interfaces, or other causes that could potentially affect patient safety, as well as providing prompt solutions for identified patient safety issues (*e.g.*, workflow guidance, features that should not be used, software updates);
4. Permitting the use of developer or vendor product information in research studies for peer reviewed journals (*e.g.*, screen shots) to facilitate learning health care systems; and
5. If the health IT is cloud-based, providing a copy of the developer's or vendor's disaster recovery plan to the health care organization, agreeing to perform disaster recovery testing involving one or more of the organization's facilities, sharing the results of such testing, and promptly advising the organization of any changes in its disaster recovery plan.

Ensuring Secure Implementation and Use of Health IT

Because health IT operates in a climate of rapidly increasing security and cybersecurity threats, the safe design, implementation, and use of health IT requires maintaining the security of protected health information (PHI) and the networks on which PHI is stored and accessed. The Health Information Technology for Economic and Clinical Health (HITECH) Act[22] requires that business associates comply with the HIPAA Security Rule provisions that mandate implementation of administrative, physical, and technical safeguards (including designation of a security official) for electronic protected health information (e-PHI), as well as development and enforcement of related policies, procedures, and documentation standards.[23] Agreements between health care organizations and health IT vendors should set forth the obligations of the health IT vendor to comply with the requirements of the HIPAA Security Rule.

Sound security practices require a continual assessment of evolving risks, technology, and relevant issues related to information security for both health care providers and health IT vendors. For example, Congress, in enacting the Cybersecurity Information Sharing Act of 2015 (CISA),[24] recognized that the health care sector could benefit from more widespread and comprehensive sharing of identified cyber security threats and created many new initiatives to foster the sharing of such information. Health IT vendors that manage data on behalf of health care provider organization customers will need to participate in those efforts to improve overall health care system security.[25] In addition to HIPAA Security Rule requirements, health care providers may wish to consider imposing the following additional contractual obligations on health IT developers or vendors to more fairly allocate responsibility for ensuring the secure implementation and use of health IT in this dynamic collaborative environment:

22 *See* 42 U.S.C. § 17921.
23 *See id.* § 17931(a); 45 C.F.R. §§ 164.308, .310, .312 and .316.
24 *See* Cybersecurity Information Sharing Act of 2015, S Res. 754, 114th Cong. (2015) (enacted), *available at* www.congress.gov/bill/114th-congress/senate-bill/754/text.
25 *Id.* § 405(c).

- completing a security assessment questionnaire;
- obtaining an independent third-party security audit and sharing the results on an annual basis or more frequently in the event of a security breach;
- complying with the health care organization's information security program, including all required network and systems security, system and application controls as may be updated from time to time, including documented policies, standards, and operational practices that meet or exceed current industry standards (e.g., NIST Common Framework);
- employing encryption methodology and secure data destruction practices; and
- adhering to all applicable federal and state data security laws and regulations such as CISA's sharing of threats.

The Path Toward Shared Responsibility for Ensuring Safe and Secure Health IT

Given the complexity of health IT and the interconnected relationship among hardware, software, the local environment, and providers, it is vital for stakeholders to share responsibility for the quality and safety of health IT.[26] This responsibility should not fall disproportionately on one stakeholder, but rather should be shared through contractual allocation of responsibility and corresponding liability among those stakeholders that are in the best position to prevent and mitigate a particular patient safety risk—and thereby control the unintended consequences of health IT. Assigning complete responsibility for performance to either a developer's or vendor's technology or to a health care

26 For example, the NQF Committee suggested that accountability for patient identification could be shared across all stakeholders, including vendors, health care organizations, clinicians, and even patients. Committee members did caution that patient accountability would need to be framed and implemented carefully, with consideration that patients are often ill and vulnerable. Identification and Prioritization of Health IT Patient Safety Measures, at 20.

organization's implementation or use of that technology is inappropriate, because overall performance is based on their combined actions. A carefully drafted agreement can serve to minimize these risks by assigning appropriate roles and responsibilities to ensure the safe and secure design, implementation, and use of health IT. The agreement should contain obligations consistent with evolving standards on quality and risk management of both clinical health IT systems and networks.[27] When risk is allocated among all stakeholders, the use of health IT can be optimized to deliver safer and more effective care. J

27 *See IEC 80001-1:2010(en): Application of Risk Management for IT-Networks Incorporating Medical Devices–Part 1: Roles, Responsibilities and Activities*, ISO, www.iso.org/standard/44863.html (last visited Mar. 27, 2017), which embraces the concept of a "Responsibility Agreement." Other related and relevant standards include ISO 31000 (Risk management), IEC 14971 (Medical device risk management), ISO 62304 (Software risk management) and IEC 27005 (IT security risk management). Standards-based guidance is being developed specifically to address risk management of clinical health IT software systems, including health management health IT, not regulated by the Food and Drug Administration. *See* AAMI, Summary: AAMI Proposal for Development of a Risk Management Process Standard(s) for Patient Safety with Health IT (2014), *available at* http://healthit.gov/facas/sites/faca/files/IUSWG_AAMI_Proposal_Package_2014-12-12.pdf.

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