

The Affordable Care Act and the Medicare Program: The Engines of True Health Reform

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ABSTRACT:

The Patient Protection and Affordable Care Act¹ and its amendments by the Health Care and Education Reconciliation Act of 2010² constitute landmark legislation known as the Affordable Care Act (ACA). The ACA has made many changes in the Medicare program as part of comprehensive health reform for the U.S. health care sector. Title III of the ACA pertains to improving the efficiency and quality of health care. Title VI calls for greater program integrity for all federally funded health insurance programs. Collectively, the changes in Medicare in these two titles address the three major problems that the Medicare program has faced since its inception: cost and volume inflation, quality assurance, and fraud and abuse. These changes, if successfully implemented, will have a dramatic impact on the reform of the American health care sector. The policy-making process in the Medicare program is exemplary of the process of “muddling through,” as described by the Yale economist Charles E. Lindblom. Nevertheless, these changes may also prepare the Medicare program to be transformed, through several incremental changes in upcoming years, into a single payer system.

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¹ Patient Protection and Affordable Care Act (PPACA), Pub. L. No. 111-148, 124 Stat. 119 (2010) (codified as amended in scattered titles of the U.S.C.). For an excellent source on Affordable Care Act (ACA) changes to the Medicare program, see Patricia A. Davis, et al., *Medicare Provisions in PPACA (P.L. 111-148)*, CONG. RES. SERV. (Apr. 21, 2010), http://assets.opencrs.com/rpts/11-148_20100421.pdf. See also Michael J. DeBoer, *Medicare Coverage Policy and Decision Making, Preventive Services, and Comparative Effectiveness Research Before and After the Affordable Care Act*, 7 J. HEALTH & BIOMEDICAL L. 493 (2011).

² Health Care and Education Reconciliation Act of 2010, Pub. L. No. 111-152, 124 Stat. 1029 (2010).

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INTRODUCTION

The Patient Protection and Affordable Care Act³ and its amendments by the Health Care and Education Reconciliation Act of 2010⁴ together establish the Affordable Care Act (ACA), the health care reform law that will be implemented in full force in 2014. The ACA has made many changes in the Medicare program. These reforms in Medicare address the three major problems facing the Medicare program since its inception: cost and volume inflation, quality assurance, and fraud and abuse. These changes, if successfully implemented, will have a dramatic impact on the reform of the American health care sector. They may also prepare the Medicare program to be transformed into a single payer system should other coverage expansions in the ACA fail.

The provisions of the ACA that will have the greatest impact on the reform of the Medicare program and the health care sector, generally, are in Titles III and VI. Historically, since its inception in 1965, the Medicare program has been at the forefront in crafting strategies to address the major problems of the health care sector with respect to escalating costs and improving quality, as well as preventing and punishing fraud and abuse. State Medicaid programs and private payers are greatly influenced by the policy developments in the Medicare program and often follow Medicare policy. At the very least, then, the ACA reforms in Titles III and VI will be influential in promoting health care reform throughout the health care sector.

However, the possibility exists that the coverage expansions in the ACA will fail and that progress toward universal coverage will stall. In this event, a reformed Medicare program will be in an excellent position to expand into a national single payer system that provides universal coverage. As an all payer system, Medicare would confront the same problems of cost and volume control, value for payment, as well as fraud and abuse. To the extent that the ACA reforms move toward addressing these problems effectively, they enhance the possibility that Medicare will become a strong and sustainable single payer system.

In understanding Medicare and crafting its reform, it is important to appreciate what the Medicare program has accomplished since its inception in 1965.⁵ Medicare has assured access to affordable health insurance and health care for elders and the severely disabled. Medicare has also contributed to a

3 Patient Protection and Affordable Care Act (PPACA), Pub. L. No. 111-148, 124 Stat. 119 (2010) (codified as amended in scattered titles of the U.S.C.).

4 Health Care and Education Reconciliation Act of 2010, Pub. L. No. 111-152, 124 Stat. 1029 (2010) (codified as amended in scattered titles of the U.S.C.).

5 Marilyn Moon, *Medicare Matters: Building on a Record of Accomplishment*, 22 HEALTH CARE FINANCING REV. 9 (2000); see *Medicare at 40: Past Accomplishments and Future Challenges*, AARP (July 2005), http://assets.aarp.org/rgcenter/health/medicare_40.pdf.

vibrant health care sector including highly profitable pharmaceutical and medical device industries. Indeed, the medical device industry leads the world with over half of the medical device manufacturers being located in the United States.⁶

It is important to appreciate the way in which Congress and Medicare policy-makers create policy. Policy-making process in the Medicare program is exemplary of the process of “muddling through,” as described by the Yale economist Charles E. Lindblom in his famous article, *The Science of “Muddling Through,”* in 1959.⁷ Lindblom describes “muddling through” as an alternative to a formal ideologically driven process of starting with values to be promoted, considering a theory for guidance, and empirically reviewing all options. In the process of “muddling through,” a policymaker sets a principal objective, without consideration of values except the most relevant. The policymaker then identifies and compares relatively few policy options without real reference to theory or to other values not immediately relevant and drawing greatly from past experience.⁸

The Medicare policymakers, in both Republican and Democratic administrations, have “muddled through” in making policy that generally, if incrementally, advances the program. Policy alternatives considered are often only those that are politically palatable—at least to political opponents and the provider community. Also, Congress and Medicare policymakers revisit Medicare initiatives annually to advance or reform the initiative. Medicare policymaking, for the most part, focuses on improving the program, while containing costs, placating providers and serving Medicare beneficiaries.

Each year since the program’s inception, Congress has made changes in the Medicare program. Generally these changes are made through amendments to the Social Security Act (SSA) or in legislation to reconcile the federal budget. Occasionally, Congress will enact legislation specifically designed to change the Medicare program directly, as was done in 2003 with the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (MMA).⁹ Figure 1 lists the annual legislation that has made major changes to the Medicare program.

In the early years of the Medicare program, Congress and the Medicare program would generally focus on each provider and supplier group independently. Further, most major reforms focused on inpatient hospitals under Part A and physician services under Part B. Since the inception of the Medicare program, the largest proportion of expenditures has gone to hospitals and

6 Yair Holtzman, *The U.S. Medical Device Industry in 2012: Challenges at Home and Abroad*, MED. DEVICE & DIAGNOSTIC INDUSTRY (July 17, 2012), <http://www.mddionline.com/article/medtech-2012-SWOT>.

7 See Charles E. Lindblom, *The Science of “Muddling Through,”* 19 PUB. ADMIN. REV. 70 (1959).

8 *Id.*

9 Medicare Prescription Drug, Improvement, and Modernization Act (MMA) of 2003, Pub. L. No. 108-173, 117 Stat. 2066 (codified as amended in scattered sections of 26 and 42 U.S.C.).

secondarily to physicians and other Part B providers.¹⁰ Since 2000, Congress and policymakers have approached reform in a more integrated fashion. They have proceeded from an understanding that physicians and hospitals were inextricably intertwined in their decisionmaking and Medicare needed to incentivize all providers to work together and coordinate care in an efficient and cost-effective manner.

In making reforms, the Medicare program follows a distinct pattern. First, Congress and policymakers recognize a problem in the program or the health care sector that needs attention. Congress will often assign the Centers for Medicare and Medicaid Services (CMS) within the U.S. Department of Health and Human Services (HHS) in statute to prepare a report describing the problem and proposing solutions. Then, if the change is major and requires a statutory modification, Congress often directs CMS to conduct a demonstration to test the contemplated changes.¹¹ After the evaluation of the demonstration, which takes several years, Congress implements the change in stages with different providers or suppliers. The reforms in the ACA Titles III and VI have been made in the same process. They would likely have been enacted in other legislation, if the ACA had not been enacted in 2010.

The Article proceeds to analyze the ACA Medicare reforms in the following manner. Part I introduces the mission and major themes of the Article. Part II outlines the historic and current challenges that rising Medicare expenditures have posed for the Medicare program. It is important to understand this historical development because the changes to the Medicare program in Titles III and VI of the ACA are, in a very real sense, simply steps in the implementation of reforms already in place. As steps in the implementation of prior reforms, their development is described as much by the policymaking process that Professor Lindblom described. Parts III and IV of this Article outline the detailed changes that Titles III and VI of the ACA made to the Medicare program. Part V of the Article concludes with an assessment of the ACA's potential success. Part V also argues that, with reforms in the ACA, the Medicare program is well positioned to become a national single payer system, should the coverage expansions in the ACA fail.

10 Marian Gornick et al., *Twenty years of Medicare and Medicaid: Covered Populations, Use of Benefits, and Program Expenditures*, 7 HEALTH CARE FINANCING REV. 13 (Supp. 1985).

11 Charles Fiegl, *Medicare Demonstration Projects: From Idea to Implementation*, AM. MED. NEWS (Nov. 28, 2011), <http://www.ama-assn.org/amednews/2011/11/28/gvsa1128.htm>.

**Figure 1
Federal Legislation Enacting Major Changes
in the Medicare Program, 1965-2012**

<p>P.L. 89-97, Social Security Amendments of 1965</p> <ul style="list-style-type: none"> Established the Medicare and Medicaid programs Established Part A, Hospital Insurance Established Part B, Supplementary Medical Insurance <p>P.L. 90-248, Social Security Amendments of 1967</p> <p>P.L. 92-603, Social Security Amendments of 1972</p> <ul style="list-style-type: none"> Established the Professional Standards Review Organization (PSRO) Program Added Severely Disabled as Medicare Beneficiaries Established Medicare Anti-Kickback Authority <p>P.L. 95-142, Medicare-Medicaid Anti-Fraud and Abuse Amendments of 1977</p> <p>P.L. 95-216, Social Security Amendments of 1977</p> <p>P.L. 96-499, Omnibus Reconciliation Act of 1980</p> <ul style="list-style-type: none"> Enacted Medicare Secondary Payer Act <p>P.L. 97-35, Omnibus Budget Reconciliation Act of 1981</p> <ul style="list-style-type: none"> Repealed the PSRO Program. Enacted Civil Monetary Penalties Law <p>P.L. 97-248, Tax Equity and Fiscal Responsibility Act of 1982</p> <ul style="list-style-type: none"> Established the Peer Review Organization Program Authorized Medicare HMOs <p>P.L. 98-21, Social Security Amendments of 1983</p> <ul style="list-style-type: none"> Established Prospective Payment for Inpatient Hospital Care <p>P.L. 98-369, Deficit Reduction Act of 1984</p> <ul style="list-style-type: none"> Initiated Payment Reform for Physicians <p>P.L. 99-272, Consolidated Omnibus Budget Reconciliation Act of 1985</p> <ul style="list-style-type: none"> Enacted the Emergency Medical Treatment and Active Labor Act <p>P.L. 99-509, Omnibus Budget Reconciliation Act of 1986</p> <p>P.L. 99-562, False Claims Amendments of 1986</p> <p>P.L. 100-93, Medicare and Medicaid Patient and Program Protection Act of 1987</p> <p>P.L. 100-203, Omnibus Budget Reconciliation Act of 1987</p>	<p>P.L. 104-191, Health Insurance Portability and Accountability Act (HIPAA) of 1996</p> <ul style="list-style-type: none"> Enhanced Fraud and Abuse Authorities Established Privacy and Security Requirements for Patient medical information <p>P.L. 105-33, Balanced Budget Act of 1997</p> <ul style="list-style-type: none"> Established the State Children's Health Insurance Program (SCHIP) Established Medicare + Choice Program (Part C) Established the Medicare Payment Advisory Commission (MEDPAC). Established the Sustainable Growth Rate for Medicare physician payment <p>P.L. 104-113, Medicare, Medicaid, and SCHIP Balanced Budget Refinement Act of 1999</p> <p>P.L. 106-554, Medicare, Medicaid and SCHIP Benefits Improvement and Protection Act of 2000</p> <ul style="list-style-type: none"> Reformed Medicare Coverage Policy and Decision-making <p>P.L. 108-173, Medicare Prescription Drug, Improvement, and Modernization Act</p> <ul style="list-style-type: none"> Established the Medicare Advantage Program in place of the Medicare + Choice Program (Part C) Established the Medicare Prescription Drug Benefit (Part D) Established Hospital Inpatient Quality Reporting Reformed Medicare Coverage Policy and Decision-making <p>P.L. 109-171, Deficit Reduction Act of 2005</p> <ul style="list-style-type: none"> Limited Payment for "never events" including "hospital-acquired conditions." <p>P.L. 109-432, Tax Relief and Health Care Act of 2006</p> <ul style="list-style-type: none"> Established Physician Quality Reporting Initiative <p>P.L. 110-173 Medicare, Medicaid, and SCHIP Extension Act of 2007</p> <p>P.L. 110-275, Medicare Improvements for Patients and Providers Act of 2008</p> <ul style="list-style-type: none"> Established the Physician Quality Feedback Program
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<ul style="list-style-type: none"> • Established National Standards for Nursing Homes P.L. 100-360 Medicare Catastrophic Coverage Act of 1988 • Established a Catastrophic Coverage benefit under Medicare P.L. 101-234, Medicare Catastrophic Coverage Repeal Act of 1989 P.L. 101-239, Omnibus Budget Reconciliation Act of 1989 • Established Physician Self-Referral Restrictions (Stark I) P.L. 101-508, Omnibus Budget Reconciliation Act of 1990 P.L. 103-66, Omnibus Budget Reconciliation Act of 1993 • Expanded Physician Self-Referral Restrictions (Stark II) P.L.103-432 Social Security Act Amendments of 1994 	<ul style="list-style-type: none"> P.L. 111-5, American Recovery and Reinvestment Act of 2009 • Funded Comparative Effectiveness Research P.L. 111-48, Patient Protection and Affordable Care Act P. L. 111-152, Health Care and Education Reconciliation Act of 2010 • Enacted comprehensive health reform including reforms of the Medicare program P.L. 112-240, American Taxpayer Relief Act of 2012
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I. TAMING THE GROWTH IN MEDICARE EXPENDITURES

The Medicare program already is a major source of coverage for a significant portion of the U.S. population. In 2011, Medicare provided insurance for 40.4 million aged 65 or older and 8.3 million disabled for a total of 48.7 million people.¹² Thus, almost one-sixth of the U.S. population depends on the Medicare program. Total Medicare expenditures in 2011 were \$549.1 billion.¹³ Medicare expenditures constituted 15 percent of total federal outlays in 2010 and over 3 percent of the gross domestic product.¹⁴ By size alone, Medicare is a tremendously important program to millions of people as well as the providers, manufacturers, and suppliers who serve them.

Amending the SSA,¹⁵ Congress established the Medicare program to provide health care coverage for the aged in 1965. Medicare, a federal social insurance program, administered by the CMS, provides insurance for hospital and extended-care services and supplementary medical insurance for physician and

12 Bds. of Trs., *2012 Annual Report of the Boards of Trustees of the Federal Hospital Insurance and Federal Supplementary Medical Insurance Trust Funds*, FED. HOSP. INS. & FED. SUPPLEMENTARY MED. INS. TR. FUNDS 6 (Apr. 23, 2012), <http://www.cms.gov/Research-Statistics-Data-and-Systems/Statistics-Trends-and-Reports/ReportsTrustFunds/Downloads/TR2012.pdf>.

13 *Id.*

14 *Medicare Spending and Financing: A Primer*, KAISER FAMILY FOUNDATION 1-2 (Feb. 2011), <http://www.kff.org/medicare/upload/7731-03.pdf>.

15 Social Security Amendments of 1965, Pub. L. No. 89-97, §§ 101-111, 121-122, 79 Stat. 286, 291-360 (codified as amended at 42 U.S.C. §§ 1395-1396 (2006)); *see also* S. REP. NO. 89-404 (1965), *reprinted in* 1965 U.S.C.C.A.N. 1943.

associated services to the aged, disabled, and certain individuals with end stage renal disease.¹⁶

The Medicare program is comprised of four parts. Parts A and B were contained in the original Medicare statute and are called “Fee-for-Service” or “original” Medicare. Part A, Hospital Insurance for the Aged, covers hospital and extended-care services.¹⁷ Part B, Supplementary Medical Insurance, covers physician and other outpatient services.¹⁸ Part C of the Medicare program, now called the Medicare Advantage program (since substantial changes to the program in the MMA¹⁹), was established in the Balanced Budget Act of 1997.²⁰ Part C authorizes the provision of Medicare benefits through private health plans and allows private health plans to augment the benefit package as well. Established in the MMA,²¹ Part D is a voluntary prescription drug benefit program.

The Medicare program is financed through two trust funds: the Hospital Insurance Trust Fund and the Supplementary Medical Insurance Trust Fund.²² The Hospital Insurance Trust Fund, which pays for items and services under Part A and Part A services provided in Medicare Advantage plans under Part C, is funded primarily by a payroll tax.²³ The Supplementary Medical Insurance Trust Fund, which pays for Part B items and services, is funded from premiums under Parts B and D, and, to a minimal extent, from general revenues.²⁴ This trust fund also pays for Part A and B services provided through Part C Medicare Advantage plans and Part D prescription drug plans.²⁵

Table 1 presents the major institutional and professional providers that serve Medicare beneficiaries. The Medicare program also contracts with Medicare Administrative Contractors to manage claims and payment of Medicare Part A

16 In 1972, Congress added the disabled and individuals with end stage renal disease to those eligible for Medicare. Social Security Amendments of 1972, Pub. L. No. 92-603, § 299I, 86 Stat. 1329, 1463 (1972) (codified as amended at 42 U.S.C. § 1395 (2006)).

17 42 U.S.C. §§ 1395c-1395i (2006).

18 *Id.* §§ 1395j-1395w-5.

19 Medicare Prescription Drug, Improvement, and Modernization Act (MMA) of 2003, Pub. L. No. 108-173, §§ 201-241, 117 Stat. 2066, 2176-2221 (2003) (codified as amended at 42 U.S.C. § 1395 (2006)); see Timothy Stoltzfus Jost, *The Most Important Health Care Legislation of the Millennium (So Far): The Medicare Modernization Act*, 5 YALE J. HEALTH POL’Y, L. & ETHICS 437 (2005).

20 Balanced Budget Act of 1997, Pub. L. No. 105-33, § 4001, 111 Stat. 251, 275 (1997) (codified as amended at 42 U.S.C. § 1395w-21 (2006)).

21 MMA § 101.

22 42 U.S.C. §§ 1395i-1395t (2006).

23 *Id.* § 1395i.

24 *Id.* § 1395t.

25 *Id.* § 1395t(g); see *How is Medicare Funded?*, MEDICARE.GOV, <http://www.medicare.gov/about-us/how-medicare-is-funded/medicare-funding.html> (last visited Apr. 23, 2013).

and B providers. Under Part C, Medicare Advantage (MA) plans handle payments to Medicare providers.

Individual and aggregate health care expenditures (HCE) are a function of the cost of an item or service multiplied by the volume of items or services. Metaphorically, the function is expressed as follows: $HCE = (\text{Cost of Items and Services in Dollars}) \times (\text{Volume of Items and Services})$. The unit measures for volume are determined by the manner in which the item or service is delivered, for example, “hospital patient days,” “physician visits,” or number of items sold. In the early years of the Medicare program, Congress and policymakers focused on reducing the two variables—cost and volume—as both had grown beyond expectations in the early years of the Medicare program.

The seriousness of the cost problem surfaced shortly after the inauguration of the Medicare program and has dominated health policymaking ever since. Congress and HEW almost immediately recognized that the costs of the Medicare program would greatly exceed the initial Medicare cost projections.²⁶ Figure 2 displays the explosive growth in Medicare expenditures since the inauguration of the program.

26 STAFF OF S. COMM. ON FINANCE, 89TH CONG., PROPOSED MEDICARE REIMBURSEMENT FORMULA, at i (Comm. Print 1966); STAFF OF THE S. COMM. ON FINANCE, 91ST CONG., MEDICARE AND MEDICAID: PROBLEMS, ISSUES, AND ALTERNATIVES 140-43 (Comm. Print 1970).

THE AFFORDABLE CARE ACT AND THE MEDICARE PROGRAM

Table 1 The Institutional and Professional Healthcare Providers that Serve Fee-for-Service Medicare Beneficiaries under Parts A and B of the Medicare Program and which also contract with MA plans to serve Medicare Beneficiaries		
Providers Paid Under Medicare Part A	Providers Paid Under Medicare Part B	
Institutional Providers	Professional Providers (and their organizations)	Suppliers (Selected)
Hospitals Acute Care Hospitals Psychiatric Hospitals Long Term Care Hospitals Rehabilitation Hospitals	Physicians Nurse Practitioners Physician Assistant Clinical Nurse Specialist Certified Registered Nurse Anesthetist Certified Nurse-Midwife Clinical Social Worker Clinical Psychologist Registered Dietitian/Nutrition Professional Podiatrists	Ambulance Service Suppliers Part B Drug Vendors Portable X-ray Suppliers Intensive Cardiac Rehabilitation Suppliers
Skilled Nursing Facilities Long Term Care Hospitals Rehabilitation Hospitals "Swing Bed" Units in Acute Care Hospitals	Outpatient Service Providers Clinic/Group Practices Hospital Outpatient Departments Ambulatory Surgical Centers Mammography Centers Independent Clinical Laboratories Independent Diagnostic Testing Facilities Radiation Therapy Centers	
Home Health Agencies	Home Health Agencies	

From the early days of the Medicare program, Congress and the administrations of presidents from both parties sought to reduce the growth in Medicare expenditures. The ostensible premise of the Social Security Amendments of 1965 was that the provider community would supply only reasonable and necessary care and would not respond to financial incentives in the program's reimbursement methodologies to provide excess and unnecessary care or engage in fraud and abuse. However, according to Wilbur Cohen, the Secretary of the Department of Health, Education and Welfare (HEW) when the Medicare program was enacted, "[t]he ideological and political issues between 1960 and 1965 were so dominating that they precluded consideration of issues such as reimbursement alternatives and efficiency options."²⁷

²⁷ Wilbur J. Cohen, *Reflections on the Enactment of Medicare and Medicaid*, 7 HEALTH CARE FINANCING REV. 3, 5 (1985).

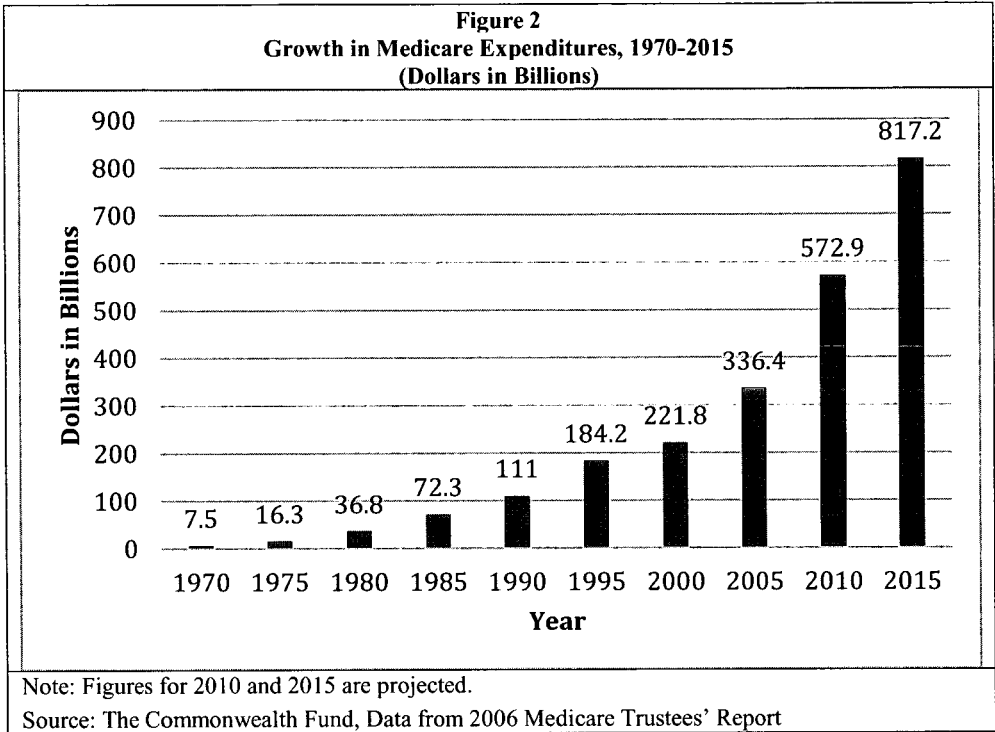


Table 2 presents elements of the Medicare program’s regulation of its expenditures. The paramount goal of this regulation is to assure that the program pays only for reasonable and necessary care for Medicare beneficiaries. Table 2 also indicates whether the strategies established to achieve this goal have had an impact on the efficiency of care delivery, the overall cost or volume of Medicare items and services, as well as the quality and effectiveness of care. Over the years, the Medicare program has had to adopt a continuum of regulation to achieve this goal, including strategies to eliminate wasteful and unnecessary care as well as outright fraudulent care that was never provided.

Table 2
Regulatory Goals and Strategies to Regulate the Volume of Medicare Items and Services and the Impact of the Goals and Strategies on the Efficiency of Care Delivery, the Impact on Equation for Medicare Expenditures and the Resulting Characteristic of Care in terms of Quality and Effectiveness

Regulatory Goals	Regulatory Strategies to Achieve Goals	Efficiency Level in the Delivery of Items and Services	Impact on HCE = Cost x Volume Equation	Resulting Character of Care
Achieve Reasonable and Necessary Items and Services	Medicare Coverage Policy	Efficient	No Adverse Impact	High Quality, Cost Effective Care
	Medicare Payment Policies Medicare Quality Measures	Inefficient	Impact on Cost Variable	High Quality, High Cost Care
Reduce Arguably Reasonable but Unnecessary Items and Services	Medicare Coverage Policy	Efficient	Impact on Volume Variable	Poor Quality, Wasteful Higher Cost Care
	Medicare Payment Policies Medicare Quality Measures	Inefficient	Impact on Cost and Volume Variables	Poorer Quality, Wasteful Higher Cost Care
Eliminate Unreasonable and Unnecessary Items and Services	Medicare Coverage Policy	Efficient	Greater Impact on Cost and Volume Variables	Wasteful and Abusive Care
	Medicare Payment Policies Medicare Fraud and Abuse Authorities	Inefficient	Lesser Impact on Cost and Volume Variables	More Wasteful and Abusive Care
Prevent Claims for Items and Services which were not Provided	Medicare Criminal Fraud and Abuse Authorities	Efficient	Greater Impact on Cost and Volume Variables	Fraudulent Care
		Inefficient	Lesser Impact on Cost and Volume Variables	Fraudulent Care

A. The Challenge of Cost Inflation

In 1965, the Medicare program paid hospitals the costs, as calculated by hospitals, of providing services to beneficiaries. The only stipulation was that the costs be “reasonable.”²⁸ Similarly, the Medicare program paid physicians a reasonable charge based on usual and customary charges in the market place.²⁹ Because both of these reimbursement methodologies placed control over the cost of, and charges for, care in the hands of the providers, providers were able to set

28 Social Security Amendments of 1965, Pub. L. No. 89-97, § 102(a), 79 Stat. 286, 296 (codified as amended at 42 U.S.C. §§ 1395(f)(b), 1395x(v) (2006)).

29 *Id.* § 102(a) (codified as amended at 42 U.S.C. § 1395(a) (2006)).

the payment rates for items or services. Not surprisingly, these methods proved very costly, and Medicare expenditures grew at alarming rates immediately upon implementation of the program.³⁰

1. Inpatient Hospital Payment

Congress focused initially on hospital costs, as these represented the greatest proportion of Medicare expenditures and were the greatest problem. In the Social Security Amendments of 1972, Congress authorized HEW, the predecessor of HHS, to impose a limit on the routine costs that Medicare paid hospitals.³¹ In addition, Congress authorized HEW to conduct demonstrations of different ways Medicare could pay for inpatient hospital and skilled nursing care services.³² Robert B. Fetter and John D. Thompson of Yale University developed diagnosis related groups (DRGs)³³ as a classification system that groups similar clinical conditions and procedures furnished by the hospital during the stay.³⁴ HEW tested the DRGs in demonstration project involving all in-patient, acute care hospitals in the state of New Jersey.³⁵

In the early 1980s, Congress and the Reagan Administration enacted the Medicare inpatient prospective payment system (IPPS) for hospitals, which used the DRGs developed at Yale and tested in New Jersey. In the Tax Equity and Fiscal Responsibility Act of 1982, Congress laid the groundwork for prospective payments by establishing limits on the costs that Medicare would pay hospitals for each patient case and calling on HHS to develop a legislative proposal for a prospective payment system by December 1982.³⁶ Following the HHS proposal

30 See *supra* note 27 and accompanying text.

31 Social Security Amendments of 1972, Pub. L. No. 92-603, § 223, 86 Stat. 1329 (codified as amended at 42 U.S.C. § 1395x(v)(1)(A) (2006)).

32 *Id.* § 222 (codified at 42 U.S.C. § 1395b-1 (2006)).

33 John D. Thompson, *The History of the Development of DRGs*, in COMPELLED BY DATA: JOHN D. THOMPSON 71 (William D. White ed., 2003); see also Robert B. Fetter et al., *A System for Cost and Reimbursement Control in Hospitals*, 49 YALE J. OF BIOLOGY & MED. 123 (1976); John D. Thompson, *DRGs Broaden Hospitals' Accountability, Responsibility*, 62 HOSP. PROGRESS, June 1981, at 46; John D. Thompson et al., *Case Mix Accounting: A New Tool*, in SAMUEL LEVEY & THOMAS MCCARTHY, HEALTH MANAGEMENT FOR TOMORROW 157 (1980); John D. Thompson & Robert B. Fetter, *Simulation of Hospital Systems*, 3 OPERATIONS RES. 689 (1965).

34 CENTERS FOR MEDICARE & MEDICAID SERVS. (CMS), *Acute Inpatient PPS*, CMS.GOV (May 3, 2013, 11:00AM), <https://www.cms.gov/AcuteInpatientPPS>; CMS, *Acute Care Hospital Inpatient Prospective Payment System*, DEP'T OF HEALTH & HUMAN SERVS. (DHHS) (Feb. 2012), <https://www.cms.gov/Outreach-and-Education/Medicare-Learning-Network-MLN/MLNProducts/downloads/AcutePaymtSysfctshst.pdf> (describing DRGs).

35 William C. Hsiao et al., *Lessons of the New Jersey DRG Payment System*, 5 HEALTH AFF., May 1986, at 32.

36 Tax Equity and Fiscal Responsibility Act of 1982, Pub. L. No. 97-248, § 101, 96 Stat. 324, 331-36 (codified as amended at 42 U.S.C. § 1395ww(a)-(c) (2006)).

for a prospective payment system based on DRG's,³⁷ Congress adopted the IPPS the following spring in the Social Security Amendments of 1983.³⁸

Under the IPPS, the Medicare program pays acute care hospitals a fixed price, adjusted for geographic and wage cost differences, for each Medicare case based on the DRG in which the patient's particular condition falls.³⁹ HHS stated in its mandatory report to Congress on the new payment system:

The ultimate objective of PPS is to set a reasonable price for a known product. This provides incentives for hospitals to produce the product more efficiently. When PPS is in place, health care providers will be confronted with strong lasting incentives to restrain costs for the first time in Medicare's history.⁴⁰

The Medicare prospective payment system for hospitals has been in place for twenty-seven years. Neither Congress nor the administrations of both parties have fundamentally changed IPPS since its inception in 1983. In 2008, CMS established a new DRG system, the Medical Severity—DRGs (MS-DRGs), to better account for differences in severity for similar conditions.⁴¹ Congress and CMS have extended prospective payment methodologies to nursing homes and other institutional providers.⁴²

2. Physician Payment

Also in the Social Security Amendments of 1983, Congress directed the Secretary of HHS to study possible methods of paying physicians according to a

37 DHHS, HOSPITAL PROSPECTIVE PAYMENT FOR MEDICARE: REPORT TO CONGRESS REQUIRED BY THE TAX EQUITY AND FISCAL RESPONSIBILITY ACT OF 1982 66 (1983).

38 Social Security Amendments of 1983, Pub. L. No. 98-21, § 601(c)(1), 97 Stat. 65, 150 (codified as amended at 42 U.S.C. § 1395ww (2006)).

39 42 U.S.C. § 1395ww(d)(1)(2006); Medicare Program; Prospective Payments for Medicare Inpatient Hospital Services (Interim Final Rule), 48 Fed. Reg. 39,752 (Sept. 1, 1983) (codified at 42 C.F.R. pts. 405, 409, 489 (2011)).

40 DHHS, *supra* note 37, at 101.

41 Medicare Program; Proposed Changes to the Hospital Inpatient Prospective Payment Systems and Fiscal Year 2009 Rates, 73 Fed. Reg. 23,528 (proposed Apr. 30, 2008) (to be codified as amended at scattered pts. of 42 C.F.R.); *see Acute Inpatient PPS*, CENTERS FOR MEDICARE & MEDICAID SERVS., <https://www.cms.gov/AcuteInpatientPPS> (last updated Apr. 10, 2013); CMS, *Acute Care Hospital Inpatient Prospective Payment System*, DHHS (Feb. 2012), <https://www.cms.gov/Outreach-and-Education/Medicare-Learning-Network-MLN/MLNProducts/downloads/AcutePaymtSysfctsht.pdf>.

42 42 U.S.C. § 1395yy (2006) (skilled nursing facilities); *Id.* § 1395fff (home health services); *see* CMS, *Skilled Nursing Prospective Payment System*, DHHS (Oct. 2012), <http://www.cms.gov/Outreach-and-Education/Medicare-Learning-Network-MLN/MLNProducts/downloads/snfprospaymtfctsht.pdf>.

methodology similar to the IPPS or hospitals.⁴³ The major reforms of physician payment methods before IPPS included limiting the permissible rate of increase in the prevailing charge to an index that reflected inflation,⁴⁴ reforming the payment methods for physicians in teaching hospitals,⁴⁵ and tightening the payment methods for hospital-based physicians, such as anesthesiologists, pathologists, and radiologists.⁴⁶

In 1989, Congress enacted a revised payment system for physician services that paid physicians based on the time and resources involved in treating specific conditions rather than on a charge basis.⁴⁷ Congress enhanced the system in the Omnibus Budget Reconciliation Act of 1990.⁴⁸ In these two pieces of legislation, Congress replaced the charge-based fee schedule with the Resource Based Relative Value Scale (RBRVS).

The RBRVS is based on relative value units (RVUs) for three cost components of medical care—physicians' work effort, physicians' practice expenses, and malpractice liability insurance expenses. These RVUs are then adjusted for geographic differences⁴⁹ and a conversion factor designed to curtail the overall increase in Part B expenditures.⁵⁰ Dr. William Hsiao, of Harvard University, and his multidisciplinary team developed the RVUs for physicians' work over many years.⁵¹ CMS annually updates the physician work RVUs for new and revised codes based on, in part, recommendations from the American Medical Association's Specialty Society Relative Value Update Committee.⁵²

43 Social Security Amendments of 1983 § 603(a)(2)(B).

44 42 U.S.C. § 1395x (2006).

45 *Id.* § 1395f(g).

46 *Id.* § 1395xx.

47 *Id.* § 1395u(b).

48 Omnibus Budget Reconciliation Act of 1990, Pub. L. No. 101-508, §§ 4101-4118, 104 Stat. 1388 (codified as amended at 42 U.S.C. § 1395 (2006)).

49 42 U.S.C. § 1395w-4(b)(1)(c) (2006).

50 See *infra* notes 54-59 and accompanying text.

51 See William C. Hsiao et al., *Estimating Physicians' Work for a Resource-Based Relative-Value Scale*, 319 NEW ENG. J. MED. 835 (1988); William C. Hsiao et al., *The Resource-Based Relative Value Scale: Toward the Development of an Alternative Physician Payment System*, 258 J. AM MED. ASS'N 799 (1987); William C. Hsiao et al., *Resource-Based Relative Values: An Overview*, 260 J. AM MED. ASS'N 2347 (1988); William C. Hsiao et al., *Results and Policy Implications of the Resource-Based Relative-Value Study*, 319 NEW ENG. J. MED. 881 (1988); William C. Hsiao et al., *Results, Potential Effects, and Implementation Issues of the Resource-Based Relative Value Scale*, 260 J. AM MED. ASS'N 2429 (1988); William C. Hsiao & Edmond R. Becker, *Paying Physicians According to their Resource-Costs: The Development of a Resource-Based Relative Value Scale*, 12 HEALTH POL'Y 257 (1989).

52 AMA/Specialty Society, *RVS Update Process*, AM. MED. ASS'N (2007), http://www.ama-assn.org/ama/pub/upload/mm/380/rvs_booklet_07.pdf.

B. The Challenge of the Burgeoning Volume of Medicare Services

The second challenge of concern to policymakers has been controlling the volume of care for Medicare beneficiaries. The issue of volume is complicated. At a minimum, increases in volume might represent an increase in the number of new beneficiaries receiving services or an increase in the number of services per beneficiary. At some point, increased volume becomes unnecessary and may lead to poor quality care and potentially program abuse. The problem historically for the Medicare program is that, by locating the definition of the content and quality of medical care with the medical profession, stewards of the Medicare program were unable to determine when care was excessive, poor in quality, or abusive. Only with the advances in health services research, discussed in D of this Part, and the empirical demonstration of poor quality and excessive care in statistical terms understandable to non-physician policymakers was the dominance of physicians in defining the content and quality of medical care reduced.

1. Retrospective Utilization Review

The Social Security Amendments of 1965 required hospitals to have utilization review committees as a condition of participation in Medicare.⁵³ Thus began Medicare's express responsibilities regarding the volume and quality of care of Medicare beneficiaries. The statute did not specify detailed requirements for these programs. However, in March 4, 1969, HEW promulgated a proposed rule requiring that hospitals engage in utilization review of hospital services for the Medicare and Medicaid programs.⁵⁴ Later, Congress required hospitals to establish more aggressive internal utilization review programs.⁵⁵

In 1972, Congress established the Professional Standards Review Organization (PSRO) program.⁵⁶ This program required the Medicare program to contract with independent physician-dominated organizations to review the utilization of health care services for Medicare beneficiaries. In 1981, the Reagan Administration and Congress repealed the program,⁵⁷ apparently in response to concerns from the medical profession about the program's intrusiveness into

⁵³ Social Security Amendments of 1965, Pub. L. No. 89-97, § 102(a), 79 Stat. 286, 313 (codified as amended at 42 U.S.C. § 1395x(k) (2006)).

⁵⁴ Federal Health Insurance for the Aged: Composition of Utilization Review Committees in Hospitals and Extended Care Facilities, 34 Fed. Reg. 16,628 (proposed Oct. 17, 1969) (codified at 20 C.F.R pt. 405).

⁵⁵ Social Security Amendments of 1972, Pub. L. No. 92-603, § 237(a)(1), 86 Stat. 1329, 1415 (codified as amended at 42 U.S.C. § 1395, 1410-1411 (2006)).

⁵⁶ *Id.* § 249F (codified as amended at 42 U.S.C. § 1301 (2006)).

⁵⁷ Omnibus Budget Reconciliation Act of 1981, Pub. L. No. 97-35, §§ 2111-2114, 95 Stat. 358, 793-96 (codified as amended at 42 U.S.C. § 1320 (2006)).

medical practice.⁵⁸ In 1982, in preparation for the enactment of new hospital prospective payment system, Congress established the Medical Utilization and Quality Control program.⁵⁹ This program established Peer Review Organizations (PROs), private physician-led organizations, to review the utilization of services provided to Medicare beneficiaries. By the late 1990s, CMS concluded that retrospective review of PROs and PSROs had not been particularly successful in addressing unnecessary volume in Medicare services or improving quality of care.⁶⁰ At that point, CMS determined to refocus the work of PROs to quality improvement.⁶¹

2. Volume Controls in Physician Payment Methodologies

Since 1972, Congress and the Medicare program have sought to control the overall spending for physician service with the imposition of limits on overall spending. Congress enacted several factors to adjust for increasing volume in Part B items and services.⁶² In the Balanced Budget Act of 1997, Congress replaced existing volume controls⁶³ with the “Sustainable Growth Rate” (SGR) factor.⁶⁴ The SGR is applied to individual physician payments to ensure that the overall growth in aggregate physician payments in a given year essentially does not exceed the rate of growth in GDP for that year. The SGR factor has proven very controversial. In recent years, if it had actually been applied to Medicare physician payments, it would have resulted in markedly lower physician payments.⁶⁵ Congress has delayed applying the SGR factor to physician payment

58 JONATHAN OBERLANDER, *THE POLITICAL LIFE OF MEDICARE* 117-20 (2003).

59 42 U.S.C. § 1320c (2006).

60 See Anita J. Bhatia et al., *Evolution of Quality Review Programs for Medicare: Quality Assurance to Quality Improvement*, 22 *HEALTH CARE FINANCING REV.*, Fall 2000, at 69 (2000); Stephen F. Jencks and Gail R. Wilensky, *The Health Care Quality Improvement Initiative: A New Approach to Quality Assurance in Medicare*, 268 *JAMA* 900 (1992); see also Claire Snyder & Gerard Anderson, *Do Quality Improvement Organizations Improve the Quality of Hospital Care for Medicare Beneficiaries?* 293 *JAMA* 2900 (2005).

61 Bhatia et al., *supra* note 60.

62 42 U.S.C. § 1395u (2006); *Id.* § 1395u(b); see John Holahan & Stephan Zuckerman, *The Future of Medicare Volume Performance Standards*, 30 *INQUIRY* 234 (1993); Thomas Rice & Jill Bernstein, *The Medicare Volume Performance Standards: Can They Control Growth in Medicare Services?* 63 *MILBANK Q.* 295 (1990).

63 Balanced Budget Act of 1997, Pub. L. No. 105-33, §§ 4502(b), 4503, 111 Stat. 251, 433-34 (codified as amended at 42 U.S.C. §§ 1395w-4(d) to (f) (2006)).

64 *Id.* § 4502(a), 111 Stat. 432 (codified as amended at 42 U.S.C. § 1395w-4(d)(3) (2006)).

65 Comm. on Legislation & Advocacy, *Medicare and the Sustainable Growth Rate*, AM. MED. ASS’N, http://www.ama-assn.org/resources/doc/mss/cola_medicare_pres.pdf (last visited Apr. 22, 2013); Jim Hahn, *Medicare Physician Payment Updates and the Sustainable Growth Rate (SGR) System*, CONGR. RES. SERVS. (Aug. 6, 2010), <http://aging.senate.gov/crs/medicare15.pdf>.

since 2008⁶⁶ and postponed application of the SGR factor for several years in the future in 2011.⁶⁷

C. The Problem of Fraud and Abuse

A major problem for the Medicare program since its inception has been fraud and abuse by providers, suppliers, and other opportunists. Health care “fraud” exists where there are intentional attempts to wrongfully collect money relating to medical services, while “abuse” exists where actions were inconsistent with acceptable business and medical practices.⁶⁸ In 2009, HHS estimated that of the \$2 trillion the federal government spent on health care, at least three percent went to fraud.⁶⁹

1. False Claims and Anti-Kickback Prohibitions

Early on in the Medicare program, it was clear that some providers and suppliers were defrauding and abusing the Medicare program through a variety of improper business and criminal practices. In the Social Security Amendments of 1972, Congress enacted the first anti-fraud prohibition for the Medicare and Medicaid programs.⁷⁰ This provision essentially prohibited kickbacks and other payments among providers for referrals of patients. As indicated in the House Ways and Means Committee report, Congress sought only to prohibit practices that had “long been regarded by professional organizations as unethical, as well as unlawful in some jurisdictions, and which contribute appreciably to the cost of the medicare and medicaid [*sic*] programs.”⁷¹

66 Medicare Improvements for Patients and Providers Act of 2008, Pub. L. No. 110-275, § 131 (codified as amended at 42 U.S.C. § 1395w-4(d)(8) (Supp. 2011)).

67 Preservation of Access to Care for Medicare Beneficiaries and Pension Relief Act of 2010, Pub. L. No. 111-192 (to be codified as amended at 42 U.S.C. § 1395w-4(d)); The Physician Payment and Therapy Relief Act of 2010, Pub. L. No. 111-286 (to be codified as amended at 42 U.S.C. § 1395w-4(d)(11)); Medicare and Medicaid Extenders Act of 2010, Pub. L. No. 111-309 (to be codified as amended at 42 U.S.C. § 1395w-4(d)).

68 CMS, *Medicare Fraud & Abuse: Prevention, Detection, and Reporting*, DHHS (Nov. 2012), https://www.cms.gov/MLNProducts/downloads/Fraud_and_Abuse.pdf; T. R. Goldman, *Eliminating Fraud and Abuse*, HEALTH AFF.: HEALTH POL’Y BRIEFS (July 31, 2012), http://healthaffairs.org/healthpolicybriefs/brief_pdfs/healthpolicybrief_72.pdf; Jennifer Staman, *Health Care Fraud and Abuse Laws Affecting Medicare and Medicaid: An Overview*, CONGR. RES. SERV. (Aug. 10, 2010), <http://www.aging.senate.gov/crs/medicaid20.pdf>; see Joan H. Krause, *Regulating, Guiding, and Enforcing Health Care Fraud*, 60 N.Y.U. ANN. SURV. AM. L. 241 (2004).

69 *Catch Me If You Can: Solutions to Stop Medicare and Medicaid Fraud from Hurting Seniors and Taxpayers: Hearing Before the S. Special Comm. on Aging*, 111th Cong. 35 (2009) (statement of Daniel R. Levinson, Inspector Gen., U.S. Department of Health and Human Services).

70 Social Security Amendments of 1972, Pub. L. No. 92-603, §§ 242(b)-(c), 278(b)(9), 86 Stat. 1329, 1419, 1454 (codified as amended at 42 U.S.C. §§ 1320a-7b, 1395nn (2006)).

71 H.R. Rep. No. 92-231 at 107-08 (1971).

Congress expanded these fraud and abuse provisions in the Medicare-Medicaid Anti-Fraud and Abuse Amendments of 1977.⁷² These amendments accorded the newly-established Office of the Inspector General (OIG) within HHS-expanded authority to identify and eliminate waste, fraud, and abuse in the department.

The anti-kickback prohibitions have created an extensive regulatory regime over the way in which health care providers do business with one another. While kickbacks are illegal or unethical in many other businesses,⁷³ the Medicare statute and its interpretations have been much stricter in defining kickbacks and have even proscribed splitting fees that are common in other professions. The Medicare anti-kickback prohibitions seek to limit entrepreneurial behavior on the part of providers to generate business.

In 1981, Congress enacted the Civil Monetary Penalties Act (CMPA) as part of the Omnibus Budget Reconciliation Act of 1981.⁷⁴ This law authorized the OIG to impose penalties on violators without having to refer cases to the U.S. Department of Justice. This authority greatly facilitated the Medicare program's ability to go after false claims because the enhanced authority of the OIG to impose penalties and sanctions.

72 Medicare-Medicaid Anti-Fraud and Abuse Amendments, Pub. L. No. 95-142, 91 Stat. 1175 (1977) (codified as amended at 42 U.S.C. §§ 1320a, 1396k); see Theodore McDowell, *The Medicare and Medicaid Anti-Fraud and Abuse Amendments: Their Impact on the Present Health Care System*, 36 EMORY L.J. 691 (1987).

73 The Legal Information Institute at Cornell University Law School defines kickback generally:

A "kickback" is a term used to refer to a misappropriation of funds that enriches a person of power or influence who uses the power or influence to make a different individual, organization, or company richer. Often, kickbacks result from a corrupt bidding scheme. Through corrupt bidding, the official can award the contract to a company, even though the company did not place the lowest bid. The company profits by having been awarded the bid and getting to perform the contract. In exchange for this corrupt practice, the company pays the official a portion of the profits. This portion is the "kickback." Such a practice falls within a sphere of practices often referred to as "anti-competitive practices." Organized crime has been traced using kickbacks for many years. Some also consider kickbacks to be a type of bribery.

Legal Info. Inst., *KICKBACKS*, CORNELL U. SCHOOL OF L., <http://www.law.cornell.edu/wex/kickbacks> (last visited Apr. 22, 2013).

74 Omnibus Budget Reconciliation Act of 1981, Pub. L. No. 97-35, § 2105(a), 95 Stat. 357, 789 (codified as amended at 42 U.S.C. § 1320a-7a (2006)); see Richard P. Kusserow, *Civil Money Penalties Law of 1981: A New Effort to Confront Fraud and Abuse in Federal Health Care Programs*, 58 NOTRE DAME L. REV. 985 (1983).

In the False Claims Act Amendments of 1986,⁷⁵ Congress strengthened the False Claims Act (FCA) to make clear that the FCA applied to claims against the Medicare and Medicaid programs. These amendments opened a new front on Medicare defrauders and abusers, by facilitating the ability of private parties, who are often internal whistle blowers that witnessed the fraud and abuse, to bring suit as “relaters” on the government’s behalf under the FCA. As a result, the federal government has been able to recover millions of dollars from health care providers under the FCA since the late 1980s.⁷⁶

The Medicare and Medicaid Patient and Program Protection Act of 1987 provided new authority to the OIG to exclude persons or entities from participation in Medicare if the party engaged in a prohibited remuneration scheme.⁷⁷ This Act also established alternative civil remedies that would facilitate the regulation of abusive business practices.⁷⁸

In the mid-1990s, Congress added significant provisions to the Medicare fraud and abuse armamentarium. In the Health Insurance Portability and Accountability Act of 1996 (HIPAA), Congress greatly strengthened and coordinated Medicare fraud and abuse authorities.⁷⁹ Specifically, HIPAA created a new crime of health care fraud,⁸⁰ which includes theft, embezzlement, false statements, obstruction of a criminal investigation, and money laundering, among others.⁸¹ HIPAA also enhanced administrative enforcement mechanisms, and strengthened provisions for exclusion from Medicare participation for offenders.⁸² In addition, HIPAA greatly increased penalties under the CMPA.⁸³ HIPAA also established the national health care fraud and abuse data collection program for the reporting of final adverse actions (not including settlements in which no findings of liability are made) against health care providers, suppliers, or practitioners.⁸⁴

75 False Claims Amendments Act of 1986, Pub. L. No. 99-562, 100 Stat. 3153 (codified as amended at 31 U.S.C. §§ 3729-3733 (2006)).

76 Thomas H. Stanton, *Fraud-And-Abuse Enforcement In Medicare: Finding Middle Ground*, 20 HEALTH AFF., July-Aug. 2001, at 28.

77 Medicare and Medicaid Patient and Program Protection Act of 1987, Pub. L. No. 100-93, 101 Stat. 680 (codified as amended at scattered sections of 42 U.S.C.).

78 See Office of the Inspector Gen., *Special Advisory Bulletin: The Effect of Exclusion from Participation in Federal Health Care Programs* DHHS (Sept. 1999), <http://oig.hhs.gov/fraud/docs/alertsandbulletins/effected.htm>.

79 Health Insurance Portability and Accountability Act of 1996 (HIPAA), Pub. L. No. 104-191, 110 Stat. 1936 (codified as amended at scattered titles of the U.S.C.); see David A. Hyman, *HIPAA and Health Care Fraud: An Empirical Perspective*, 22 CATO J. 9 (2002).

80 HIPAA § 242.

81 *Id.* §§ 241-250.

82 *Id.* §§ 211-218.

83 *Id.* §§ 231-232.

84 *Id.* § 221.

HIPAA also created three distinct new programs with designated funding streams: the Fraud and Abuse Control Program, the Medicare Integrity Program, and the Beneficiary Incentive Program. The Fraud and Abuse Control Program is jointly administered by the Attorney General and the Secretary of HHS and coordinates fraud control work throughout the government.⁸⁵ Pursuant to the Medicare Integrity Program, HHS contracts with private companies to perform fraud control functions in which fiscal intermediaries and carriers had historically shown little interest.⁸⁶ Finally, the Beneficiary Incentives Program offers incentive payments to beneficiaries who provide information that lead to monetary recoveries.⁸⁷

2. Physician Self-Referral Prohibition

In 1989, Congress enacted fraud and abuse legislation targeted at addressing physician referrals to clinical laboratories that the physicians owned.⁸⁸ There had been much controversy and commentary about the growing practice of physicians of referring patients to their own service providers.⁸⁹ In response, Congress, in the Omnibus Budget Reconciliation Act of 1993, expanded the restriction to a range of additional health services and applied it to both Medicare and Medicaid.⁹⁰ This legislation, known as “Stark II,” also contained clarifications and modifications to the exceptions in the original law.

The Medicare statute includes the so-called whole hospital exception to the physician self-referral prohibitions.⁹¹ This exception has become controversial in recent years with the emergence of physician-owned specialty hospitals in many states. In the late 1990s, physicians began building and investing in medical specialty hospitals that were independent of community hospitals in highly lucrative specialties such as cardiology and orthopedics. Physicians, who had

85 *Id.* § 201.

86 *Id.* § 202; see Hyman, *supra* note 79.

87 HIPAA § 203.

88 Omnibus Budget Reconciliation Act of 1989, Pub. L. No. 101-239, § 6204, 103 Stat. 2106, 2236-43 (codified as amended at 42 U.S.C. § 1395nn (2006)); see Jennifer O’Sullivan, *Medicare: Physician Self-Referral (“Stark I and II”)*, CONGR. RES. SERVS. (Sept. 27, 2007), <http://aging.senate.gov/crs/medicare19.pdf>; *History of the Stark Law*, U.S. LEGAL, <http://starklaws.uslegal.com/history-of-stark-law> (last visited Apr. 10, 2013).

89 See, e.g., David A. Hyman & Joel V. Williamson, *Fraud and Abuse: Setting the Limits on Physicians’ Entrepreneurship*, 320 NEW ENG. J. MED. 1275 (1989); MARC A. RODWIN, *MEDICINE, MONEY, AND MORALS: PHYSICIANS’ CONFLICTS OF INTEREST* (1995).

90 Omnibus Budget Reconciliation Act of 1993, Pub. L. No. 103-66, § 13562(a), 107 Stat. 312, 596 (codified as amended at 42 U.S.C. § 1395nn (2006)).

91 42 U.S.C. § 1395nn(d)(3) (2006); see CMS, *MLN Matters No. MM3036, MMA-Clarifications to Certain Exceptions to Medicare Limits on Physician Referrals*, DHHS (Mar. 2004), http://www.cms.gov/Outreach-and-Education/Medicare-Learning-Network-MLN/MLN_MattersArticles/Downloads/MM3036.pdf.

been tussling with community hospitals and managed care companies throughout the 1990s to get their perceived fair share of patient revenue, moved toward specialty hospitals to gain greater corporate and financial control.⁹² Their advent was very controversial, especially for community hospitals, which lost lucrative services and procedures to specialty hospitals.⁹³

The rise of physician-owned specialty hospitals raised concerns among policymakers. In 2003, the U.S. General Accounting Office (now the U.S. Government Accountability Office (GAO)) conducted two studies of these emerging developments and raised concerns about their profitability vis-à-vis not-for-profit hospitals and other matters.⁹⁴ In the MMA of 2003,⁹⁵ Congress imposed an eighteen month moratorium on the whole hospital exception for new specialty hospitals in the physician self-referral prohibitions and directed the Medicare Payment Advisory Committee (MEDPAC), established as an official body to advise Congress on Medicare payment issues in 1997,⁹⁶ to study and report on physician-owned medical specialty hospitals.

The MEDPAC conducted a study and gave some remarkable recommendations about the future treatment of physician-owned specialty hospitals.⁹⁷ The conclusions of MEDPAC were mixed, reflecting external studies of specialty hospitals.⁹⁸ MEDPAC concluded:

We found that physicians may establish physician-owned specialty hospitals to gain greater control over how the hospital

⁹² Ron Winslow, *Fed-Up Cardiologists Invest in Own Hospital: They'll Regain Autonomy but Critics See a Grab for More Profitable Care*, WALL ST. J., June 22, 1999, at A1.

⁹³ Rebecca Voelker, *Specialty Hospitals Generate Revenue and Controversy*, 289 JAMA 409 (2003).

⁹⁴ U.S. GEN. ACCOUNTING OFFICE, GAO-03-683R, SPECIALTY HOSPITALS: INFORMATION ON NATIONAL MARKET SHARE, PHYSICIAN OWNERSHIP, AND PATIENTS SERVED (2003); U.S. GEN. ACCOUNTING OFFICE, GAO-04-167, SPECIALTY HOSPITALS: GEOGRAPHIC LOCATION, SERVICES PROVIDED, AND FINANCIAL PERFORMANCE (2003).

⁹⁵ Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (MMA) Pub. L. No. 108-173, § 507, 117 Stat. 2066, 2295 (codified at 42 U.S.C. § 1395nn(d)(3) (2006)).

⁹⁶ Balanced Budget Act of 1997, Pub. L. No. 105-33, § 4022, 111 Stat. 251, 350 (codified at 42 U.S.C. § 1395b-6) (2006)).

⁹⁷ *Report to Congress: Physician-Owned Specialty Hospitals*, MEDICARE PAYMENT ADVISORY COMMISSION (MEDPAC) (Mar. 2005), http://www.medpac.gov/documents/Mar05_SpecHospitals.pdf.

⁹⁸ Lawrence P. Casalino et al., *Focused Factories? Physician-Owned Specialty Facilities*, 22 HEALTH AFF., Nov. 2003, at 56; Jeff Goldsmith, *Technology and the Boundaries of the Hospital: Three Emerging Technologies*, 23 HEALTH AFF., Nov. 2004, at 149; Leslie Greenwald et al., *Specialty Versus Community Hospitals: Referrals, Quality, and Community Benefits*, 25 HEALTH AFF., Jan. 2006, at 106; David N. Heard, Jr., *The Specialty Hospital Debate: The Difficulty of Promoting Fair Competition Without Stifling Efficiency*, 6 HOUS. J. HEALTH L. & POL'Y 215 (2005); John K. Iglehart, *The Emergence of Physician-Owned Specialty Hospitals*, 352 NEW ENG. J. MED. 78 (2005).

is run, to increase their productivity, and to provide greater satisfaction for them and their patients. They may also be motivated by the financial rewards, some of which derive from inaccuracies in the Medicare payment system.⁹⁹

In 2005, MEDPAC recommended addressing “inaccuracies, which result in the system paying too much for some DRGs relative to others and too much for patients with relatively less severe conditions.”¹⁰⁰ Such reforms would make competition between community hospitals and specialty hospitals more equitable. As noted above,¹⁰¹ CMS changed the DRG system to the MS-DRG system to address these concerns. MEDPAC also recommended promoting gainsharing to align physician and hospital incentives to allow physicians and hospitals “to share savings from more efficient practices and might serve as an alternative to direct physician ownership.”¹⁰²

In 2006, MEDPAC revisited physician-owned specialty hospitals and reported on its empirical study of physician-owned specialty hospitals.¹⁰³ In general, the study found that in communities with physician-owned specialty hospitals, rates of cardiac and other procedures were a little higher, but that community hospitals seemed able to maintain financial stability.¹⁰⁴ MEDPAC offered no recommendations on further policy action regarding these hospitals.

D. Medicare and Healthcare Quality

The initial approach of the Medicare program toward assuring quality of care for Medicare beneficiaries was focused mainly on required licensure or accreditation of health care providers.¹⁰⁵ Physicians, hospitals, and other providers were responsible for quality assurance and improvements. Indeed, Title II of the Social Security Amendments of 1965 pertains to Medicare’s mention the word “quality” only once in connection with the responsibilities of state agencies in managing survey and certification responsibility for facilities participating in Medicare.¹⁰⁶ In the 1980s, spurred on by health services research indicating that little was known about whether expensive medical procedures were more

99 MEDPAC, *supra* note 97, at vii.

100 *Id.*

101 *See supra* note 41 and accompanying text.

102 MEDPAC, *supra* note 97, at viii.

103 *Report to Congress: Physician-Owned Specialty Hospitals Revisited*, MEDPAC (Aug. 2006), http://www.medpac.gov/documents/Aug06_specialtyhospital_mandated_report.pdf.

104 *Id.*

105 *See Eleanor D. Kinney, The Affordable Care Act and the Medicare Program: Linking Medicare Payment to Quality Performance*, 67 N.Y.U. ANN. SURV. AM. L. (forthcoming 2012).

106 Social Security Amendments of 1965, Pub. L. No. 89-97, § 102(a), 79 Stat. 286, 326 (codified as amended at 42 U.S.C. § 1395aa (2006)).

efficacious than less expensive treatment approaches, medical researchers and third party payers promoted outcome measures as the appropriate indicators of quality in quality assurance and improvement activities.¹⁰⁷ Health services researchers demonstrated that not all costly medical procedures were more effective than less costly care.¹⁰⁸

Extensive health services research shaped the future of quality science in medicine and paved the way for reforms that reduced volume and improved quality. For health services, research produced empirical evidence on high quality and appropriate health care services in a form comprehensible to non-physicians. First, the work of Dr. John Wennberg and his colleagues demonstrated sharp variation in services provided to Medicare beneficiaries among different geographic areas for the same conditions.¹⁰⁹ The finding dramatically documented provider induced demand for services and the resulting inefficiencies and provision of health care.

A second important development was the application of the theories of Total Quality Management (TQM) and Continuous Quality Improvement (CQI), developed by William E. Deming and Joseph Juran,¹¹⁰ to health care institutions.¹¹¹ According to TQM/CQI theory, quality management should strive to reduce statistical variation in products and production to a level that is uniform and predictable, and also meets the expectations of the customer. Since the

107 ROBERT H. BROOK ET AL., QUALITY OF MEDICAL CARE ASSESSMENT USING OUTCOME MEASURES: AN OVERVIEW OF THE METHOD (1976); Robert H. Brook & Kathleen N. Lohr, *Monitoring Quality of Care in the Medicare Program*, 258 JAMA 3138 (1987); Paul M. Ellwood, *Shattuck Lecture, Outcomes Management: A Technology of Patient Experience*, 318 NEW ENG. J. MED. 1549 (1988).

108 See, e.g., Robert H. Brook & Kathleen N. Lohr, *Efficacy, Effectiveness, Variations, and Quality: Boundary-Crossing Research*, 23 MED. CARE 710 (1985); David M. Eddy, *Variation in Physician Practice: The Role of Uncertainty*, 3 HEALTH AFF., May 1984 at 74; David M. Eddy & John Billings, *The Quality of Medical Evidence: Implications for Quality of Care*, 7 HEALTH AFF., Feb. 1988, at 19.

109 John E. Wennberg et al., *Professional Uncertainty and the Problem of Supplier-Induced Demand*, 16 SOC. SCI. & MED. 811 (1982); John E. Wennberg & Alan Gittelsohn, *Small Area Variation in Health Care Delivery*, 182 SCIENCE 1102 (1973); John E. Wennberg & Alan Gittelsohn, *Variations in Medical Care Among Small Areas*, 246 SCI. AM., Apr. 1982, at 120.

110 W. EDWARDS DEMING, *OUT OF THE CRISIS* (1986); W. EDWARD DEMING, *THE NEW ECONOMICS* (1993); J.M. JURAN, *JURAN ON LEADERSHIP FOR QUALITY: AN EXECUTIVE HANDBOOK* (1989); J.M. JURAN, *MANAGERIAL BREAKTHROUGH: A NEW CONCEPT OF THE MANAGER'S JOB* (1964).

111 DONALD M. BERWICK ET AL., *CURING HEALTH CARE: NEW STRATEGIES FOR QUALITY IMPROVEMENT* (1990); Donald M. Berwick, *Continuous Improvement as an Ideal in Health Care*, 320 NEW ENG. J. MED. 53 (1989); Glenn Laffel & David Blumenthal, *The Case for Using Industrial Quality Control Management Science in Health Care Organizations*, 262 JAMA 2869 (1989).

1990s, data-driven TQM/CQI theory and practice has become an integral part of quality assurance and improvement concepts in the health care field.¹¹²

A third critical development was the patient safety movement inspired by the Institute of Medicine's (IOM) report, *To Err Is Human*.¹¹³ This report made two factual findings that were so ground-breaking that they precipitated a revolution in U.S. health care: (1) an estimated 44,000 to 98,000 people die each year in hospitals from medical injury; and (2) systems failures, rather than poor performance by individual practitioners, cause at least half of patient injuries.¹¹⁴ The IOM report recommended that providers create a culture of safety in institutions by borrowing from quality science in the engineering industries.¹¹⁵ Providers were largely persuaded by these findings and instituted data driven strategies to reduce risks to patient safety.¹¹⁶

In 2001, CMS began launching quality initiatives "to assure quality health care for all Americans through accountability and public disclosure."¹¹⁷ CMS established the Health Care Quality Improvement Initiative (HCQII) to move from addressing individual clinical errors to helping providers improve care generally.¹¹⁸ In 2002, hospital associations, employers, payers, consumer organizations, the Joint Commission and also CMS established the Hospital Quality Alliance to make "meaningful, relevant, and easily understood information about hospital performance accessible to the public and to informing and encouraging efforts to improve quality."¹¹⁹

In July 2003, CMS launched the National Voluntary Hospital Reporting Initiative. This initiative is now known as the "Hospital Quality Alliance: Improving Care through Information," which is a public-private collaboration to improve the quality of care provided by the nation's hospitals by measuring and

112 ELLEN MARSZALEK-GAUCHER & RICHARD J. COFFEY, *TRANSFORMING HEALTHCARE ORGANIZATIONS: HOW TO ACHIEVE AND SUSTAIN ORGANIZATIONAL EXCELLENCE* (1990); CURTIS P. McLAUGHLIN & ARNOLD D. KALUZNY, *CONTINUOUS QUALITY IMPROVEMENT IN HEALTH CARE: THEORY, IMPLEMENTATIONS, AND APPLICATIONS* (3rd ed. 2006).

113 INST. OF MED., *TO ERR IS HUMAN: BUILDING A SAFER HEALTH CARE SYSTEM* (Linda T. Kohn et al. eds., 2000).

114 *Id.*

115 *Id.*

116 INST. OF MED., *PATIENT SAFETY: ACHIEVING A NEW STANDARD FOR CARE* (Philip Apsden et al. eds., 2004).

117 CMS, *Quality Initiatives—General Information*, CMS, <https://www.cms.gov/qualityinitiativesgeninfo>, CMS.GOV (Apr. 12, 2013).

118 Stephen F. Jencks & Gail R. Wilensky, *The Health Care Quality Improvement Initiative: A New Approach to Quality Assurance in Medicare*, 268 JAMA 900 (1992).

119 HOSPITAL QUALITY ALLIANCE, <http://qualitynet.org/dcs/ContentServer?c=Page&pagename=QnetPublic%2FPage%2FQnetTier2&cid=1121785350618> (last visited Jun. 2, 2013).

publicly reporting on that care.¹²⁰ In CMS' Hospital Quality Initiative, CMS works with the HQA and other key stakeholders with the support of Agency for Healthcare Research and Quality (AHRQ), the National Quality Forum (NQF), and the Joint Commission, among other organizations.¹²¹ Through this initiative, CMS developed a standardized set of hospital quality measures for use in voluntary public reporting. As part of this initiative, CMS has launched the website, *Hospital Compare*, to provide information on the comparative performance of hospitals on health care quality.¹²²

The MMA of 2003 established the Hospital Inpatient Quality Reporting program.¹²³ Since 2003, CMS has been moving forward with value-based purchasing first for inpatient, acute care hospitals and then for other institutional providers.¹²⁴ The Deficit Reduction Act of 2005 (DRA) authorized the launch of the value-based purchasing program.¹²⁵ DRA required a reduction by two percent of the applicable percentage increase in payment for covered hospitals that do not submit quality data in a form and manner and by a time specified by the Secretary of HHS.¹²⁶ The DRA called for the Secretary to develop a plan for the hospital value-based purchasing program which would begin in FY 2009.¹²⁷ In 2007, CMS submitted this plan to Congress.¹²⁸ In the FY 2007 final rule for the inpatient prospective payment system, CMS implemented this reduction requirement for deficient quality reporting.¹²⁹

120 CMS, *Roadmap for Implementing Value Driven Healthcare in the Traditional Medicare Fee-for-Senate Program*, DHHS (Jan. 2009), https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/QualityInitiativesGenInfo/downloads/VBPRoadmap_OEA_1-16_508.pdf.

121 *Hospital Quality Initiative Overview*, CMS (July 2008), <https://www.cms.gov/hospitalqualityinits/downloads/HospitalOverview.pdf>.

122 *Hospital Compare*, MEDICARE.GOV, <http://www.medicare.gov/hospitalcompare> (last visited Apr. 10, 2013).

123 Medicare Prescription Drug, Improvement, and Modernization Act (MMA) of 2003, Pub. L. No. 108-173, § 501(b), 117 Stat. 2066, 2289 (codified as amended at 42 U.S.C. § 1395ww (2006)).

124 CMS, *supra* note 120.

125 Deficit Reduction Act (DRA) of 2005, Pub. L. No. 109-171, § 5001(a), 120 Stat. 4, 28 (codified as amended at 42 U.S.C. § 1395ww (2006)).

126 *Id.*

127 *Id.*

128 CMS, *Report to Congress: Plan to Implement a Medicare Hospital Value-Based Purchasing Program*, DHHS (Nov. 2007), <http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/AcuteInpatientPPS/downloads/HospitalVBPPlanRTCFINALSUBMITTED2007.pdf>.

129 Prospective Payment Systems for Inpatient Hospital Services, 42 C.F.R. pt. 412; see Christopher P. Tompkins et al., *Measuring Outcomes and Efficiency in Medicare Value-Based Purchasing*, 28 HEALTH AFF., Jan. 2009, at w251.

A very important step in the development of value-based purchasing was the Premier Hospital Incentive demonstration initiated in 2003.¹³⁰ This Demonstration was conducted in partnership with the Premier Healthcare Alliance, a national health care performance improvement organization, and tested whether paying hospitals for performance on various quality metrics would shift performance upward.¹³¹ In evaluation results announced in 2010,¹³² participating hospitals improved performance across the board.¹³³ Subsequent research findings suggest that the actual impact of the value-based purchasing initiative may not have a great effect on Medicare payment to either high or low performing hospitals.¹³⁴

In 2006, Congress turned to quality reporting for physicians. In the Tax Relief and Health Care Act of 2006, Congress established a quality reporting program—the Physician Quality Reporting Initiative (PQRI)—for physicians and other eligible professionals.¹³⁵ The Medicare Improvements for Patients and

130 CMS, *Premier Hospital Quality Incentive Demonstration*, CMS.GOV (Apr. 23, 2013, 1:00PM), <http://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/HospitalQualityInits/HospitalPremier.html>.

131 CMS, *Premier Hospital Quality Incentive Demonstration: Rewarding Superior Quality Care: Fact Sheet*, DHHS (Dec. 2011), <http://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/HospitalQualityInits/Downloads/HospitalPremierPressRelease-FactSheet.pdf>.

132 CMS, *Medicare Demonstrations Illustrate Benefits in Paying for Quality Health Care*, MED. NEWS TODAY (Dec. 13, 2010), <http://www.medicalnewstoday.com/releases/211115.php>.

133 See 1 & 2 STEPHEN KENNEDY ET AL., *EVALUATION OF THE PREMIER HOSPITAL QUALITY INCENTIVE DEMONSTRATION: IMPACTS ON QUALITY, MEDICARE REIMBURSEMENTS, AND MEDICARE LENGTHS OF STAY* (2008); Div. of Research on Traditional Medicare, *Evaluation of the Premier Hospital Quality Incentive Demonstration—Executive Summary: Impacts on Quality of Care, Medicare Reimbursements, and Medicare Beneficiaries' Length of Stay during the First Three Years of the Demonstration*, CMS (Mar. 3, 2009), https://www.cms.gov/reports/downloads/Premier_ExecSum_2010.pdf; see also New Directions for Policy, *Theory and Reality of Value-Based Purchasing: Lessons from the Pioneer*, AGENCY FOR HEALTHCARE RES. & QUALITY (Nov. 2007), <http://www.ahrq.gov/qual/meyerrpt.htm>.

134 Rachel M. Werner & R. Adams Dudley, *Medicare's New Hospital Value-Based Purchasing Program Is Likely to Have Only a Small Impact on Hospital Payments*, 31 HEALTH AFF., Sept. 2012, at 1932.

135 Tax Relief and Health Care Act of 2006 (TRHCA), Pub. L. No. 109-432, Div. B § 101, 120 Stat. 2922, 2975 (codified as amended at 42 U.S.C. § 1395w-4 (Supp. 2011)); see CMS, *Physician Quality Reporting System*, CMS.GOV (Apr. 3, 2013, 2:00PM), <https://www.cms.gov/PQRS>.

Providers Act of 2008 made the PQRI permanent.¹³⁶ This act also initiated Physician Feedback Reporting.¹³⁷

The DRA also established a formal role for the National Quality Forum (NQF), which proved a very important development in quality reporting and payment reform. NQF is a nonprofit organization with a mission “to improve quality of American health care by: (1) building consensus on national priorities and goals for performance improvement and working in partnership to achieve them; (2) endorsing national consensus standards for measuring and publicly reporting on performance; and (3) promoting the attainment of national goals through education and outreach programs.”¹³⁸

The membership of NQF is diverse and includes a wide variety of health care stakeholders, including consumer organizations, public and private purchasers, physicians, nurses, hospitals, accrediting and certifying bodies, supporting industries, and health care research and quality improvement organizations.¹³⁹ As NQF asserts, “NQF’s unique structure enables private- and public-sector stakeholders to work together to craft and implement cross-cutting solutions to drive continuous quality improvement in the American healthcare system.”¹⁴⁰

The Medicare Improvements for Patients and Providers Act of 2008 required the Secretary to contract with a consensus-based entity, “such as the National Quality Forum,” regarding performance measurement.¹⁴¹ The central duty of this consensus-based entity is to “synthesize evidence and convene key stakeholders to make recommendations on an integrated national strategy and priorities for health care performance measurement in all applicable settings.”¹⁴² The entity also has to be a private nonprofit organization with a board of designated representatives of stakeholders such as insurers, providers and consumers. The entity’s membership must include people with experience in urban health care issues, safety net health care issues, rural and frontier health care issues, and health care quality and safety issues. The entity must conduct its business in an open, transparent manner and provide the opportunity for public comment on its

136 Medicare Improvements for Patients and Providers Act of 2008, Pub. L. No. 110-275, § 131(b)(1), 122 Stat. 2494, 2521-22 (codified as amended at 42 U.S.C. § 1395w-4(k)(2) (Supp. 2011)); see Jonah Stulberg, *The Physician Quality Reporting Initiative—A Gateway to Pay for Performance: What Every Health Care Professional Should Know*, 17 QUALITY MGMT. IN HEALTH CARE 2 (2008).

137 Medicare Improvements for Patients and Providers Act of 2008 § 131(c) (codified as amended at 42 U.S.C. § 1395w-4(n)(1) (Supp. 2011)).

138 *About NQF*, NAT’L QUALITY F., http://www.qualityforum.org/About_NQF/About_NQF.aspx (last visited Apr. 22, 2013).

139 *Id.*

140 *Id.*

141 Medicare Improvements for Patients and Providers Act of 2008 § 183 (codified as amended at 42 U.S.C. § 1395aaa (a) (Supp. 2011)).

142 *Id.*

activities. Finally, the entity has to have at least four years of experience in establishing national consensus standards.

CMS awarded the contract to NQF to serve as the “consensus-based entity.” NQF has specific responsibility regarding the endorsement of measures. Regarding endorsements of measures, the entity must consider whether a measure meets the following criteria. First, the measure is “evidence-based, reliable, valid, verifiable, relevant to enhanced health outcomes, actionable at the caregiver level, feasible to collect and report, and responsive to variations in patient characteristics, such as health status, language capabilities, race or ethnicity, and income level.”¹⁴³ Second, the measure is “consistent across types of health care providers, including hospitals and physicians.”¹⁴⁴

In addition, the entity is required to maintain and update measures,¹⁴⁵ promote the development of electronic health records,¹⁴⁶ and make reports to Congress.¹⁴⁷ Finally, in more recent years, there has been great interest in comparative effectiveness research as a tool to reduce health care expenditures.¹⁴⁸ In 2009, the American Recovery and Reinvestment Act (ARRA) launched a major research initiative on comparative effectiveness research.¹⁴⁹ The ARRA also called on the IOM to develop national priorities for comparative effectiveness research for this initiative.¹⁵⁰ In 2009, the IOM published national priorities for research that have been the basis of the comparative effectiveness

143 *Id.*

144 42 U.S.C. § 1395aaa (b)(1)(B)(2) (Supp. 2011).

145 *Id.* § 1395aaa (b)(1)(B)(3).

146 *Id.* § 1395aaa (b)(1)(B)(4).

147 *Id.* § 1395aaa (b)(1)(B)(5).

148 *Pub. No. 2975, Research on the Comparative Effectiveness of Medical Treatments: Issues and Options for an Expanded Federal Role*, CONG. BUDGET OFFICE (Dec. 2007), <http://www.cbo.gov/ftpdocs/88xx/doc8891/12-18-ComparativeEffectiveness.pdf>; Patrick H. Conway & Carolyn Clancy, *Charting a Path From Comparative Effectiveness Funding to Improved Patient-Centered Health Care*, 303 JAMA 985 (2010); Richard K. Murray & Newell E. McElwee, *Comparative Effectiveness Research: Critically Intertwined with Health Care Reform and the Future of Biomedical Innovation*, 170 ARCHIVES OF INTERNAL MED. 596 (2010); Harold Sox, *Comparative Effectiveness Research: A Progress Report*, 153 ANNALS OF INTERNAL MED. 469 (2010); Gail R. Wilensky, *The Policies and Politics of Creating a Comparative Clinical Effectiveness Research Center*, 28 HEALTH AFF., July-Aug. 2009, at w719; see Eleanor D. Kinney, *Comparative Effectiveness Research under the Patient Protection and Affordable Care Act: Can New Bottles Accommodate Old Wine?* 37 AM. J. L. & MED. 522 (2011).

149 American Recovery and Reinvestment Act of 2009, Pub. L. No. 111-5, § 804, 123 Stat. 115, 187 (codified at 42 U.S.C. § 299b-8 (Supp. 2011)).

150 *Id.*; see John K. Iglehart, *Prioritizing Comparative-Effectiveness Research—IOM Recommendations*, 361 NEW ENG. J. MED. 325 (2009); Harold C. Sox & Sidney Greenfield, *Comparative Effectiveness Research: A Report from the Institute of Medicine*, 153 ANNALS OF INTERNAL MED. 203 (2009).

research initiative in the ACA.¹⁵¹ Whether comparative effectiveness research will have the impact warranted by the federal investment remains unclear.¹⁵²

II. IMPROVING THE QUALITY AND EFFICIENCY OF HEALTH CARE (TITLE III)

The reforms in Title III of the ACA are intended to improve the quality and efficiency of health care. In reality, the reforms are targeted at the Medicare program. Table 3 lists all of the subtitles in Title III that pertain to the Medicare program.

A. Transforming the Health Care Delivery System (Subtitle A)

The reforms in Subtitle A have two common goals. The first is to link Medicare payment to measurable clinical performance. The second is to integrate Part A and Part B services to facilitate the innovative delivery of health care services and bundled payments methodologies.

Table 3 Title III: Improving the Quality and Efficiency of Health Care
Subtitle A—Transforming The Health Care Delivery System Part 1—Linking Payment to Quality Outcomes Under the Medicare Program Part 2—National Strategy to Improve Health Care Quality Part 3—Encouraging Development of New Patient Care Models Subtitle B—Improving Medicare for Patients and Providers Part I—Ensuring Beneficiary Access to Physician Care and Other Services Part II—Rural Protections Part III—Improving Payment Accuracy Subtitle C—Provisions Relating to Part C Subtitle D—Medicare Part D Improvements for Prescription Drug Plans and MA-PD Plans Subtitle E—Ensuring Medicare Sustainability Subtitle F—Health Care Quality Improvements Subtitle G—Protecting and Improving Guaranteed Medicare Benefits

Subtitle A of the ACA contains many of the critical reforms in Medicare that are intended to ultimately transform the U.S. health care sector and make it more efficient and effective. If these measures falter and fail, it is hard to envision

¹⁵¹ BD. OF HEALTH CARE SERVS., INST. OF MED., INITIAL NATIONAL PRIORITIES FOR COMPARATIVE EFFECTIVENESS RESEARCH (2009).

¹⁵² Symposium, *Current Challenges In Comparative Effectiveness Research*, 31 HEALTH AFF., Oct. 2012, at 2160.

substitutes that will be effective in making the Medicare program sustainable over the long term or put the program in a position to evolve into a single payer system.

*1. Linking Payment to Quality Outcomes under the Medicare Program
(Subtitle A, Part 1)*

Subtitle A, Part 1 essentially advances the Medicare value-based purchasing program for hospitals, physicians, and other providers.¹⁵³ Table 4 lists the sections in Title III, Subtitle A, Part 1.

Table 4
Subtitle A—Transforming the Health Care Delivery System
Part 1—Linking Payment to Quality Outcomes Under the Medicare Program
Sec. 3001. Hospital Value-Based purchasing program
Sec. 3002. Improvements to the physician quality reporting system
Sec. 3003. Improvements to the physician feedback program
Sec. 3004. Quality reporting for long-term care hospitals, inpatient rehabilitation hospitals, and hospice programs
Sec. 3005. Quality reporting for PPS-exempt cancer hospitals
Sec. 3006. Plans for a Value-Based purchasing program for skilled nursing facilities and home health agencies
Sec. 3007. Value-based payment modifier under the physician fee schedule
Sec. 3008. Payment adjustment for conditions acquired in hospitals

a. Value-Based Purchasing for Hospitals and other Institutional Providers (Sections 3001, 3004-3006)

Section 3001 of the ACA establishes the value-based purchasing program for IPPS hospitals.¹⁵⁴ This program covers 3,500 hospitals in the United States.¹⁵⁵ In spring 2011, CMS issued the final rule establishing the Hospital Value-Based

153 ACA § 3001(a) (codified as amended at 42 U.S.C. § 1395ww(o) (Supp. 2011)); see CMS, *Medicare Learning Network, Sheet: Hospital Value-Based Purchasing Program*, DHHS, (Nov. 2011), http://www.cms.gov/Outreach-and-Education/Medicare-Learning-Network-MLN/MLNProducts/downloads/Hospital_VBPurchasing_Fact_Sheet_ICN907664.pdf; Health Affairs Blog, *Health Policy Brief: Pay For Performance* (Oct. 11, 2012), available at <http://healthaffairs.org/blog/2012/10/11/health-policy-brief-pay-for-performance/>; see Eleanor D. Kinney, *The Affordable Care Act and the Medicare Program: Linking Medicare Payment to Quality Performance*, 67 *New York University Annual Survey of American Law* (forthcoming 2013).

154 CMS Issues Final Rule for First Year of Hospital Value-Based Purchasing Program: Final Rule Will Promote Better Clinical Outcomes and Patient Experiences of Care, OFFICE OF PUBLIC AFF., CMS (Apr. 29, 2011), <http://www.cms.gov/apps/media/press/factsheet.asp?Counter=3947>.

155 *Id.*

Purchasing Program under the Medicare IPPS.¹⁵⁶ The ACA Value-Based Purchasing Program marks a definite departure from how the Medicare program has paid hospitals in the past. CMS asserts:

Starting in October 2012, Medicare will reward hospitals that provide high quality care for their patients through the new Hospital Value-Based Purchasing Program. This program marks the beginning of an historic change in how Medicare pays health care providers and facilities—for the first time, hospitals across the country will be paid for inpatient acute care services based on care quality, not just the quantity of the services they provide.¹⁵⁷

The program applies to all Medicare inpatient hospitals' discharges on or after October 1, 2012.¹⁵⁸ The ACA establishes a process for the selection of performance measures and a formula for calculating final payment to hospitals.¹⁵⁹ Funding for value-based incentive payments will come from assigned payment to hospitals under the Medicare prospective payment system.¹⁶⁰ The amount of reduction in FY 2013 is 1.0% and moves to 2.0% by 2017.¹⁶¹

Section 3006 of the ACA requires the Secretary to develop a plan to implement a value-based purchasing program for skilled nursing facilities,¹⁶² home health agencies,¹⁶³ and ambulatory surgery centers.¹⁶⁴

The ACA also launches value-based purchasing for other institutional providers. By 2014, Section 3005 of the ACA extends the quality-reporting requirement to long-term care hospitals,¹⁶⁵ inpatient rehabilitation hospitals,¹⁶⁶

¹⁵⁶ Final Rule, Medicare Program; Hospital Inpatient Value-Based Purchasing Program, 76 Fed. Reg. 26,490 (May 6, 2011) (42 C.F.R. Parts 422 and 480); *see also* Proposed Rule, Medicare Program; Hospital Inpatient Value-Based Purchasing Program, 76 Fed. Reg. 2454 (Jan. 13, 2011).

¹⁵⁷ *Administration Implements New Health Reform Provision to Improve Care Quality, Lower Costs*, HEALTHCARE.GOV (Dec. 22, 2012), <http://www.healthcare.gov/news/factsheets/2011/04/valuebasedpurchasing04292011a.html>.

¹⁵⁸ ACA § 3001(a) (codified as amended at 42 U.S.C. § 1395ww(o)(a)(1)(B) (Supp. 2011)).

¹⁵⁹ *Id.* § 3001(a) (codified as amended at 42 U.S.C. § 1395ww(o)(a) (Supp. 2011)); *see* Eleanor D. Kinney, *The Affordable Care Act and the Medicare Program: Linking Medicare Payment To Quality Performance*, New York University Annual Survey of American Law (Forthcoming 2013).

¹⁶⁰ ACA § 3001(a) (codified as amended at 42 U.S.C. § 1395ww(o)(a)(7)(A) (Supp. 2011)).

¹⁶¹ *Id.* § 3001(a) (codified as amended at 42 U.S.C. § 1395ww(o)(a)(7)(C) (Supp. 2011)).

¹⁶² *Id.* § 3006(a).

¹⁶³ *Id.* § 3006(b).

¹⁶⁴ *Id.* § 3006(f).

¹⁶⁵ *Id.* § 3004(a) (codified as amended at 42 U.S.C. § 1395ww(m) (Supp. 2011)).

¹⁶⁶ *Id.* § 3004 (codified as amended at 42 U.S.C. § 1395ww(j) (Supp. 2011)).

and hospice programs.¹⁶⁷ The Secretary of HHS must develop and publish the quality measures for these institutions by 2012 and make quality data from these institutions available to the public through a website.¹⁶⁸

Section 3005 of the ACA establishes a quality-reporting program for PPS-Exempt cancer hospitals.¹⁶⁹ Historically, the Medicare program has exempted major cancer hospitals that are designated as comprehensive or clinical cancer centers by the National Institutes of Health from the prospective payment system.¹⁷⁰ Beginning in 2014, cancer hospitals will have to submit data on quality measures to the Secretary in a manner the Secretary specifies.¹⁷¹ By October 1, 2012, the Secretary must publish quality measures for cancer hospitals that will be effective in fiscal year 2014.¹⁷²

The Medicare program is clearly banking on connecting payment to quality measures to address the cost curve in launching value-based purchasing for hospitals and physicians and moving toward value-based purchasing for other providers. Value-based purchasing is very data driven and depends on generating, collecting, and analyzing large amounts of data from individual providers. Whether the quality measures will be specific and comprehensive enough to generate improvements in care remains a question and has been a consistent concern since CMS has explored value-based payment. It is also possible that the process of collecting data and enforcing payment cuts for failures to meet quality measures will antagonize providers to the point of not participating in the Medicare program.

167 *Id.* § 3004(c) (codified as amended at 42 U.S.C. § 1395f(i) (Supp. 2011)).

168 *Id.* §§ 3004(a)-(c) (codified as amended at 42 U.S.C. §§ 1395f(i)(5), 1395ww(j)(7) & 1395f(i)(5) (Supp. 2011)); see Proposed Rule, Medicare Program; Hospital Inpatient Prospective Payment Systems for Acute Care Hospitals and the Long-Term Care Hospital Prospective Payment System and Fiscal Year 2013 Rates; Hospitals' Resident Caps for Graduate Medical Education Payment Purposes; Quality Reporting Requirements for Specific Providers and for Ambulatory Surgical Centers, 77 Fed. Reg. 27,869 (May 11, 2012); Proposed Rule, Medicare Program; Revisions to Payment Policies Under the Physician Fee Schedule . . . Inpatient Rehabilitation Facilities Quality Reporting Program; Quality Improvement Organization Regulations, 77 Fed. Reg. 44,722 (Jul. 30, 2012) (42 C.F.R. pts. 410, 414, 415, 421, 423, 425, 486, and 495).

169 ACA § 3005 (codified as amended at 42 U.S.C. § 1395cc (Supp. 2011)).

170 42 U.S.C. § 1395ww(d)(1)(B)(v); see CMS, *Medicare PPS Excluded Cancer Hospitals*, CMS.GOV (May 10, 2013, 3:45 PM), https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/AcuteInpatientPPS/PPS_Exc_Cancer_Hospasp.html.

171 ACA § 3005(2) (codified as amended at 42 U.S.C. § 1395cc(k) (Supp. 2011)).

172 *Id.* § 3005(3) (codified as amended at 42 U.S.C. § 1395cc(k)(W)(3) (Supp. 2011)); see NAT'L QUALITY F., PERFORMANCE MEASUREMENT COORDINATION STRATEGY FOR PPS-EXEMPT CANCER HOSPITALS: FINAL REPORT 2 (2012), available at http://www.google.com/url?sa=t&rct=j&q=&esrc=s&source=web&cd=1&ved=0CB4QFjAA&url=http%3A%2F%2Fwww.qualityforum.org%2FWorkArea%2Flinkit.aspx%3FLinkIdentifier%3Did%26ItemID%3D71217&ei=mD-UUM_1LaPz0gGG1oDwDg&usq=AFQjCNGwbObNny3ND4t5wCY-UZOgF2XIA&sig2=2x Cv v0FGM2QhbTfLRBp8g.pdf.

However, it seems that value-based payment is the only way to ensure that providers provide only necessary, but not excessive, care. The federal government has invested, and continues to invest, enormous funds to develop value-based purchasing and other quality initiatives. Time will tell if the federal government, out of concerns about the federal budget deficit, will continue this investment.

*b. Payment Adjustment for Hospital-Acquired Conditions
(Section 3008)*

An important step toward linking Medicare payment to quality performance was the Medicare program's identification of so-called "never events" and not paying for associated hospital care needed because of the never event.¹⁷³ In 2002, NQF published a report, *Serious Reportable Events in Healthcare*, identifying 27 adverse events occurring in hospitals that are "unambiguous, largely preventable, and serious," and that are of concern to both the public and healthcare providers.¹⁷⁴ According to NQF, the report's objective was establishment of "the consensus arrived at by consumers, providers, purchasers, researchers, and other healthcare stakeholders about preventable adverse events, and it expands on the earlier report by including implementation guidance to facilitate consistent reporting."¹⁷⁵

In the DRA of 2005, Congress required the Secretary to identify conditions that (1) were high cost or high volume or both, (2) result in the assignment of a case to a DRG that has a higher payment when present as a secondary diagnosis, and (3) could reasonably have been prevented through the application of evidence based guidelines.¹⁷⁶ In August 2007, CMS adopted a final rule identifying eight "never events" for which, beginning Oct. 1, 2008, Medicare would not provide additional payment to hospitals unless the events were present on admission.¹⁷⁷

173 See CMS, *Medicare Learning Network, Fact Sheet: Hospital-Acquired Conditions (HAC) in Acute Inpatient Prospective Payment System (IPPS) Hospitals*, DHHS (Oct. 2012), <http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/HospitalAcqCond/downloads/hacfactsheet.pdf>.

174 NAT'L QUALITY F., *SERIOUS REPORTABLE EVENTS IN HEALTHCARE—2011 UPDATE: A CONSENSUS REPORT 5* (2011), available at <http://www.doh.wa.gov/Portals/1/Documents/2900/NQF2011Update.pdf>.

175 *Id.*

176 Deficit Reduction Act (DRA) of 2005, Pub. L. No. 109-171, § 5001(c), 120 Stat. 4 (codified as amended at 42 U.S.C. § 1395ww (2006)); see CMS, *Hospital-Acquired Conditions (HAC) in Acute Inpatient Prospective Payment System (IPPS) Hospitals*, DHHS (Oct. 2012), <https://www.cms.gov/HospitalAcqCond/downloads/HACFactsheet.pdf>.

177 Medicare Program; Changes to the Hospital Inpatient Prospective Payment Systems for Acute Care Hospitals and Fiscal Year 2010 Rates, etc., 74 Fed. Reg. 43,754 (Aug. 27, 2009) (42 C.F.R. pts. 412, 413, 415, 485, and 489).

Adverse payment adjustments mark a great change in Medicare's relationship with providers. Formerly, the Medicare program paid providers regardless of whether they generated expenses associated with their errors without question. Now hospitals must bear the cost when they provide highly substandard care. Presumably this will give hospitals a greater incentive to improve safety for their patients.

c. Quality Reporting for Physicians (Sections 3002-3003 & 3007)

The ACA establishes the Physician Feedback/Value-Based Modifier Program, which provides comparative performance information to physicians as part of Medicare's efforts to improve the quality and efficiency of medical care.¹⁷⁸ These goals are achieved, in the words of CMS, "by providing meaningful and actionable information to physicians so they can improve the care they furnish, and by moving toward physician reimbursement that rewards value rather than volume."¹⁷⁹ The Program contains two primary components: (1) the preparation of the Physician Quality and Resource Use Reports (QRURs), and (2) the development and implementation of a Value-Based Payment Modifier (VBPM).¹⁸⁰

Congress established the Physician Quality Reporting Initiative in the Tax Relief and Health Care Act of 2006.¹⁸¹ The Physician Quality Reporting Initiative now is a voluntary program for eligible practitioners and provides an incentive payment to physicians and practices that satisfactorily report data on specified quality measures.¹⁸² The ACA extends this voluntary program until 2014.¹⁸³

The ACA expands the current Physician Feedback Reporting initiative.¹⁸⁴ Specifically, the feedback-reporting program uses claims data to provide reports

178 ACA § 3008(b) (codified at 42 U.S.C. § 1395ww (Supp. 2011)).

179 CMS, *supra* note 120; CMS, *Medicare FFS Physician Feedback Program/Value-Based Payment Modifier: Background*, CMS.GOV (May 13, 3:55 PM), <http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/PhysicianFeedbackProgram/Background.html>; American Medical Association, *2012 Physician Quality Reporting System (2012)*, <http://www.ama-assn.org/ama/pub/physician-resources/clinical-practice-improvement/clinical-quality/physician-quality-reporting-system-2012.page>.

180 *See* CMS, *supra* note 120, at 1.

181 THRCAs, Pub. L. No. 109-432, Div. B, § 101(b) 120 Stat. 2922 (codified as amended at 42 U.S.C. § 1395w-4 (2006)).

182 CMS, *Physician Quality Reporting System*, CMS.GOV (May 20, 2013, 4:00 PM), <http://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/PQRS/index.html?redirect=/PQRS/>.

183 ACA § 3002(a) (codified as amended at 42 U.S.C. § 1395w-4(m) (Supp. 2011)).

184 *Id.* § 3003(a)(1) (codified as amended at 42 U.S.C. § 1395w-4(n) (Supp. 2011)); *see* Medicare Program; Payment Policies Under the Physician Fee Schedule and Other Revisions to

to physicians and physician groups in the QRURs.¹⁸⁵ The QRURs contain information on resource use and the costs and quality of care provided to Medicare patients, including quantification and comparisons of patterns of resource use and costs among physicians and medical practice groups.¹⁸⁶

For reports on utilization, the Secretary developed an “episode grouper” that combines separate, but clinically related, items and services into an episode of care for an individual patient.¹⁸⁷ The grouper enables production of individualized reports that compare the per capita utilization of physicians to other physicians who see similar patients. The details of the grouper must be made available to the public and endorsed by NQR.¹⁸⁸ Additionally, the methodologies used must meet statutory standards and be available to the public as well.¹⁸⁹ Finally, the feedback program must be coordinated with other value-based purchasing programs.¹⁹⁰ CMS promulgated a proposed rule to implement these and other changes in physician payment in July 2012.¹⁹¹

The ACA also consolidated this initiative into the Physician Quality Reporting System (PQRS) and established the *Physician Compare* website.¹⁹² By 2015, eligible professionals must submit data on quality measures for covered professional services or incur a percent reduction in the fee schedule amount for service provided for that pay period.¹⁹³ The percentage reductions will be 1.5% in 2015 and 2.0% thereafter.¹⁹⁴ CMS addressed these and other changes in its proposed rule on physician payment in July 2012.¹⁹⁵

The ACA also contains incentives for physicians to participate in the Maintenance of Certification (MOC) Program operated by the American Board

Part B for CY 2011, 75 Fed. Reg. 73,169 (Nov. 29, 2010) (42 C.F.R. pts. 405, 409, 410, 411, 413, 414, 415, and 424).

185 CMS, *Medicare FFS Physician Feedback Program/Value-Based Payment Modifier*, CMS.gov (May 20, 2013: 4:10PM), <http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/PhysicianFeedbackProgram/index.html?redirect=/physicianfeedbackprogram>.

186 *Id.*

187 ACA § 3003(a)(4) (codified as amended at 42 U.S.C. § 1395w-4(n)(9)(A) (i),(ii) (Supp. 2011)).

188 *Id.* § 3003(a)(4) (codified as amended at 42 U.S.C. § 1395w-4(n)(A)(9) (iii),(iv) (Supp. 2011)).

189 *Id.* § 3003(a)(4) (codified as amended at 42 U.S.C. §§ 1395w-4(n)(9)(A) (C),(F) (Supp. 2011)).

190 *Id.* § 3003(a)(4) (codified as amended at 42 U.S.C. § 1395w-4(n)(10) (Supp. 2011)).

191 Medicare Program; Changes to the Hospital Inpatient Prospective Payment Systems for Acute Care Hospitals and Fiscal Year 2010 Rates, etc., 74 Fed. Reg. 43,754 (Aug. 27, 2009) (42 C.F.R. pts. 412, 413, 415, 485, and 489).

192 *Id.*

193 ACA § 3002(b) (codified as amended at 42 U.S.C. § 1395w-4(a)(8)(A) (Supp. 2011)).

194 *Id.*

195 *See*, Medicare Program, 74 Fed. Reg. 43, 754.

of Medical Specialties.¹⁹⁶ This program requires physicians with medical specialty certifications to participate in continuing medical education and other activities to maintain current in their specialty.¹⁹⁷ The ACA provides that physicians who are eligible for the PQRS can receive an additional 0.5% incentive payment if they meet the MOC requirements as well.¹⁹⁸

The ACA section 3007 mandates that, by 2015, the Secretary must establish the VBPM that provides for differential payment to physicians or physicians groups based on quality performance.¹⁹⁹ To establish the VBPM, the Secretary must develop appropriate risk adjusted measures of quality of care, which also reflects outcomes of care. ACA requires that implementation begin with rulemaking for Fiscal Year 2013.²⁰⁰

Beginning January 1, 2015, CMS must apply the VBPM to specific physicians and physician groups that CMS determines appropriate. By no later than January 1, 2017, the VBPM must be applied to all physicians and physician groups.²⁰¹ In applying the payment modifier, the Secretary must take into account the special circumstances of physicians or groups of physicians in rural areas and other underserved communities.²⁰²

Quality reporting and value-based purchasing for physicians should hopefully impose the same incentives on physicians for quality of care over volume of care as a way to maximize payment. However, quality reporting and value-based purchasing pose special problems for physicians. Quality reporting and value-based purchasing are data-intensive enterprises. Thus, to participate in these initiatives, physicians and their practices will need to submit large quantities of patient data to participate in this program. Such requirements could have an impact on patient care, as physicians often enter data on patients as they provide care. Such an enterprise, to say the least, could be distracting from the important physician-patient encounters, which are so necessary for high-quality care.

196 AM. BD. MED. SPECIALTIES, *About ABMS Maintenance of Certification*, (2012) http://www.abms.org/maintenance_of_certification/.

197 *Id.*

198 ACA § 3002(c) as amended by § 10327(b) (codified as amended at 42 U.S.C. § 1395w-4(k)(4) (Supp. 2011)).

199 *Id.* § 3007 (codified as amended at 42 U.S.C. § 1395w-4(p)(2) (Supp. 2011)).

200 *Id.* § 3007 (codified as amended at 42 U.S.C. § 1395w-4(p)(4) (Supp. 2011)).

201 *Id.* § 3007 (codified as amended at 42 U.S.C. § 1395w-4(p)(4) (Supp. 2011)).

202 *Id.* § 3007 (codified as amended at 42 U.S.C. § 1395w-4(p)(6) (Supp. 2011)).

2. *Developing a National Strategy to Improve Health Care Quality (Subtitle A, Part 2)*

Subtitle A, Part 2, calls for the development of a National Strategy to Improve Health Care Quality.²⁰³ To develop this strategy, the Secretary of HHS is to convene an interagency working group on health care quality that will focus primarily on developing quality measures and methods for measuring quality.²⁰⁴ HHS has initiated the development of a national strategy as directed.²⁰⁵ In the first mandated report to Congress, CMS established 3 aims and 6 priorities, which are displayed in Table 5.²⁰⁶ HHS presented a second report to Congress on progress with this initiative in April 2012.²⁰⁷

The first mandated report also required CMS to report on a process of developing a universal quality strategy that will reconcile and harmonize the development of quality performance measures and other standards of the various public and private organizations involved in the development of these measures and standards. In its second 2012 report to Congress on this strategy, CMS stated:

One of the primary objectives of the National Quality Strategy is to build a national consensus on how to measure quality so that stakeholders can align their efforts for maximum results. The strategy itself serves as a framework for quality measurement, measure development, and analysis of where everyone can do more, including across HHS agencies and programs as well as in the private sector. This alignment of measurement creates shared accountability across health systems and stakeholders around the country for improving patient-centered outcomes.²⁰⁸

203 *Id.* § 3011.

204 *Id.* §§ 3012-3014.

205 National Quality Strategy Will Promote Better Health, Quality Care for Americans, HHS.GOV, (Mar. 21, 2011), <http://www.hhs.gov/news/press/2011pres/03/20110321a.html>.

206 CMS, REPORT TO CONGRESS: NATIONAL STRATEGY FOR QUALITY IMPROVEMENT IN HEALTH CARE (2011), *available at* http://www.healthcare.gov/law/resources/reports/quality_03212011a.html.

207 CMS, 2012 ANNUAL REPORT TO CONGRESS: NATIONAL STRATEGY FOR QUALITY IMPROVEMENT IN HEALTH CARE, DHHS 1 (2012), *available at* <http://www.ahrq.gov/workingforquality/nqs/nqs2012annlrpt.pdf>.

208 *Id.* at 2.

Table 5
National Quality Strategy Aims and Priorities

National Quality Strategy's three aims:

1. Better Care: Improve the overall quality of care, by making health care more patient-centered, reliable, accessible, and safe
2. Healthy People/Healthy Communities: Improve the health of the U.S. population by supporting proven interventions to address behavioral, social, and environmental determinants of health in addition to delivering higher-quality care
3. Affordable Care: Reduce the cost of quality health care for individuals, families, employers, and government

National Quality Strategy's six priorities:

1. Making care safer by reducing harm caused in the delivery of care
2. Ensuring that each person and family are engaged as partners in their care
3. Promoting effective communication and coordination of care
4. Promoting the most effective prevention and treatment practices for the leading causes of mortality, starting with cardiovascular disease
5. Working with communities to promote wide use of best practices to enable healthy living.
6. Making quality care more affordable for individuals, families, employers, and governments by developing and spreading new health care delivery models

The successful development and implementation of the National Quality Strategy is important and will greatly facilitate other approaches to improve quality and efficiency throughout the ACA. So far, it seems that this effort to develop a National Quality Strategy has been relatively well received among stakeholders, which is an important indicator of success.²⁰⁹

3. Developing New Patient Care Models (Subtitle A, Part 3)

Subtitle A, Part 3, Encouraging Development of New Patient Care Models, includes other strategies to control Medicare expenditures.²¹⁰ Table 6 lists the authorities for these new patient care models. These models are designed to make the delivery of, and payment for, health care services to Medicare fee-for-service beneficiaries more integrated and efficient and therefore, less costly. Subtitle A, Part 3, contains most of the innovative programs to reform the way in which medical care is delivered, particularly for those with chronic disease.

²⁰⁹ See, e.g., David Nash, *National Quality Strategy: Right Idea at the Right Time*, MEDPAGE TODAY (May 11, 2013, 5:00PM), <http://www.medpagetoday.com/Columns/FocusonPolicy/23303>, NORTHEAST BUSINESS GROUP ON HEALTH, *HHS Releases National Quality Strategy that Aims to Promote Better Health, Quality Care* (2011), <http://nebgh.org/blog/?p=95>.

²¹⁰ ACA §§ 3021-3027.

Table 6
Subtitle A—Transforming The Health Care Delivery System
Part 3—Encouraging Development of New Patient Care Models

<p>Sec. 3021. Establishment of Center for Medicare and Medicaid Innovation within CMS</p> <p>Sec. 3022. Medicare shared savings program</p> <p>Sec. 3023. National pilot program on payment bundling</p> <p>Sec. 3024. Independence at home demonstration program</p> <p>Sec. 3025. Hospital readmissions reduction program</p> <p>Sec. 3026. Community-Based Care Transitions Program</p> <p>Sec. 3027. Extension of gainsharing demonstration</p>

a. Center for Medicare and Medicaid Innovation (CMI) (Section 3021)

Section 3021 of the ACA calls for the creation of the Center for Medicare and Medicaid Innovation (CMI).²¹¹ The purpose of CMI is “to test innovative payment and service delivery models to reduce program expenditures” and “improve the coordination, quality, and efficiency of health care services.”²¹² CMI has been quite active in launching new and continuing old initiatives.²¹³ Currently, it is engaged in research and analysis on the following Medicare issues: accountable care organization demonstrations, bundled payment demonstrations, and the independence at home demonstration, among other projects.²¹⁴

b. Medicare Shared Savings Program (Section 3022)

A very important strategy that compliments value-based purchasing is the Medicare shared savings program in Section 3022 of the ACA.²¹⁵ This shared savings program is intended to facilitate coordination and cooperation among

211 *Id.* § 3021(a) (codified as amended at 42 U.S.C. § 1315a (Supp. 2011)).

212 See Stuart Guterman et al., *Innovation in Medicare and Medicaid will be Central to Health Reform's Success*, 29 HEALTH AFF. 1188, 1188-92 (2010); Meredith B. Rosenthal, *Hard Choices—Alternatives for Reining in Medicare and Medicaid Spending*, NEW ENG. J. MED. 364, 1887-88 (2011).

213 CMS, *One Year of Innovation: Taking Action to Improve Care and Reduce Costs*, DHHS (Jan. 2012), <http://www.innovations.cms.gov/Files/reports/Innovation-Center-Year-One-Summary-document.pdf>.

214 CMS, *Welcome to the CMS Innovation Center*, CMS.GOV (May 1, 2013, 5:50 PM), <http://www.innovations.cms.gov/>.

215 ACA § 3022 (codified at 42 U.S.C. § 1395(jjj) (Supp. 2011)); Medicare Program; Medicare Shared Savings Program: Accountable Care Organizations, 76 Fed. Reg. 67, 802 (Nov. 2, 2011) (42 C.F.R. pt. 425); see Paul B. Ginsburg, *Spending to Save—ACOs and the Medicare Shared Savings Program*, 365 NEW ENG. J. MED. 2085, 2085-86 (2011).

providers to improve the quality of care for fee-for-service Medicare beneficiaries. Eligible providers, hospitals, and suppliers may participate in the Shared Savings Program by creating or participating in an Accountable Care Organization (ACO).²¹⁶

CMS defines ACOs as “groups of doctors, hospitals, and other health care providers, who come together voluntarily to give coordinated high quality care to their Medicare patients.”²¹⁷ The goal of coordinated care is “to ensure that patients, especially the chronically ill, get the right care at the right time, while avoiding unnecessary duplication of services and preventing medical errors.”²¹⁸ Under the program, groups of providers of services and suppliers can work together to manage and coordinate care in an ACO, and, if they meet quality performance standards, they may receive payments for shared savings.²¹⁹

CMS has initiated a demonstration to test two models of ACOs: the Pioneer ACO Model and the Advance Payment ACO Model.²²⁰ The Pioneer ACO Model was designed specifically for organizations with “experience offering coordinated, patient-centered care, and operating in ACO-like arrangements.”²²¹ There are thirty-two organizations participating in the Pioneer ACO Model. The Advanced Payment ACO Model provides additional support to physician-owned and rural providers who would benefit from additional start-up resources to build the necessary infrastructure, such as new staff or information technology systems.²²²

The number of providers who have launched ACOs is impressive. According to CMS, as of January 2013, there were 106 ACOs, saving up to \$940 million over four years.²²³ Roughly half of ACOs are physician-led organizations that serve fewer than 10,000 beneficiaries and about 20 percent of ACOs include community health centers, rural health clinics, and critical access hospitals that serve low-income and rural communities.²²⁴

216 CMS, *Shared Savings Program*, CMS.gov (Apr. 30, 2013, 11:56 PM), <http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/sharesavingsprogram/index.html?redirect=/sharesavingsprogram/>.

217 CMS, *Accountable Care Organizations*, CMS.gov (Mar. 22, 2013, 5:38 AM), <http://innovation.cms.gov/initiatives/aco/>.

218 *Id.*

219 ACA § 3023 (codified as amended at 45 U.S.C. § 1395cc-4 (Supp. 2011)).

220 CMS, *Pioneer Accountable Care Organization Model: General Fact Sheet*, DHHS (Sept. 2012), <http://innovations.cms.gov/Files/fact-sheet/Pioneer-ACO-General-Fact-Sheet.pdf>.

221 *Id.*

222 *Id.*

223 More Doctors, Hospitals Partner to Coordinate Care for People with Medicare Providers Form 106 New Accountable Care Organizations, HHS.gov, <http://www.cms.gov/apps/media/press/release.asp?Counter=4501&intNumPerPage=10&checkDate=&checkKey=&srchType=1&numDays=3500&srchOpt=0&srchData=&keywordType=All&chkNewsType=1%2C+2%2C+3%2C+4%2C+5&intPage=&showAll=&pYear=&year=&desc=&cboOrder=date>.

224 *Id.*

Although the provider community was initially skeptical of ACOs,²²⁵ as the numbers indicate, they have responded to the initiative relatively enthusiastically. Donald Berwick, the former CMS administrator, has indicated that CMS made many changes in the final rules for ACOs to accommodate provider comments and facilitate provider participation.²²⁶ Empirical research suggests that, while there is much to be done, ACOs are very promising with respect to meeting their goals.²²⁷ Even *Forbes Magazine* lauds the performance of ACOs.²²⁸ An interesting report from an industry study is remarkably positive about ACOs and their accomplishments to date:

For many of us in the healthcare industry, the real potential game-changer in the Affordable Care Act was not the highly publicized provisions—the creation of insurance exchanges or its embrace of guaranteed issue, community rating, and regulated medical loss ratios. Rather, it was the way ACA opened the door to accountable care organizations (ACOs) in Medicare. Here at last was a development in US healthcare that would shift the focus to delivery and encourage provider organizations to compete on quality and price—something the traditional fee-for-service system has failed at rather spectacularly. We believed—and still do—that as this sort of competition is successfully introduced into the US system, it will inevitably spread, enabling and accelerating a movement toward healthcare that is priced and paid for in terms of value, not volume of services rendered.²²⁹

225 Elliott S. Fisher & Stephen M. Shortell, *Accountable Care Organizations Accountable for What, to Whom, and How*, 304 JAMA 1715, 1715-16 (2010).

226 Donald M. Berwick, *Making Good on ACOs' Promise—The Final Rule for the Medicare Shared Savings Program*, 365 NEW ENG. J. MED. 1753, 1754 (2011).

227 Elliott S. Fisher et al., *A Framework For Evaluating The Formation, Implementation, And Performance Of Accountable Care Organizations*, 31 HEALTH AFF. 2368, 2368-69 (2012); Bridget K. Larson et al., *Insights From Transformations Under Way At Four Brookings-Dartmouth Accountable Care Organization Pilot Sites*, 31 HEALTH AFF. 2395, 2395 (2012).

228 Bruce Japsen, *Obamacare's Accountable Care Approach Reaches 1 in 10 In U.S.*, FORBES (Nov. 26, 2012, 9:00 AM), <http://www.forbes.com/sites/brucejapsen/2012/11/26/obamacares-accountable-care-approach-reaches-1-in-10-in-u-s/>.

229 NIYUM GANDHI & RICHARD WEIL, *THE ACO SURPRISE* (2012), available at http://www.oliverwyman.com/media/OW_ENG_HLS_PUBL_The_ACO_Surprise.pdf.

c. Other Reforms to Improve Efficiency of Care (Sections 3023-3027)

There are several initiatives in the ACA that seek to make payment methodologies encouraging providers to make efficiencies. A major payment reform in this regard is the shared savings program with ACOs discussed above.

The ACA section 3027 extends the “gainsharing demonstration” established under the DRA of 2005.²³⁰ The basic theory of this demonstration is that providing payments to physicians that “represent solely a share of the savings incurred as a result of collaborative efforts” will “improve overall quality and efficiency.”²³¹ This demonstration examines whether the practice of “gainsharing” is an effective means of aligning financial incentives to enhance quality and efficiency of care.²³²

The ACA section 3023 also calls for a national pilot program on payment bundling.²³³ The pilot program explores ways to pay groups of providers for services associated with an episode of care and move away from the practice of essentially paying the bills of lots of individual providers. The basic idea is that such bundling encourages providers to work together in efficient ways to care for the patient in a cost effective manner and not seek to maximize their individual reimbursements. In this program, CMS will pay a subset of Medicare providers a single payment for an episode of acute care in a hospital, followed by post acute care in a skilled nursing or rehabilitation facility, the patient’s home, or other appropriate setting.²³⁴

The ACA section 3026 establishes a Community-Based Care Transitions Program under which CMS will fund entities that furnish improved care transition services to high-risk Medicare beneficiaries without reducing quality.²³⁵ The idea is that various entities, typically hospitals and community-

230 ACA § 3027 (codified at § 5007 of the DFA).

231 CMS, *Medicare Hospital Gainsharing Demonstration*, CMS.GOV (2006), http://www.cms.gov/DemoProjectsEvalRpts/downloads/DRA5007_Fact_Sheet.pdf.

232 CMS.gov, *Demonstrations, Details for DRA 5007* (2011), <http://www.cms.gov/Medicare/Demonstration-Projects/DemoProjectsEvalRpts/Medicare-Demonstrations-Items/CMS1186805.html>.

233 ACA § 3024 (codified at 42 U.S.C. § 1395cc–5 (Supp. 2011)); see Neeraj Sood et al., *Medicare’s Bundled Payment Pilot for Acute and Postacute Care: Analysis and Recommendations on Where To Begin*, 30 HEALTH AFF. 1708, 1708-09 (2011).

234 Neeraj Sood et al., *Medicare’s Bundled Payment Pilot for Acute and Postacute Care: Analysis and Recommendations on Where To Begin*, 30 HEALTH AFF. 1708, 1708-09 (2011).

235 ACA § 3026; see CMS, *Community-Based Care Transitions Program*, CMS.GOV (2012), <http://www.innovations.cms.gov/initiatives/Partnership-for-Patients/CCTP/index.html?itemID=CMS1239313>; Chris Fleming, *Health Policy Brief: Improving Transitions*, HEALTH AFF. BLOG (Sept. 21, 2012), <http://healthaffairs.org/blog/2012/09/21/health-policy-brief-improving-care-transitions/>; Eric A. Coleman et al., *The Care Transitions Intervention: Results of a Randomized Controlled Trial*, 166 ARCHIVES INTERNAL MED. 1822 (2006).

based organizations, will formally collaborate and provide transition services for high-risk Medicare beneficiaries to ensure timely post-discharge follow-up services.²³⁶ The partnership would submit a proposal on how it would deliver these transition services.²³⁷

Section 3024 of the ACA establishes the “Independence at Home Demonstration program.”²³⁸ This program will test payment incentives and service delivery models for the care of chronically ill patients that utilize physician and nurse practitioner directed home-based primary care teams.

Many of the initiatives in Subtitle A, Part 3 endeavor to bundle payments, change incentives, and move toward better coordinated care. However, these initiatives must be executed with care to be sure that providers use of the bundled payment for patient care and, more importantly, not avoid taking care of sicker and more difficult patients.²³⁹ And it is also important to maintain funding levels to make success possible. The success of these reforms would put the Medicare program in a better position to evolve into a sustainable single payer system.

The ACA section 3025 establishes authority for reducing payment for readmissions to hospitals.²⁴⁰ Readmissions to hospitals have been a difficult and costly problem for the Medicare program since the implementation of the Medicare prospective payment system in the early 1980s.²⁴¹ The problem reflects deficiencies in discharge planning for patients with multiple chronic conditions or poor support systems at home. In 2005, MEDPAC reported that in 2005, 17.6% of hospital admissions resulted in readmissions within thirty days of discharge, 11.3% within fifteen days, and 6.2% within seven days.²⁴² Other research reported similar findings.²⁴³ Through demonstrations and other analysis, CMS has been working on how to tailor Medicare payment rates for hospital

236 ACA § 3026(a)(2); see *Independence at Home Demonstration*, (2012), <http://www.innovations.cms.gov/Files/fact-sheet/IAHfactsheet.pdf>.

237 *Id.* § 3026(a)(2).

238 *Id.* § 3024 (codified at 42 U.S.C. § 1395cc-5 (Supp. 2011)).

239 Meredith B. Rosenthal, *Hard choices—Alternatives for Reining in Medicare and Medicaid Spending*, 364 NEW ENG. J. MED. 1887, 1887 (2011).

240 ACA § 3025 (codified at 42 U.S.C. § 1395www (Supp. 2011)); see JULIE STONE & GEOFFREY J. HOFFMAN, MEDICARE HOSPITAL READMISSIONS: ISSUES, POLICY OPTIONS AND PPACA, available at http://www.hospitalmedicine.org/AM/pdf/advocacy/CRS_Readmissions_Report.pdf.

241 Gerard F. Anderson & Earl P. Steinberg, *Hospital Readmissions in the Medicare Population*, 311 NEW ENG. J. MED. 1349, 1349-52 (1984).

242 *Report to Congress: Promoting Greater Efficiency in Medicare*, MEDPAC (Jun. 2007), www.medpac.gov/documents/Jun07_EntireReport.pdf; JULIE STONE & GEOFFREY J. HOFFMAN, MEDICARE HOSPITAL READMISSIONS: ISSUES, POLICY OPTIONS AND PPACA (2010), available at http://www.hospitalmedicine.org/AM/pdf/advocacy/CRS_Readmissions_Report.pdf.

243 Stephen F. Jencks et al., *Rehospitalizations Among Patients in the Medicare Fee-for-Service Program*, 360 NEW ENG. J. MED. 1418 (2009); see also JENNY MINOT, REDUCING HOSPITAL READMISSIONS 2 (2008), available at http://www.academyhealth.org/files/publications/Reducing_Hospital_Readmissions.pdf.

readmissions.²⁴⁴ The ACA established the Hospital Readmissions Reduction Program, effective October 1, 2012.²⁴⁵ Under this program, payments for certain readmissions of eligible hospitals are reduced in order to account for excess readmissions.²⁴⁶ CMS has promulgated regulations to implement the Hospitals Readmissions Reduction Program.²⁴⁷

The initiative to reduce readmissions to hospitals is a critical reform. Implementation of the program has been controversial with 2,217 hospitals sustaining penalties in the program's first year.²⁴⁸ While quite controversial among hospitals, there are indications that hospitals are taking steps to address the readmissions problem with serious effort.²⁴⁹ This initiative is persuasive conformation that payment methodologies can influence provider behavior.

B. Improving Medicare for Patients and Providers (Title III, Subtitle B)

Subtitle B contains an assortment of provisions directed at improving various Medicare program policies. The changes are contained in three parts: (1) Ensuring Beneficiary Access to Physician Care and Other services, (2) Rural Protections, and (3) Improving Payment Accuracy. Table 7 displays the statutory sections in Subtitle B, Part I.

244 See Richard F. Averill et al., *Redesigning the Medicare Inpatient PPS to Reduce Payments to Hospitals with High Readmission Rates*, 30 HEALTH CARE FIN. REV. 1 (2009).

245 ACA § 3025 (codified at 42 U.S.C. § 1395ww(q) (Supp. 2011), as amended by ACA §§ 3001, 3008); see CMS, *Community-based Care Transitions Program*, CMS.GOV (2012), <http://www.innovations.cms.gov/initiatives/Partnership-for-Patients/CCTP/index.html?itemid=cms1239313>.

246 ACA § 3025 (codified at 42 U.S.C. § 1395ww(q)(q) (Supp. 2011), as amended by ACA §§ 3001, 3008); see CMS, *Hospital Readmissions Reduction Program*, CMS.GOV (2012), <http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/AcuteInpatientPPS/Readmissions-Reduction-Program.html>.

247 Medicare Program; Hospital Inpatient Prospective Payment Systems for Acute Care Hospitals and the Long-Term Care Hospital Prospective Payment System and FY 2012 Rates; Hospitals' FTE Resident Caps for Graduate Medical Education Payment, 76 Fed. Reg. 51,476 (Aug. 18, 2011) (42 C.F.R. pts. 412, 413 and 476).

248 Jordan Rau, *Medicare Revises Hospitals' Readmissions Penalties*, KAISER HEALTH NEWS (Oct. 2, 2012), <http://www.kaiserhealthnews.org/Stories/2012/October/03/medicare-revises-hospitals-readmissions-penalties.aspx>.

249 Douglas McCarthy et al., *Recasting Readmissions by Placing the Hospital Role in Community Context*, 309 JAMA 351 (2013); Amy Boutwell, *Time To Get Serious About Hospital Readmissions*, HEALTH AFF. BLOG (Oct. 10, 2012), <http://healthaffairs.org/blog/2012/10/10/time-to-get-serious-about-hospital-readmissions/>.

Table 7
Subtitle B—Improving Medicare for Patients and Providers
Part I—Ensuring Beneficiary Access to Physician Care and Other Services
Sec. 3101. Increase in the physician payment update (repealed)
Sec. 3102. Extension of the work geographic index floor and revisions to the practice expense geographic adjustment under the Medicare physician fee schedule
Sec. 3103. Extension of exceptions process for Medicare therapy caps
Sec. 3104. Extension of payment for technical component of certain physician pathology services
Sec. 3105. Extension of ambulance add-ons
Sec. 3106. Extension of certain payment rules for long-term care hospital services and of moratorium on the establishment of certain hospitals and facilities
Sec. 3107. Extension of physician fee schedule mental health add-on
Sec. 3108. Permitting physician assistants to order post-Hospital extended care services
Sec. 3109. Exemption of certain pharmacies from accreditation requirements
Sec. 3110. Part B special enrollment period for disabled TRICARE beneficiaries
Sec. 3111. Payment for bone density tests
Sec. 3112. Revision to the Medicare Improvement Fund
Sec. 3113. Treatment of certain complex diagnostic laboratory tests
Sec. 3114. Improved access for certified nurse-midwife services

1. Ensuring Beneficiary Access to Physician Care and Other Services (Subtitle B, Part I).

This part contains fourteen sections with provisions modifying physician payment methodologies under Part B of the Medicare Program. Perhaps the most important change is the extension of the work geographic index floor²⁵⁰ and revisions to the practice expense geographic adjustment under the Medicare physician fee schedule.²⁵¹ A geographic practice cost index (GPCI) has been established for every Medicare payment locality for each of the three components of a procedure's relative value unit (i.e., the RVUs for work, practice expense, and malpractice).²⁵² The GPCIs are applied in the calculation of a fee schedule payment amount by multiplying the RVU for each component times the GPCI for that component.

250 ACA § 3102(a) (codified as amended at 42 U.S.C. § 1395w-4(e)(1)(E) (Supp. 2011)).

251 *Id.* § 3102(b) (codified as amended at 42 U.S.C. § 1395w4(e)(1) (Supp. 2011)).

252 CMS, Overview. CMS.GOV (Mar. 18, 2013), <https://www.cms.gov/apps/physician-fee-schedule/overview.aspx>; see THOMAS MACURDY ET AL., REVISIONS TO THE SIXTH UPDATE OF THE GEOGRAPHIC PRACTICE COST INDEX: FINAL REPORT (2011), available at https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/PhysicianFeeSched/Downloads/CY2012_Revisions_to_the_6th_GPCI_Update-Final_Report.pdf.

The ACA originally had a provision to perform the so-called “doc fix” and finally readjust the impact of the SGR.²⁵³ Because of political controversy, this provision was repealed in the Health Care and Education Reconciliation Act of 2010.²⁵⁴ The American Taxpayer Relief Act of 2012 (ATRA) recently enacted to address the so-called “fiscal cliff,” postponed implementation of the statutory reduction of Medicare payments to physicians of approximately 26.5% as required under the SGR for another few years.²⁵⁵

2. Rural Protections (Subtitle B, Part II).

Part II, displayed in Table 8, contains seven sections that address problems of rural providers, particularly hospitals.²⁵⁶ Rural hospitals today and historically have experienced unique problems with respect to Medicare payment because of their comparably smaller sizes and more limited assets.²⁵⁷ Rural hospitals experience “Medicare payment challenges” due to workforce shortages, rising health care liability premiums and poor access to capital.²⁵⁸ Part II also contains a host of different payment policies to assist rural hospitals in maintaining financial sustainability.

These measures appear to be proceeding with relatively little controversy. They are essentially modifications and continuations of existing programs that are generally quite popular with providers.

3. Improving Payment Accuracy (Subtitle B, Part III).

Part III, as displayed in Table 8, contains provisions for improving payment accuracy through the reform of payment methods for home health care,²⁵⁹ hospice services,²⁶⁰ medical imaging,²⁶¹ electronic wheelchairs,²⁶² among many other items and services. The ACA also updates Disproportionate Share (DSH) payments to hospitals that serve large numbers of Medicare, Medicaid and

253 ACA § 3101.

254 Health Care and Education Reconciliation Act of 2010, Pub. L. 111-152, 124 Stat. 1029 (codified as amended in scattered sections of the U.S.C.).

255 American Tax Payer Relief Act of 2012, Pub. L. No. 112-240, 126 Stat. 2313 (codified as amended in scattered sections of the U.S.C.).

256 ACA §§ 3121-3129.

257 Am. Hosp. Ass’n, *Rural Health Care* (Apr. 15, 2013), <http://www.aha.org/advocacy-issues/rural/index.shtml>.

258 *Id.*

259 ACA § 3131.

260 *Id.* § 3132.

261 *Id.* § 3135.

262 *Id.* § 3136.

uninsured patients.²⁶³ Specifically, section 3133 modifies Medicare DSH payments to reflect lower uncompensated care costs associated with decreases in the number of uninsured.²⁶⁴

Table 8 Subtitle B—Improving Medicare for Patients and Providers Part II—Rural Protections
<p>PART II—RURAL PROTECTIONS</p> <p>Sec. 3121. Extension of outpatient hold harmless provision</p> <p>Sec. 3122. Extension of Medicare reasonable costs payments for certain clinical diagnostic laboratory tests furnished to hospital patients in certain rural areas</p> <p>Sec. 3123. Extension of the Rural Community Hospital Demonstration Program</p> <p>Sec. 3124. Extension of the Medicare-dependent hospital (MDH) program</p> <p>Sec. 3125. Temporary improvements to the Medicare inpatient hospital payment adjustment for low-volume hospitals</p> <p>Sec. 3126. Improvements to the demonstration project on community health integration models in certain rural counties</p> <p>Sec. 3127. MedPAC study on adequacy of Medicare payments for health care providers serving in rural areas</p> <p>Sec. 3128. Technical correction related to critical access hospital services</p> <p>Sec. 3129. Extension of and revisions to Medicare rural hospital flexibility Program</p>

The ACA modification of Medicare DSH payments may have to be changed in light of the Supreme Court’s decision in *National Federation of Independent Business v. Sebelius*.²⁶⁵ In this decision, the Supreme Court ruled that the federal government could not terminate all federal matching funds for state Medicaid programs if states declined to implement the Medicaid expansion in Title II of the ACA.²⁶⁶ The ACA provisions reducing Medicare DSH payments are predicated on the expectation that states would have to adopt the ACA Medicaid expansions. Of note, the ARRA actually rebased state disproportionate share hospital payments achieving substantial savings.²⁶⁷

263 *Id.* § 3133, as amended by HCERA § 1104 (codified as amended at 2 U.S.C. § 1395ww(r) (Supp. 2011)); CMS, *Disproportionate Share Payments: Rural Hospital Fact Sheet Series*, DHHS (Jan. 2013), http://www.cms.gov/Outreach-and-Education/Medicare-Learning-Network-MLN/MLNProducts/downloads/Disproportionate_Share_Hospital.pdf.

264 ACA § 3133, as amended by HCERA § 1104 (codified as amended at 2 U.S.C. § 1395ww(r) (Supp. 2011)); see Irwin Redlener & Roy Grant, *America’s Safety Net and Health Care Reform—What Lies Ahead?* 361 NEW ENG. J. MED. 2201 (2009).

265 132 S. Ct. 2566, 2591-93 (2012).

266 ACA, Title II.

267 ARRA § 641 (codified as amended at 42 U.S.C. § 1396r-4(f)(8) (Supp. 2011)).

C. Provisions Relating to Part C (Title III, Subtitle C)

The ACA also made substantial changes to Medicare Part C (the Medicare Advantage (MA) program), which are presented in Table 9. The ACA will reduce payments to MA plans over time to bring Part C expenditures in line with fee-for-service Medicare.²⁶⁸ Since the MMA of 2003, the Medicare program has paid higher rates for beneficiaries enrolled in MA plans than for beneficiaries in fee-for service Medicare.²⁶⁹ In 2010, MEDPAC reported that the Medicare program spent roughly \$14 billion more for beneficiaries enrolled in MA plans than for beneficiaries in the Medicare Fee-for Service program.²⁷⁰ Under the ACA, Medicare payments to plans will be predicated on the average of the bids submitted by plans in each market.²⁷¹ New payments will be implemented over a four-year transition period.²⁷²

The ACA imposed significant cuts in payments to MA plans that have proven difficult to implement. The ACA required that, effective January 1, 2012, CMS must provide quality bonus payments to MA plans based on a 5-star quality rating system it developed.²⁷³ Instead, in November 2010, CMS announced that it would waive the ACA 5-star quality rating system provisions and that it would determine quality bonus payments for 2012 through 2014 under the massive Medicare Advantage Quality Bonus Payment Demonstration.²⁷⁴ There is considerable political debate over the advisability of CMS' decision given the cost and scope of the demonstration.²⁷⁵ The U.S. GAO took the position that

268 ACA § 3201 as amended by HCERA § 1102(b) (codified as amended at 42 U.S.C. § 1395w-23 (Supp. 2011)).

269 Medicare Prescription Drug Improvement and Modernization Act of 2003, Pub. L. No. 108-173, 117 Stat. 2066 (codified in scattered sections of 42 U.S.C and 26 U.S.C.).

270 *Report to Congress: Medicare Payment Policy*, MEDPAC (Mar. 2010), http://medpac.gov/documents/Mar10_EntireReport.pdf.

271 ACA § 3201(a) as amended by HCERA § 1102(b) (codified as amended at 42 U.S.C. § 1395w-23 (Supp. 2011)).

272 *Id.* § 3201(b) as amended by HCERA § 1102(b) (codified as amended at 42 U.S.C. § 1395w-23 (Supp. 2011)).

273 *Id.* § 3201(c) as amended by HCERA § 1102(b) (codified as amended at 42 U.S.C. § 1395w-23 (Supp. 2011)).

274 *Health Policy Briefs: Medicare Advantage Plans*, HEALTH AFF. (Jun. 15, 2011), http://www.healthaffairs.org/healthpolicybriefs/brief.php?brief_id=48; *Medicare Advantage Plan Star Ratings and Bonus Payments in 2012*, KAISER FAM. FOUND. (Nov. 1, 2011), <http://www.kff.org/medicare/upload/8257.pdf>.

275 See *GAO Report, The Obama Administration's \$8 Billion Extralegal Healthcare Spending Project*, COMM. OVERSIGHT & GOV'T. REFORM (Jul. 25, 2012, 9:30 AM), <http://oversight.house.gov/hearing/gao-report-the-obama-administrations-8-billion-extralegal-healthcare-spending-project/>.

HHS exceeded its authority in launching this demonstration rather than implementing the ACA.²⁷⁶

Table 9 Subtitle C—Provisions Relating to Part C
Sec. 3201. Medicare Advantage payment
Sec. 3202. Benefit protection and simplification
Sec. 3203. Application of coding intensity adjustment during MA payment transition
Sec. 3204. Simplification of annual beneficiary election periods
Sec. 3205. Extension for specialized MA plans for special needs individuals
Sec. 3206. Extension of reasonable cost contracts
Sec. 3207. Technical correction to MA private fee-for-service plans
Sec. 3208. Making senior housing facility demonstration permanent
Sec. 3209. Authority to deny plan bids
Sec. 3210. Development of new standards for certain Medigap plans

D. Medicare Part D Improvements for Prescription Drug Plans and MA-PD Plans (Title III, Subtitle D)

Perhaps the largest Medicare expansion in the ACA is closing the so-called “donut hole” coverage gap in the Medicare prescription drug benefit. The ACA started the process of closing the donut hole by providing a rebate for beneficiaries who had reached the gap in coverage in 2010.²⁷⁷ Also as a condition of having their drugs included in the Part D program, pharmaceutical manufacturers must provide a fifty percent discount to Part D beneficiaries for brand name pharmaceuticals during the coverage gap.²⁷⁸ As is evident from Table 10, many provisions in Subtitle D are intended to reduce the cost of coverage to lower income Medicare beneficiaries and reduce subsidies for higher income beneficiaries. Other important changes include improvements in the appeal procedures associated with Part D benefits.²⁷⁹

While the ACA closes the “donut hole” in the Medicare prescription drug benefit, neither the ACA nor subsequent legislation has authorized the federal

276 Letter from Lynn H. Gibson, General Counsel of the US Government Accounting Office to the Honorable Kathleen Sebelius, Secretary of Health and Human Services regarding Medicare Advantage Quality Bonus Payment Demonstration (July 11, 2012), <http://www.gao.gov/assets/60.0/592303.pdf>.

277 ACA § 3315 as amended by HCERA § 1101(a) (codified at 42 U.S.C. § 1395w-152 (Supp. 2011)).

278 *Id.* § 3301(b) as amended by HCERA § 1101(b)(2)(A) (codified as amended at 42 U.S.C. § 1395w-114a (Supp. 2011)).

279 *Id.* §§ 3311-3312 (codified as amended at 42 U.S.C. §§ 1395w-154, 1395w-104(b)(3)(H) (Supp. 2011)).

government to negotiate prices with pharmaceutical manufacturers. This block on negotiating prices is costing the government millions of dollars.²⁸⁰ Another issue is how Congress will fully implement the plan of closing the donut hole by 2020. It seems likely that this expansion will be the target of budget cutters as such cuts would not take away benefits but just postpone new benefits.

Table 10 Subtitle D—Medicare Part D Improvements for Prescription Drug Plans and MA–PD Plans
Sec. 3301. Medicare coverage gap discount program
Sec. 3302. Improvement in determination of Medicare part D low-income benchmark premium
Sec. 3303. Voluntary de minimis policy for subsidy eligible individuals under prescription drug plans and MA–PD plans
Sec. 3304. Special rule for widows and widowers regarding eligibility for low-income assistance
Sec. 3305. Improved information for subsidy eligible individuals reassigned to prescription drug plans and MA–PD plans
Sec. 3306. Funding outreach and assistance for low-income programs
Sec. 3307. Improving formulary requirements for prescription drug plans and MA–PD plans with respect to certain categories or classes of drugs
Sec. 3308. Reducing part D premium subsidy for high-income beneficiaries
Sec. 3309. Elimination of cost sharing for certain dual eligible individuals
Sec. 3310. Reducing wasteful dispensing of outpatient prescription drugs in long-term care facilities under prescription drug plans and MA–PD plans
Sec. 3311. Improved Medicare prescription drug plan and MA–PD plan complaint system
Sec. 3312. Uniform exceptions and appeals process for prescription drug plans and MA–PD plans
Sec. 3313. Office of the Inspector General studies and reports
Sec. 3314. Including costs incurred by AIDS drug assistance programs and Indian Health Service in providing prescription drugs toward the annual out-of-pocket threshold under part D
Sec. 3315. Immediate reduction in coverage gap in 2010

E. Ensuring Medicare Sustainability (Title III, Subtitle E)

Subtitle E, Ensuring Medicare Sustainability, is one of the more controversial provisions of the ACA. The first two provisions of Subtitle E are relatively straightforward. Section 3401 adds a productivity adjustment to the market basket update for inpatient hospitals, home health providers, nursing homes,

²⁸⁰ Richard G. Frank & Joseph P. Newhouse, *Should Drug Prices Be Negotiated Under Part D Of Medicare? And If So, How?* 27 HEALTH AFF. 33, 33-35 (2008).

hospice providers, inpatient psychiatric facilities, long-term care hospitals, and inpatient rehabilitation facilities.²⁸¹ Section 3402 provides a temporary adjustment to the calculation of Part B premiums.²⁸²

Table 11 Subtitle E—Ensuring Medicare Sustainability
Sec. 3401. Revision of certain market basket updates and incorporation of productivity improvements into market basket updates that do not already incorporate such improvements
Sec. 3402. Temporary adjustment to the calculation of part B premiums
Sec. 3403. Independent Payment Advisory Board

The controversial provision is the establishment of the Independent Payment Advisory Board (IPAB), which is intended to reduce the per capita rate of growth in Medicare spending.²⁸³ The IPAB is a 15-member panel charged with recommending a set of Medicare program changes if program spending growth exceeds specified targets in 2015.²⁸⁴ Section 3403 establishes a complicated procedure by which the Chief Actuary of CMS annually determines the projected per capita growth rate of Medicare beneficiaries for that year and the next year.²⁸⁵ If the projection for the second year exceeds the target growth rate for that year, the board is required to develop and submit a proposal containing recommendations to reduce the Medicare per capita growth rate as directed by statute.²⁸⁶ The Secretary must implement such proposals, unless Congress enacts legislation pursuant to this section.

The IPAB is one of the most politically controversial reforms in the ACA.²⁸⁷ It is so politically controversial that President Obama has yet to nominate the board's members as the Senate Republicans are likely to hold up confirmation. The AMA is bitterly opposed to the Board, stating, "The AMA continues to fight

281 ACA § 3401.

282 *Id.* § 3402 (codified as amended at 42 U.S.C. § 1395r(i) (Supp. 2011)).

283 *Id.* § 3403(a) (codified as amended at 42 U.S.C. § 1395kkk(b) (Supp. 2011)).

284 *A Primer on Medicare Financing*, KAISER FAM. FOUND. (Jan 31, 2011), <http://kff.org/health-reform/issue-brief/a-primer-on-medicare-financing/>.

285 ACA § 3202(a) (codified as amended at 42 U.S.C. § 1395kkk(v)(b)(1) (Supp. 2011)).

286 *Id.* § 3202(a) (codified as amended at 42 U.S.C. § 1395kkk(v)(b)(2) (Supp. 2011)).

287 *See, e.g., Paul Ryan Said "15 Unelected, Unaccountable Bureaucrats" Could "Lead to Denied Care for Current Seniors,"* POLITIFACT.COM (Aug. 18, 2012), <http://www.politifact.com/florida/statements/2012/aug/23/paul-ryan/paul-ryan-said-15-unelected-unaccountable-bureaucr/>.

for the elimination of the Independent Payment Advisory Board, which will impose arbitrary across-the-board cuts to physicians and other providers.”²⁸⁸ Hopefully the other reforms in the ACA will make the implementation of the board unnecessary. It would be politically difficult to execute, given past experience with unsuccessful physician payment reductions dictated by the SGR and the consequent annual doc fix would indicate.

F. Health Care Quality Improvements (Title III, Subtitle F)

Subtitle F contains 11 sections establishing various research initiatives on health care quality improvement, which are displayed at Table 12.²⁸⁹ Section 3501 establishes an extensive health services research agenda for the AHRQ in the Public Health Service.²⁹⁰ The Director of AHRQ is directed to, “identify, develop, evaluate, disseminate, and provide training in innovative methodologies and strategies for quality improvement practices in the delivery of health care services that represent best practices in health care quality, safety, and value.”²⁹¹

The Director of AHRQ must also furnish technical assistance to providers in implementing models and practices identified in its research.²⁹² The remainder of Subtitle F contains a variety of initiatives, such as the exemplary initiative establishing community health teams to support patient-centered medical homes.²⁹³ Research on health care quality improvements, to be funded under this Subtitle and supervised by the Agency for Healthcare Research and Quality, is currently proceeding.

288 *Independent Patient Advisory Board*, AM. MED. ASS’N, <http://www.ama-assn.org/ama/pub/advocacy/topics/independent-payment-advisory-board.page> (last visited May 30, 2013, 8:30 PM).

289 ACA §§ 3501-3512.

290 *Id.* § 3501 (codified as amended at 42 U.S.C. § 299b-33 (Supp. 2011)).

291 *Id.*

292 *Id.* § 3501 (codified as amended at 42 U.S.C. § 299b-34 (Supp. 2011)).

293 *Id.* § 3502 (codified at 42 U.S.C. § 256a (Supp. 2011)).

Table 12
Subtitle F—Health Care Quality Improvements
Sec. 3501. Health care delivery system research; Quality improvement technical assistance
Sec. 3502. Establishing community health teams to support the patient centered medical home
Sec. 3503. Medication management services in treatment of chronic disease
Sec. 3504. Design and implementation of regionalized systems for emergency care
Sec. 3505. Trauma care centers and service availability
Sec. 3506. Program to facilitate shared decisionmaking
Sec. 3507. Presentation of prescription drug benefit and risk information
Sec. 3508. Demonstration program to integrate quality improvement and patient safety training into clinical education of health professionals
Sec. 3509. Improving women’s health
Sec. 3510. Patient navigator program
Sec. 3511. Authorization of appropriations
Sec. 3512. GAO study and report on causes of action

G. Protecting and Improving Guaranteed Medicare Benefits (Title III, Subtitle G)

Subtitle G contains two provisions that establish the principle that nothing in the ACA will compromise the guaranteed benefits in the Medicare program. Section 3601 states:

(a) **PROTECTING GUARANTEED MEDICARE BENEFITS.**—Nothing in the provisions of, or amendments made by, this Act shall result in a reduction of guaranteed benefits under title XVIII of the Social Security Act [42 U.S.C. 1395 et seq.].

(b) **ENSURING THAT MEDICARE SAVINGS BENEFIT THE MEDICARE PROGRAM AND MEDICARE BENEFICIARIES.**—Savings generated for the Medicare program under title XVIII of the Social Security Act under the provisions of, and amendments made by, this Act shall extend the solvency of the Medicare trust funds, reduce Medicare premiums and other cost-sharing for beneficiaries, and improve or expand guaranteed Medicare benefits and protect access to Medicare providers.²⁹⁴

294 *Id.* § 3601.

Section 3602 affirms that the ACA will not cut guaranteed benefits in Medicare Advantage plans, stating “Nothing in this Act shall result in the reduction or elimination of any benefits guaranteed by law to participants in Medicare Advantage plans.”²⁹⁵ The two sections in this title are simply promises to maintain benefits. The question remains whether these promises can be kept in practice when faced with deficit reduction efforts and funding cuts.

III. IMPROVING TRANSPARENCY AND PROGRAM INTEGRITY (TITLE VI)

Title VI contains measures to improve transparency and program integrity in the Medicare and Medicaid programs. These provisions are displayed in Table 13. Title VI is somewhat of a hodgepodge of provisions. Only Subtitles A, B, D and E actually pertain to the Medicare program.

Table 13 Title VI: Transparency and Program Integrity
Subtitle A—Physician Ownership and Other Transparency Subtitle B—Nursing Home Transparency and Improvement Part 1—Improving Transparency of Information Part 2—Targeting Enforcement Part 3—Improving Staff Training Subtitle C—Nationwide Program for National and State Background Checks on Direct Patient Access Employees of Long-term Care Facilities and Providers Subtitle D—Patient-Centered Outcomes Research Subtitle E—Medicare, Medicaid, and CHIP Program Integrity Provisions Subtitle F—Additional Medicaid Program Integrity Provisions Subtitle G—Additional Program Integrity Provisions Subtitle H—Elder Justice Act Subtitle I—Sense of the Senate Regarding Medical Malpractice

The transparency provisions in Subtitle A of Title IV concern physicians’ financial activities with respect to investments in health care enterprises. Subtitle B addresses transparency and fraud and abuse enforcement in nursing homes. Subtitle D establishes an agency and program to conduct patient-centered outcomes research, which is essentially research on the comparative effectiveness of medical treatment modalities and products. Subtitle E contains improvement in existing Medicare, Medicaid, and CHIP program integrity programs. Subtitle E also includes extensive provisions on new procedures screening health care providers.

²⁹⁵ *Id.* § 3602.

A. Physician Ownership and Other Transparency (Title VI, Subtitle A)

The ACA specifically addresses physician ownership of specialty hospitals as well as other physician investments in health care. These provisions are displayed in Table 14. The ACA section 6001 provides that physician-owned hospitals that do not have a provider agreement prior to February 2010 will not be able to participate in Medicare.²⁹⁶

Table 14
Subtitle A—Physician Ownership and Other Transparency
Sec. 6001. Limitation on Medicare exception to the prohibition on certain physician referrals for hospitals.
Sec. 6002. Transparency reports and reporting of physician ownership or investment interests.
Sec. 6003. Disclosure requirements for in-office ancillary services exception to the prohibition on physician self-referral for certain imaging services.
Sec. 6004. Prescription drug sample transparency.
Sec. 6005. Pharmacy benefit managers transparency requirements.

The remaining sections of Subtitle A establish a transparency reporting program for pharmaceutical and medical device manufacturers with respect to transactions with physicians and teaching hospitals as well as reporting requirements for physicians regarding various ownership and investment interests.²⁹⁷ This transparency and reporting program responds to concerns that physicians and teaching hospitals receive remuneration from industry, which create conflicts of interest for physicians and teaching hospitals in selecting items and services for patient care.²⁹⁸

Although directly related to Medicare, but relevant for all health care payers, the ACA section 6002 imposes new transparency and reporting requirements on suppliers of medical devices and other items about financial transactions with physicians, teaching hospitals and other covered recipients.²⁹⁹ Specifically, suppliers must report electronically to the Secretary of HHS the following information regarding each transaction: the name and contact information of the

²⁹⁶ *Id.* § 6001 (codified as amended at 42 U.S.C. § 1395nn (Supp. 2011)); see David Whelan, *ObamaCare's First Victim: Physician-Owned Specialty Hospitals*, FORBES (Apr. 5, 2010, 4:46 PM), <http://www.forbes.com/sites/sciencebiz/2010/04/05/obamacares-first-victim-physician-owned-specialty-hospitals/>.

²⁹⁷ ACA § 6002 (codified as amended at 42 U.S.C. § 1320a-7h (Supp. 2011)); see Robert Steinbrook & Joseph S. Ross, *Transparency Reports" on Industry Payments to Physicians and Teaching Hospitals*, 307 JAMA 1029, 1029-30 (2012).

²⁹⁸ See Troyen A. Brennan et al., *Health Industry Practices That Create Conflicts of Interest: A Policy Proposal for Academic Medical Centers*, 295 JAMA 429, 430 (2006).

²⁹⁹ ACA § 6002 (codified as amended at 42 U.S.C. § 1320a-7h (Supp. 2011)).

recipient, the date and amount of payment or transfers of value, a description of the form and nature of payment, and whether the payment was related to marketing, education, or research specific to a covered drug, device, biological, or medical supply.³⁰⁰ The ACA section 6002 also requires manufacturers and suppliers to report any investment and ownership interests of physicians in their organizations.³⁰¹ In December 2011, CMS issued a proposed rule to implement Section 6002. A final rule has not been promulgated. By September 2013, CMS must publish “transparency reports” that disclose industry payments on a public website in a search manner.³⁰²

Pursuant to section 6004, pharmaceutical and medical device manufacturers and suppliers must report any gifts to physicians, physicians groups, or teaching hospitals.³⁰³ The ACA 6004 imposes comparable reporting and transparency requirements on pharmaceutical and medical device manufacturers and suppliers regarding the provision of drug samples.³⁰⁴ Of more relevance to Medicare specifically, the ACA section 6003 imposes disclosure requirements for physicians with respect to specified medical imaging services excluded for the in-office ancillary services exception to Stark physician self-referral prohibitions.³⁰⁵ Physicians referring patients to imaging services in which they or members of their practice have investments must notify patients of this interest in writing.³⁰⁶ Also, the ACA section 6005 requires that pharmacy benefit managers (PBM), or health benefits plans that provide PMB services, which contract with health plans under Medicare or health insurance exchange must report information regarding payment reductions negotiated by the PBM.³⁰⁷

The moratorium on expanding the number of physician-owned specialty hospitals in the ACA remains controversial. From a political perspective, the ACA sides with the community hospital, which resents the rise of physician-owned hospitals in attracting lucrative procedures with healthier patients. Physician-owned specialty hospitals might be able to prosper in the future by joining accountable care organizations and finding innovations that promote efficiency and high quality.

The other transparency provisions pertaining to physicians and other health care providers and suppliers require extensive reporting of transactions,

300 *Id.*

301 *Id.*

302 Medicare, Medicaid, Children’s Health Insurance Program; Transparency Reports and Reporting of Physician Ownership or Investment Interests; 76 Fed. Reg. 78,742 (Dec. 19, 2011) (to be codified at 42 C.F.R. pts. 402 and 403).

303 ACA § 6004 (codified as amended at 42 U.S.C. § 1320a-7h (Supp. 2011)).

304 *Id.*

305 *Id.* § 6003 (codified as amended at 42 U.S.C. § 1395nn(b)(2) (Supp. 2011)).

306 *Id.* § 6004 (codified as amended at 42 U.S.C. § 1320a-7h (Supp. 2011)).

307 *Id.* § 6005 (codified as amended at 42 U.S.C. § 1395nn(b)(2) (Supp. 2011)).

contributions, and the like, which impose a great burden on physicians, other providers, and manufacturers of pharmaceuticals and medical devices. Of note, CMS has not promulgated the final rule to implement the transparency and reporting requirements on physicians, which may suggest controversy over its contents.

B. Nursing Home Reforms

Subtitle B of Title VI pertains to program integrity measures for nursing homes. Part A of Subtitle B addresses nursing home transparency and improvement. Specifically, the ACA section 6101 requires that skilled nursing facilities under Medicare and nursing facilities under Medicaid make available information on their ownership.³⁰⁸ They must also implement a compliance and ethics program to promote greater accountability.³⁰⁹ CMS will also publish information on staffing data, number of complaints, and criminal violations along with data on the Nursing Home Compare Medicare Website.³¹⁰ The Secretary of HHS is charged with making other changes to achieve greater nursing home accountability,³¹¹ including the development of a standardized complaint form for beneficiaries.³¹² Part 2 of Subtitle B contains provisions to strengthen enforcement.³¹³ Subtitle C contains measures to improve staff training on dementia and abuse prevention.³¹⁴ The Secretary must establish a nationwide program for national and state background checks of direct patient access employees of certain long-term care facilities.³¹⁵

The transparency and program integrity provisions for nursing homes seem to have been implemented with little difficulty or controversy.³¹⁶ The nursing home industry is one of the most regulated industries in the United States. However, there have been problems for years with nursing home compliance with regulatory requirements, which the provisions in the ACA are intended to address.³¹⁷

308 *Id.* § 6101 (codified as amended at 42 U.S.C. § 1320a-3 (Supp. 2011)).

309 *Id.* § 6102 (codified as amended at 42 U.S.C. § 1302a-7k (Supp. 2011)).

310 *Id.* § 6103 (codified as amended at 42 U.S.C. § 1395i-3 (Supp. 2011)).

311 *Id.* §§ 6104-6105 (codified as amended at 42 U.S.C. § 1395yy (Supp. 2011)).

312 *Id.* § 6106 (codified as amended at 42 U.S.C. § 1395yy (Supp. 2011)).

313 *Id.* §§ 6111-6114.

314 *Id.* § 6121.

315 *Id.* § 6201.

316 See Guidance on the Nursing Home Transparency Provisions of the Patient Protection and Affordable Care Act, AM. HEALTH CARE ASS'N, http://www.ahcancal.org/facility_operations/survey_certification/Pages/GuidanceNHTransparencyProvisions.aspx (last visited May 30, 2013, 7:50 PM).

317 Kaiser Commission on Medicaid and the Uninsured, Implementation of Affordable Care Act Provisions To Improve Nursing Home Transparency, Care Quality, and Abuse Prevention (Jan. 2013), <http://www.kff.org/medicare/upload/8406.pdf>.

C. Subtitle D—Patient-Centered Outcomes Research

Of several initiatives to improve the quality and control the cost of health care services in the ACA, the most important is support for comparative effectiveness research through the establishment of the Patient-Centered Outcomes Research Institute (PCORI).³¹⁸

The ACA establishes a new organization for federally funded comparative effectiveness research. The PCORI has a unique structure.³¹⁹ It is a private, nonprofit entity organized under the District of Columbia Nonprofit Corporation Act³²⁰ and governed by a public-private sector board of directors appointed by the Comptroller General.³²¹ It is independently funded through a federal trust fund, contributions from the Medicare program trust funds, and from private health plans and insurers.³²²

The specific duties of the PCORI are straightforward and described in the statute in great detail.³²³ The duties all concern developing and executing a research project agenda. Several “duties” pertain to establishing processes to ensure the quality of the research, the proper dissemination of research results, and the transparency and integrity of the research process. The statute is unusually detailed in the degree to which it specifies processes for developing

318 “Comparative clinical effectiveness research” and “research” are defined in § 6301(a) of the ACA:

The terms “comparative clinical effectiveness research” and “research” mean research evaluating and comparing health outcomes and the clinical effectiveness, risks, and benefits of 2 or more medical treatments, services, and items described in subparagraph (B).

Subparagraph (B) describes the medical products, procedures and services subject to comparative effectiveness research under the act as follows:

The medical treatments, services, and items described in this subparagraph are health care interventions, protocols for treatment, care management, and delivery, procedures, medical devices, diagnostic tools, pharmaceuticals (including drugs and biologicals), integrative health practices, and any other strategies or items being used in the treatment, management, and diagnosis of, or prevention of illness or injury in, individuals.

ACA § 6301(a).

319 See Eleanor D. Kinney, *Comparative Effectiveness Research under the Patient Protection and Affordable Care Act: Can New Bottles Accommodate Old Wine?* 37 AM. J. L. & MED. 522 (2011).

320 District of Columbia Code, § 29-401.01.

321 ACA § 6301(a).

322 *Id.* §§ 6301(d)-(e).

323 *Id.* § 6301(a).

methodologies for comparative effectiveness research and other aspects of PCORI's supervision of research.

The ACA imposed several important limits on the use of PCORI comparative effectiveness research.³²⁴ Specifically, the statute provides, "nothing in this section shall be construed . . . to permit the Institute to mandate coverage, reimbursement, or other policies for any public or private payer . . ." ³²⁵ Nor can the PCORI develop or employ a "dollars-per-quality adjusted life year" or similar measures that discount the value of a life because of disability as a threshold to establish what type of health care is cost effective or recommended.³²⁶ Further, the ACA prohibits CMS, except with complete transparency and with extensive procedural safeguards, from using such measures as a threshold to determine Medicare coverage or reimbursement or in other incentive programs.³²⁷ These limits were imposed to address concerns among patients, consumers, providers, as well as more conservative politicians that the federal government would use the results of comparative effectiveness research to ration health care based on bloodless criteria.

The PCORI and the associated comparative effectiveness research have been controversial initiatives, under the ACA.³²⁸ However, progress in implementation of the Institute has proceeded as planned, and work is underway.³²⁹ As of yet, it is too early to have a definitive contribution to the evidence, and methods of measuring success are still evolving.³³⁰

D. Medicare, Medicaid, and SCHIP Program Integrity Provisions (Subtitle E)

Subtitle E, which includes extensive provisions on new procedures for screening health care providers, requires the Secretary to establish new, stricter procedures and criteria to screen providers and suppliers who are enrolling or re-enrolling in Medicare, including criminal background checks and finger

324 *Id.* § 6301(c).

325 *Id.* § 6301(a).

326 *Id.* § 6301(c).

327 *Id.*

328 See Eleanor D. Kinney, *The Real Truth about Death Panels: Comparative Effectiveness Research and the Health Reform Legislation*, 36 OKLA. CITY L. REV. 667, 672 (2011).

329 PATIENT-CENTERED OUTCOMES RES. INST., (PCORI), <http://www.pcori.org> (last visited Apr. 10, 2013); see A. Eugene Washington & Steven H. Lipstein, *The Patient-Centered Outcomes Research Institute—Promoting Better Information, Decisions, and Health*, 365 NEW ENG. J. MED. e31 (2011).

330 Sean D. Sullivan et al., *Comparative Effectiveness Research in the United States: A Progress Report*, 16 J. MED. ECON. 295, 295-97 (2013); Danielle C Lavalley et al., *Stakeholder Engagement in Comparative Effectiveness Research: How Will We Measure Success?* 1 J. COMP. EFFECTIVENESS RES. 397, 397-400 (2012); Eleanor Kinney, *Prospects for Comparative Effectiveness Research under Federal Health Reform*, 21 ANNALS HEALTH L. 79, 82-85 (2012).

printing.³³¹ These provisions are presented in Table 15. Other matters to be screened are licensure checks, which may include such checks across states, unscheduled and unannounced site visits, database checks, and other screening as the Secretary determines appropriate.³³² They are required to disclose all affiliations with any provider or supplier that has uncollected debt, has had their payments suspended, has been excluded from participating in a federal health care program, or has had their billing privileges revoked.³³³ They are also required to establish a compliance program that contains the core elements developed by the Secretary in consultation with the OIG.³³⁴

The ACA section 6402 includes several so-called enhanced Medicare and Medicaid program integrity provisions.³³⁵ These include the integrated data repository claims and payment data from all parts of Medicare, Medicaid, SCHIP, health-related programs administered by the Departments of Veterans Affairs and Defense, the Social Security Administration, and the Indian Health Service which will allow Medicare to access information about the activities of providers in other federal programs.³³⁶ Section 6402 also imposes new penalties on providers or suppliers who make false statements in connection with seeking Medicare payment.³³⁷

331 ACA § 6401 (codified as amended at 42 U.S.C. § 1395cc(j) (Supp. 2011)); see *Medicare and Medicaid Fraud, Waste, and Abuse: Effective Implementation of Recent Laws and, Agency Actions Could Help Reduce Improper Payments: Hearing Before the S. Comm. on Federal Financial Management, Government Information, Federal Services, and International Security and S. Comm. on Homeland Security and Governmental Affairs*, 112th Cong. 7 (2011) (statement of Kathleen M. King, Dir. Health Care and Kay L. Daly, Dir. Fin. Assurance Mgmt.), available at <http://www.gao.gov/assets/130/125646.pdf>.

332 ACA § 6401 (codified as amended at 42 U.S.C. § 1395cc(j)(2) (Supp. 2011)).

333 *Id.* § 6401 (codified as amended at 42 U.S.C. § 1395cc(j)(5) (Supp. 2011)).

334 *Id.* § 6401 (codified as amended at 42 U.S.C. § 1395cc(j)(8) (Supp. 2011)).

335 *Id.* § 6402 (codified as amended at 42 U.S.C. § 1320a-7k (Supp. 2011)).

336 *Id.* § 6402 (codified as amended at 42 U.S.C. § 1320a-7k(a) (Supp. 2011)).

337 *Id.* § 6402 (codified as amended at 42 U.S.C. § 1320a-7k (Supp. 2011)).

Table 15
Subtitle E—Medicare, Medicaid, and SCHIP Program Integrity Provisions

<p>Sec. 6401. Provider screening and other enrollment requirements under Medicare, Medicaid, and CHIP</p> <p>Sec. 6402. Enhanced Medicare and Medicaid program integrity provisions</p> <p>Sec. 6403. Elimination of duplication between the Healthcare Integrity and Protection Data Bank and the National Practitioner Data Bank</p> <p>Sec. 6404. Maximum period for submission of Medicare claims reduced to not more than 12 months</p> <p>Sec. 6405. Physicians who order items or services required to be Medicare enrolled physicians or eligible professionals</p> <p>Sec. 6406. Requirement for physicians to provide documentation on referrals to programs at high risk of waste and abuse</p> <p>Sec. 6407. Face to face encounter with patient required before physicians may certify eligibility for home health services or durable medical equipment under Medicare</p> <p>Sec. 6408. Enhanced penalties</p> <p>Sec. 6409. Medicare self-referral disclosure protocol</p> <p>Sec. 6410. Adjustments to the Medicare durable medical equipment, prosthetics, orthotics, and supplies competitive acquisition program</p> <p style="padding-left: 40px;">Sec. 6411. Expansion of the Recovery Audit Contractor (RAC) program</p>

Section 6403 of the ACA eliminates duplication between the Healthcare Integrity and Protection Data Bank and the National Practitioner Data Bank, consolidating the two databanks.³³⁸ The Secretary will enhance national health care fraud and abuse data collection program for reporting adverse actions taken against health care providers, suppliers, and practitioners, and submit information on the actions to the National Practitioner Data Bank.

Subtitle E closes with various sections to improve the integrity of the Medicare program. The ACA section 6404 establishes a maximum period for submission of Medicare claims of not more than twelve months.³³⁹ Next, Section 6405 requires physicians who order items or services to be Medicare enrolled physicians or eligible professionals.³⁴⁰ Section 6406 enhances documentation requirements for physicians on referrals to items or services at high risk of waste and abuse.³⁴¹ Subsequently, Section 6407 requires a face-to-face encounter with the patient before physicians may certify eligibility for home health services or durable medical equipment.³⁴² Section 6408 enhances penalties for violations of the CMPA.³⁴³ In April 2010, CMS promulgated the final rule to implement the

338 *Id.* § 6403 (codified as amended at 42 U.S.C. § 1320a–7 (Supp. 2011)).

339 *Id.* § 6404 (codified as amended at 42 U.S.C. § 1395f(a)(1) (Supp. 2011)).

340 *Id.* § 6405 (codified as amended at 42 U.S.C. § 1395m(a)(11)(B) (Supp. 2011)).

341 *Id.* § 6406 (codified as amended at 42 U.S.C. § 1395u(h) (Supp. 2011)).

342 *Id.* § 6407(a) (codified as amended at 42 U.S.C. § 1395m(a)(11) (Supp. 2011)).

343 *Id.* § 6408 (codified as amended at 42 U.S.C. § 1320a–7a(a) (Supp. 2011)).

enrollment, ordering, referring and documentation retirements.³⁴⁴ And in February 2011, CMS promulgated the final rule to implement the enrollment screening provisions.³⁴⁵ The ACA section 6409 requires the Secretary, in cooperation with the OIG, to establish a protocol to enable health care providers of services and suppliers to disclose an actual or potential violation of section 1877 of the SSA³⁴⁶ pursuant to a self-referral disclosure protocol.³⁴⁷ Lastly, the final provisions of Subtitle E pertain to durable medical equipment (DME): expanding the competitive acquisition program for DME and addressing other issues.³⁴⁸

The ACA provisions in this subtitle are an important departure from earlier Medicare fraud and abuse authorities. These provisions focus more on fraud prevention and move away from the traditional approach of paying first and recouping payments later. The provisions and the rules thereunder focus on making sure that only legitimate providers are in the program and only legitimate claims are paid. This approach to Medicare fraud and abuse control has been long in coming.

According to the OIG,³⁴⁹ the reformed fraud and abuse programs have been quite successful in increasing government recoveries in fraud cases and protecting the Medicare program. In 2013, the OIG reported that for every dollar spent on health-care-related fraud and abuse investigations in the last three years, the government recovered \$7.90, which is the highest return on investment since the inception of the Fraud and Abuse Control Program.³⁵⁰ In February 2012, HHS reported that for 2011, federal health care fraud abuse prevention and enforcement efforts recovered nearly \$4.1 billion—the largest ever in a single year.³⁵¹

344 Changes in Provider and Supplier Enrollment, Ordering and Referring, and Documentation Requirements, and Changes in Provider Agreements, 77 Fed. Reg. 25,284 (Apr. 27, 2012) (to be codified at 42 C.F.R. pts. 424 and 431).

345 Additional Screening Requirements, Application Fees, Temporary Enrollment Moratoria, Payment Suspensions and Compliance Plans for Providers and Suppliers, 76 Fed. Reg. 5,862 (Feb. 2, 2011) (to be codified at 42 C.F.R. pt. 1007).

346 42 U.S.C. § 1395nn (Supp. 2011).

347 ACA § 6409.

348 *Id.* § 6410 (codified as amended at 42 U.S.C. § 1395w(a) (Supp. 2011)).

349 OIG, HEALTH CARE FRAUD AND ABUSE CONTROL PROGRAM REPORT: FISCAL YEAR 2010 (2011), available at <http://org.hhs.gov/publications/doc/hcfac/hcfacreport2012.pdf>.

350 *Departments of Justice and Health and Human Services Announce Record-Breaking Recoveries Resulting from Joint Efforts to Combat Health Care Fraud*, DHHS (Feb. 11, 2013), <http://www.hhs.gov/news/press/2013pres/02/20130211a.html>.

351 *Health Care Fraud Prevention and Enforcement Efforts Result in Record-Breaking Recoveries Totaling Nearly \$4.1 Billion: Largest Sum Ever Recovered in Single Year*, DHHS (Feb. 14, 2012), <http://www.hhs.gov/news/press/2012pres/02/20120214a.html>.

IV. CURBING EXPENDITURES AND MOVING TOWARD A SINGLE-PAYER SYSTEM

The ACA has made many changes in the Medicare program that will strengthen the program and enhance its sustainability. At the very least, these changes will serve as a model for state Medicaid programs and other private payers and thus will constitute a major impetus of health reform for the U.S. health care sector. These changes address the three major problems facing the Medicare program since its inception—cost and volume inflation, quality assurance, and fraud and abuse. These changes, if successfully implemented, will have a dramatic impact on the reform of the American health care sector. They may also prepare the Medicare program to be transformed into a single payer system should other coverage expansions in the ACA fail.

A. Reducing Medicare Expenditures under the ACA

The history of Medicare payment methodologies has been driven by the federal government's struggle to gain control of the cost and volume variables in the fundamental equation for all health care expenditures: Medicare Expenditures = (Cost) x (Volume). By necessity, the original architects of the Medicare program placed the levers controlling the cost of care in the hands of providers. As described in Part III above, in the 1980s and 1990s, the federal government gained control of the cost of and charges for care with IPPS for hospitals and the Medicare Physician Fee Schedule for physicians. These actions were a tremendous first step for the Medicare program, especially in an environment in which physicians and hospitals in which they practiced had tight control over the content of medical care and the definition of its quality.

However, these payment reforms for hospitals and physicians did not address the problem with the high volume of services. Nor did they address the increasingly complex and costly content of health care services or the role of provider entrepreneurialism in the provision of these services. Specifically, entrepreneurial physicians and providers have had great incentives to provide more and arguably unnecessary services even under current Medicare payment methods. CMS' efforts to control volume and expense of physician services proved difficult, if not impossible, as seen with the experience with the Medicare SGR.

As discussed above, the federal government turned to health services research to determine how to measure and assess the quality of care empirically and determine if Medicare expenditures were going for care of good value with respect to outcomes and efficiency. The focus on quality outcomes and other data-driven reforms had created a new environment of accountability for physicians, hospitals, and the entire health care sector. The definition of quality became empirically and statistically-based and was no longer the sole province of physicians. The stage was set for the quality reporting and value-based

purchasing programs of the next century. Also, it became inherently easier for the stewards of the Medicare program to identify unnecessary and unsafe care as data were increasingly available to identify these types of care.

The schematic at Table 2, *supra*, illustrates the focus of the Medicare program's regulation of payment for health care. Medicare payment regulation seeks to prevent fraud and abuse that provides unreasonable or unnecessary care as well as non-existent care. Medicare payment regulation also seeks to reduce care that is inefficient. The ultimate goal of having payment regulation linked to quality measures is to promote care that is reasonable, necessary, and efficient, as determined by established measures of high quality care. Medicare does not want to pay for any unnecessary services, even if they are not harmful to the beneficiaries.

The quality and payment initiatives in Title III of the ACA are designed to achieve these policy goals, as are the transparency and integrity initiatives of Title VI. By making the connection between payment and quality performance, Medicare endeavors to recognize redundant and excess care that is not necessarily abusive, but rather is useless. This is a very important step in Medicare's effort to control the volume of Medicare services and thereby Medicare expenditures.

The trustees of the Medicare trust funds have estimated that ACA will have a positive impact on controlling Medicare expenditures.³⁵² The Medicare Trust Fund Trustees report states:

Projected Medicare costs over 75 years are about 25 percent lower because of provisions in the . . . ACA Most of the ACA-related cost saving is attributable to a reduction in the annual payment updates for most Medicare services (other than physicians' services and drugs) by total economy multifactor productivity growth, which is projected to average 1.1 percent per year In addition, an almost 30-percent reduction in Medicare payment rates for physician services is assumed to be implemented in 2012, notwithstanding experience to the contrary.³⁵³

352 *Trustees Announce Solvency of Medicare Trust Fund Extended by 12 Years to 2029*, DHHS (Aug. 5, 2010), <http://www.hhs.gov/news/press/2010pres/08/20100805d.html>.

353 *Status of the Social Security and Medicare Programs, A Summary of the 2011 Annual Reports*, U.S. SOC. SEC. ADMIN., <http://www.ssa.gov/oact/TRSUM/tr11summary.pdf> (last accessed Jun. 4, 2013, 11:11 PM).

There are other reports of slowing growth in Medicare and other health care expenditures.³⁵⁴ Analysts at CMS published an article in leading health policy journal *Health Affairs* describing very encouraging trends in Medicare expenditures and attributing them to the economic conditions since 2008.³⁵⁵ Specifically, CMS reported that Medicare spending in 2020 is now estimated to be \$150 billion lower than the \$1.07 trillion projected by CMS if reforms had not been enacted.³⁵⁶

B. Curbing Provider and Supplier Entrepreneurialism

The reforms in Titles III and IV are also intended to curb the entrepreneurial impulses of physicians and other providers and suppliers. These entrepreneurial impulses serve to increase the volume of services at great cost to the Medicare program. Medicare program payments are comprised almost exclusively from public funds generated from regressive wage taxes for Part A of the Medicare program, general revenues and beneficiary premiums under Parts B, and D.

Capitalism and free markets are the prevailing economic system in the United States. Under this system, entrepreneurialism among economic actors is generally a good thing as it generates more economic activity. Even if sellers sell items and services to buyers who do not need them is not a problem in a capitalist system. These purchasing decisions are private matters that have no bearing on public policy.

However, such entrepreneurial conduct is not appropriate when supplying items and services to public programs. Nor is appropriate in a situation with market failure where public subsidies are necessary to get needed goods and services to all. Currently, public spending on health constitutes about 45 percent of health care expenditures.³⁵⁷ Policy makers and economists have long observed that the markets for health care services and health insurance have been in failure for many years due to the fact they rely on massive public subsidies to meet the needs of all consumers.³⁵⁸

354 John Holahan & Stacey McMorrow, *Medicare and Medicaid Spending Trends and the Deficit Debate*, 367 *NEW ENG. J. MED.* 393 (2012); Chapin White & Paul B. Ginsburg, *Slower Growth in Medicare Spending—Is This the New Normal?* 366 *NEW ENG. J. MED.* 1073 (2012); Karen Davis, *The Commonwealth Fund Blog: What's Working to Control Costs* (Jun. 12, 2012), <http://www.commonwealthfund.org/Blog/2012/Jun/Whats-Working-Control-Costs.aspx>.

355 Anne B. Martin et al., *Growth in US Health Spending Remained Slow in 2010; Health Share of Gross Domestic Product Was Unchanged from 2009*, 31 *HEALTH AFF.* 208 (2012).

356 *Id.*

357 Nellie Bristol, *'Big Picture' Financing Study: Public Spending on Health Care Rises to 45 Percent*, *COMMONWEALTH FUND, WASH. HEALTH POL'Y WEEK IN REV.* (Jun. 1, 2012), <http://www.commonwealthfund.org/Newsletters/Washington-Health-Policy-in-Review/2012/Jun/June-4-2012/Public-Spending-on-Health-Care-Rises-to-45-Percent.aspx>.

358 Kenneth J. Arrow, *Uncertainty and the Welfare Economics of Medical Care*, 53 *AM. ECON. REV.* 941 (1963); Martin S. Feldstein, *Hospital Cost Inflation: A Study of Nonprofit Price*

Too often health care institutional providers, physicians and insurers, who operate MA plans, and manufacturers and suppliers of medical devices and other items, operate as capitalistic entrepreneurs, seeking to maximize revenues and profits.³⁵⁹ Such behavior is laudable in a conventional free market, but not in a failed market. Excess demand that does not represent the need for reasonable or necessary items or services is not desirable even if it generates more economic activity. Such demand and meeting that demand translate into unnecessary government expenditures at the taxpayers' expense.

The Medicare fraud and abuse prohibitions in Title VI of the ACA are first and foremost about preventing outright fraud in obtaining money from for the Medicare program. Of note, in February 2012, HHS reported that for 2011, federal health care fraud abuse prevention and enforcement efforts recovered nearly \$4.1 billion—the largest ever in a single year.³⁶⁰

But the prohibitions serve a larger mission of preventing inappropriate profiteering from the Medicare program through program abuse. Over-prescription of items and services that are not necessary or even marginally necessary for the diagnosis and treatment of illness or injury are abuse. However, this principle is contrary to the theory of capitalistic markets in which the desired amount of items and services that an individual may need or buy depends on individual preferences and actions and there is no normative assessment of the necessity of the items or services. Indeed, in a capitalistic market, providers and suppliers would be rewarded for “creating demand” among consumers for their items and services. Increased sales of these items and services would be applauded, from a public benefit prospective, as a contribution to increased economic activity.

Nevertheless, there is room for entrepreneurialism in the health care sector and the Medicare program. Entrepreneurs who imagine more efficient and effective delivery of health care services for Medicare beneficiaries are welcome and, indeed, invited. The experience to date with the shared savings program and accountable care organizations suggests that providers have engaged in true innovation and advancement with entrepreneurial initiative.

Dynamics, 61 AM. ECON. REV. 853 (1971); Milton I. Roemer, *Market Failure and Health Care Policy*, 3 J. PUB. HEALTH POL'Y 419 (1982).

³⁵⁹ See Eleanor D. Kinney, Kinney, *For-Profit Enterprise in Health Care: Can It Contribute to Health Reform?*, 36 AM. J. L. & MED. 405, 420 (2010).

³⁶⁰ *Health Care Fraud Prevention and Enforcement Efforts Result in Record-Breaking Recoveries Totaling Nearly \$4.1 Billion: Largest Sum Ever Recovered in Single Year*, DHHS (Feb. 14, 2012), <http://www.hhs.gov/news/press/2012pres/02/20120214a.html>.

C. Positioning Medicare to Become a Single Payer System

The final and probably unintentional potential benefit of the ACA's Medicare reforms is to facilitate a strong Medicare program that can serve as a single payer system in the event other ACA coverage expansions fail. Of note, Medicare as the basis of a single payer system is hardly a new idea.³⁶¹ The Medicare program, with successfully implemented ACA reforms, could easily be transformed into a single payer system if private health insurance were to become inaccessible or unaffordable and/or state Medicaid programs for the poor were to not expand.

Efforts to implement Title I of the ACA which authorizes the creation of state health insurance exchanges for private health insurance are underway.³⁶² The IRS issues a proposed rule in January 2013 to implement the mandate to purchase insurance.³⁶³ However, smooth implementation in all states is by no means certain.³⁶⁴ Some evidence suggests that private insurance companies are leaving the health insurance market already.³⁶⁵ Evidence also suggests that health insurance exchanges may not be large enough to keep premiums low and may in

361 See *Single-Payer Health Care, Improved Medicare for All*, <http://www.medicareforall.org/pages/Explanation> (last visited Jun. 4, 2013); see also Paul Krugman, *Why Americans Hate Single-Payer Insurance*, N.Y. TIMES (Jul. 28, 2009, 11:45 AM), <http://krugman.blogs.nytimes.com/2009/07/28/why-americans-hate-single-payer-insurance/>; David Himmelstein & Steffie Woolhandler, *There is a Better Way*, N.Y. TIMES (May 28, 2013, 12:42 PM), <http://www.medicareforall.org/pages/Explanation>.

362 Health Insurance Market Rules, 78 Fed. Reg. 13,406 (Feb. 27, 2013) (45 CFR Parts 144, 147, 150, 154 and 156); Patient Protection and Affordable Care Act; Establishment of Exchanges and Qualified Health Plans; Exchange Standards for Employers, 77 Fed. Reg. 18,311 (Mar. 27, 2012) (45 C.F.R. pts. 155, 156, and 157).

363 Shared Responsibility Payment for Not Maintaining Minimum Essential Coverage, Notice of Proposed Rulemaking and Notice of Public Hearing, 78 Fed. Reg. 7314 (Feb. 1, 2013) (26 C.F.R. pt. 1); see Michelle M. Mello & I. Glenn Cohen, *The Taxing Power and the Public's Health*, 367 NEW ENG. J. MED. 1777, 1777-79 (2012).

364 See *State Health Exchange Profiles*, KAISER FAM. FOUND. <http://healthreform.kff.org/State-Exchange-Profiles-Page.aspx> (last accessed Jun. 4, 2013, 10:44 PM); see *Establishing Health Insurance Exchanges: An Overview of State Efforts* (May. 2, 2013), <http://www.kff.org/healthreform/upload/8213-2.pdf>; see Katie Keith et al., *Implementing the Affordable Care Act: State Action on the 2014 Market Reforms* (The Commonwealth Fund, Feb. 2013), <http://www.commonwealthfund.org/Publications/Fund-Reports/2013/Jan/State-Action-2014-Market-Reforms.aspx>; see also Deloitte LPP, Issue Brief: The Impact of Health Reform on the Individual Insurance Market: *A Strategic Assessment* (2011), http://www.deloitte.com/assets/Dcom-UnitedStates/Local%20Assets/Documents/Health%20Reform%20Issues%20Briefs/us_chs_HealthReformAndTheIndividualInsuranceMarket_IssueBrief_101011.pdf; see also Len M. Nichols, *Implementing Insurance Market Reforms Under The Federal Health Reform Law*, 29 HEALTH AFF. 1152 (2010); see generally Timothy Stoltzfus Jost, *Health Insurance Exchanges: Legal Issues*, 37 J. L., MED. & ETHICS 51 (2009).

365 The Robert Wood Johnson Found: Issue Brief: Recognizing Destabilization in the Individual Health Insurance Market, (Jul. 2010), <http://www.maine.gov/legis/opla/RWJbrief-medlossratio.pdf>.

fact lead to increases in premiums and higher payments to providers as competition among insurers may not work as anticipated.³⁶⁶ There are also credible reports that premiums for private commercial insurance will rise to unacceptable levels. According to the Society of Actuaries:

[I]nsurers will have to pay out an average of 32 percent more for claims on individual health policies under the Act, a cost likely to be passed on to consumers. By 2017, the estimated increase would be 62 percent for California, about 80 percent in Ohio and Wisconsin, more than 20 percent for Florida and 67 percent for Maryland. The report also predicts the law will reduce the number of Americans without health insurance from 16.6 percent to as low as 6.6 percent after three years.³⁶⁷

If the private insurers are unable to provide affordable health insurance coverage through these exchanges, then some kind of public program will be necessary to achieve coverage expansions. Also, the expansion of Medicaid, the other major coverage expansion strategy in the ACA, is in doubt. The Supreme Court of the United States ruled, in *National Federation of Independent Business v. Sebelius*,³⁶⁸ that the federal government cannot eliminate funding for a state's Medicaid program if the state elects not to adopt the ACA Medicaid expansions. This decision has created uncertainty in whether states will actually proceed with the Medicaid expansion.³⁶⁹ There is already considerable evidence that many states may not proceed with the expansion, at least not in the near future.³⁷⁰ There is even discussion of states purchasing private insurance for Medicaid recipients.³⁷¹ If states are not required to proceed with federally mandated

366 Dana P. Goldman et al., *Health Insurance Exchanges May Be Too Small to Succeed*, N.Y. TIMES (Nov. 23, 2012, 6:00 AM).

367 *Society of Actuaries Reaches the Same Conclusion as Health Partners America: Rising Costs for Individual Insurance Coverage Plans Under Obama Health Care Law* (Mar. 29, 2013), <http://insurancenewsnet.com/article.aspx?id=376941#UVsBZZNg9KJ>.

368 No. 11–393 (June 28, 2012); see Timothy S. Jost & Sara Rosenbaum, *The Supreme Court and the Future of Medicaid*, 367 NEW ENG. J. MED. 983 (2012).

369 *The Cost and Coverage Implications of the ACA Medicaid Expansion: National and State-by-State Analysis*, KAISER FAM. FOUND. (Nov. 1, 2012), <http://kff.org/health-reform/report/the-cost-and-coverage-implications-of-the/>.

370 Benjamin D. Sommers & Arnold M. Epstein, *U.S. Governors and the Medicaid Expansion—No Quick Resolution in Sight* 368 NEW ENG. J. MED. 496, 497–99 (2013); see also Benjamin D. Sommers and Arnold M. Epstein, *Medicaid Expansion—The Soft Underbelly of Health Care Reform?* 363 NEW ENG. J. MED. 2085 (2010).

371 Josh Barro, *When the Affordable Care Act Becomes Unaffordable*, BLOOMBERG NEWS (Mar. 26, 2013, 10:22 AM), <http://www.bloomberg.com/news/2013-03-26/when-the-affordable-care-act-becomes-unaffordable.html>; Editorial Board, *Using Medicaid Dollars for Private*

expansions under the ACA, there may be greater pressure for the expansion of the Medicare program to cover persons otherwise not covered under the ACA Medicaid expansions.

To ensure the sustainability of the Medicare program as a single payer system, the funding streams that have supported state Medicaid programs and private health insurance should likewise be tapped to fund the Medicare program as a single payer system. Thus, the design of the Medicare program would be a little more complex than simply enrolling people into the program and abolishing the Medicaid program. As indicated in Part II of this article, Medicare is currently financed by a federal wage tax and premiums paid by beneficiaries. State Medicaid programs pay the premiums for their recipients who are otherwise eligible for Medicare. Private employers contribute significantly toward their employees' health insurance. States and private employers should continue to support the Medicare program through payment of premiums for people for whom they are responsible.

The easiest way to transform Medicare into a single payer system is through incremental steps. The first incremental step would be to allow individuals ages 55 to 64 to "buy into" Medicare at a subsidized rate. According to the Kaiser Family Foundation, one in eight people in this age group are uninsured and tend to be in poorer health.³⁷² This approach was originally part of the ACA, but dropped in order to ensure the support of Senator Joe Lieberman from Connecticut for passage of the ACA.³⁷³ The initiatives in Title III to reorganize medical practice to provide better care for chronically ill patients is important to implement, in order to accommodate these beneficiaries in a cost effective manner.

The next incremental step could be to expand the group of Medicaid recipients who could enroll in Medicare. The Medicare program currently permits states to enroll Medicare eligible Medicaid recipients in Medicare.³⁷⁴ So-called "dual eligibles" constitute the poorest and sickest group of Medicaid beneficiaries.³⁷⁵ Historically, dual eligibles have not been served particularly well by either the Medicare or the Medicaid programs as there has been poor

Insurance, N.Y. TIMES (Mar. 31, 2013), http://www.nytimes.com/2013/04/01/opinion/using-medicaid-dollars-for-private-insurance.html?_r=0.

³⁷² Gretchen Jacobson et al., *Health Insurance Coverage for Older Adults: Implications of a Medicare Buy-In*, KAISER FAM. FOUND. (Nov. 30, 2009) <http://kaiserfamilyfoundation.files.wordpress.com/2013/01/7904-02.pdf>.

³⁷³ Jacob Goldstein, *Why Joe Lieberman Is Opposed to Expanding Medicare*, WALL ST. J. HEALTH BLOG (Dec. 14, 2009, 9:07 AM), <http://blogs.wsj.com/health/2009/12/14/why-joe-lieberman-is-opposed-to-expanding-medicare/>.

³⁷⁴ 42 U.S.C. § 1396 (2006).

³⁷⁵ Katherine Young et al., *Kaiser Commission on Medicaid and the Uninsured: Medicaid's Role for Dual Eligible Beneficiaries*, KAISER FAM. FOUND. (Apr. 1, 2012) <http://kaiserfamilyfoundation.files.wordpress.com/2013/01/7846-03.pdf>.

coordination of the two programs in serving dual eligibles.³⁷⁶ The ACA endeavors to address this problem with the creation of a new office within CMS, the Federal Coordinated Health Care Office, to bring together relevant staff of the Medicare and Medicaid programs at CMS to more effectively integrate benefits under the two programs and improve the coordination between the federal government and states to ensure that dual eligibles get the benefits of both programs.³⁷⁷ The ACA contains other provisions that would facilitate the participation of dual eligibles in the reforms to improve quality and efficiency of care in Title III.³⁷⁸

This effort to integrate and coordinate benefits under the two programs for dual eligibles is an essential step in moving Medicare to a single payer system. To promote sustainability of the Medicare single payer system, it would be desirable to have states participate financially and administratively. States would pay the premiums for Medicaid beneficiaries for Parts B and D as they do now for dual eligibles. They could also operate continue to operate their health plans for Medicaid recipients as they do now. States already have extensive administrative assets devoted to the Medicaid program that would be greatly benefit the administration of a Medicare single payer system at the state level.

The final step toward making the Medicare program into a single payer system would be to establish Medicare as a public option plan that would be available to any person through state health insurance exchanges. A public option was originally in the health reform bill that passed the House.³⁷⁹ It was dropped in the bill finally passed in the Senate, primarily on ideological grounds.³⁸⁰ The original public option in the health care reform legislation created a public plan that would meet the conditions for health insurance plan requirements established for health insurance exchange but not through the Medicare statute.

It would be more efficient to establish a public option directly through the Medicare program with the enactment of Part E of the Medicare program. Part E could be available for any person who elected to join the plan and would operate the same way as Medicare works now. Beneficiaries could elect traditional fee-

376 Judy Kasper et al., *Chronic Disease and Co-Morbidity Among Dual Eligibles: Implications for Patterns of Medicaid and Medicare Service Use and Spending*, KAISER FAM. FOUND. (Jul. 10, 2010), <http://www.kff.org/medicaid/upload/8081.pdf>.

377 ACA § 2602.

378 *Affordable Care Act Provisions Relating to the Care of Dually Eligible Medicare and Medicaid Beneficiaries* (May 30, 2011), KAISER FAM. FOUND. <http://www.kff.org/healthreform/upload/8192.pdf>.

379 ACA §§ 321-331.

380 Helen A. Halpin & Peter Harbage, *The Origins And Demise of The Public Option*, 29 HEALTH AFF. 1117, 1119 (2010); see James Brasfield, *The Politics of Ideas: Where Did the Public Option Come from and Where Is It Going?*, 36 J. HEALTH POL., POL'Y & L. 455 (2011); see also Theodore Marmor & Jonathan Oberlander, *The Patchwork: Health Reform, American Style*, 72 SOC. SCI. & MED. 125 (2011).

for-service Medicare or join Medicare Advantage plan. Beneficiaries could join Part D prescription drug plans as needed. Also, establishing Medicare Part E as a public option would facilitate contributions from employers. The ACA already has provisions requiring the contributions from larger employers.³⁸¹

A provision allowing Medicaid beneficiaries to enroll in Medicare and be treated as dual eligibles could also be added to Part E, to assist states with the anticipated high cost of Medicaid expansions by transferring part of the responsibility for paying for care from state Medicaid programs to Medicare. Such an approach might help the coverage expansions that were anticipated in ACA Title II, and thwarted by the Supreme Court's decision in *National Federation of Independent Business v. Sebelius*, to finally become a reality.

CONCLUSION

When considering issues such as which provisions of the ACA are likely to be successful, needed, or improved, thinking incrementally is appropriate. Moving forward, policy reformers should focus on what changes might be made to the Medicare program in the next budget cycle or legislative year, as most Medicare initiatives are long-term projects that are tweaked annually in the "muddling through" policy-making process. Also, CMS generally conducts evaluations of larger policy initiatives to determine their value empirically.

In sum, a strong Medicare program, made stronger with the ACA reforms to improve quality and efficiency (through Title III) as well as promote transparency and program integrity (through Title VI), stands ready to be the health insurer of all Americans. At the very least, the ACA Medicare reforms will hopefully make the current program more efficient and fiscally sustainable. Certainly improving health care through reforming Medicare is a better approach to assuring health security for the elderly and disabled than approaches that disengage the government as a payer from the health care sector and let people fare alone as health care costs continue to escalate and access to care is compromised.

381 ACA §§ 1511-1515.