Medicare Coverage Policy and Decision Making, Preventive Services, and Comparative Effectiveness Research Before and After the Affordable Care Act

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I. Introduction

The Medicare program is the largest health insurance program in the United States and handles more than one billion claims each year. In 2010, the Medicare program served 47.1 million elderly and disabled Americans enrolled in the program, and cost an estimated $451 billion, which was approximately 12 percent of the overall 2010 federal budget of $3.7 trillion. Medicare spending is projected to grow more than 6 percent each year from 2009 to 2019. In 2009, the Medicare program expenses

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2 CRS. FOR MEDICARE & MEDICAID SERVS., U.S. DEPT. OF HEALTH & HUMAN SERVS., 2010 EDITION DATA COMPRENDIUM, TABLE IV.1 (2010), available at https://www.cms.gov/DataCompendium/14_2010_Data_Compendium.asp. The 47.1 million elderly and disabled enrollees in the program included 39.1 million beneficiaries who were 65 years of age and older and 8 million who were disabled. Id.
4 See CRS. FOR MEDICARE & MEDICAID SERVS., supra note 3. The projected estimate for Medicare growth is 6.1 percent per year. Id.
accounted for approximately 20 percent of all health care expenses nationally. The Congressional Budget Office estimated that Medicare spending would constitute 3.6 percent of the gross domestic product in 2010.

For decades, the cost of the Medicare program has remained a major policy concern warranting attention from federal policymakers. The swelling cost of the Medicare program has led some policymakers and analysts to propose explicit rationing of health care and the use of cost effectiveness in Medicare coverage decision making as a means of controlling cost. In 2009, as the nation’s attention turned to the federal legislative effort to reform health care and health insurance, many Americans worried that the reform legislation would adopt such measures, especially in the Medicare program. Since the two days in March 2010 when President Barack Obama signed into law the Patient Protection and Affordable Care Act (“PPACA”) and the Health Care and Education Reconciliation Act of 2010 (“HCERA”), Medicare beneficiaries have

5 Id.
7 See JOHN E. MCDONOUGH, INSIDE NATIONAL HEALTH REFORM 25 (2011); Jacqueline Fox, Medicare Should, but Cannot, Consider Cost: Legal Impediments to a Sound Policy, 53 BUFF. L. REV. 577, 596, 603-09 (2005) (stating that “[w]hen Medicare began it quickly became clear that there appeared to be no limit on what you could spend on medical care” and discussing federal efforts to rein in escalating costs that extend back nearly to the inception of the program). Health care costs became a prominent concern for federal and state governments with the creation of Medicare and Medicaid in 1965. MCDONOUGH, supra, at 25.

These two new programs accelerated medical inflation on the government’s dime. Ever since, federal and state governments have constantly sought ways to reduce medical-related spending or at least to reduce its relentless rate of growth. From the late 1960s into the 1980s, the most common tools were regulatory; beginning in the late 1970s and then more actively in the 1980s and 1990s, federal and state governments sought to use market forces and competition to tame spending.

continued to question what impact the Affordable Care Act ("ACA"), the final amended version of the comprehensive health care and health insurance reform law that includes the PPACA and the HCERA, would have on their benefits and coverage under the Medicare program.

This Article offers five overarching observations regarding the reforms and initiatives in the ACA that relate to the package of Medicare benefits and coverage. First, in the ACA, Congress did not undertake to address the cost of the Medicare program directly. Instead, Congress put forward initiatives that will affect the cost of the program in a more indirect way over time.

Second, the ACA made no changes to the established Medicare coverage policy and decision-making processes or the basic Medicare coverage standard, which has largely remained unchanged since the Medicare program was created. This standard is that the Medicare program will cover and pay for an item or service (1) when the item or service falls within or is classified in a specific statutory benefit category, (2) when no statutory exclusion from coverage applies, and (3) when the item or service is reasonable and necessary to diagnose or treat illness or injury or to improve the function of a malformed body member.

Third, the ACA made important changes to the Medicare benefit and coverage package in the area of preventive care services and care/case management.

10 This Article will reference the Affordable Care Act as the ACA when speaking of these two pieces of reform legislation collectively.

11 See Darrel J. Grinstead, *Evolution of Medicare’s Coverage Policy-Making Process*, in *GUIDE TO MEDICARE COVERAGE DECISION-MAKING AND APPEALS* 4 (Eleanor D. Kinney ed., 2002) ("[The] limitation to provide payment only for those services that are ‘reasonable and necessary’ has formed the basis for the development of most of Medicare’s coverage rules."). Medicare coverage involves the decision by the Medicare program administrators and contractors and the processes they follow in deciding whether the Medicare program will cover and pay for items and services provided to Medicare beneficiaries. *See infra* Sections II.A.4 & III. Medicare coverage is distinct from Medicare reimbursement, by which is meant the amount that the Medicare program will pay for covered items and services and the methods by which the program goes about determining the amount. For additional discussion of the Medicare coverage standard, *see infra* Section II.B.

12 See Ron Z. Goetzel, *Do Prevention or Treatment Services Save Money? The Wrong Debate*, 28 HEALTH AFF. 37, 38-40 (2009). The term “prevention” is an elastic term that can include efforts to prevent the occurrence of high-cost illnesses among healthy individuals and efforts to manage high-cost illnesses among sick beneficiaries. *Id.* at 38. At least three varieties of prevention are identifiable: (1) primary prevention, which are health promotion measures designed to keep
of Medicare coverage in the area of preventive care and care management manifests a recognition that the traditional Medicare benefits and coverage package along with its “reasonable and necessary” standard, which focuses coverage decision-making upon the medical necessity of items or services to diagnose or treat illness or injury, does not permit the Medicare program to cover the range of health-related services that are warranted based upon the needs of Medicare beneficiaries, sound medical practices, and information developed by medical and other sciences.

Fourth, the ACA includes a number of initiatives that have implications for the future of the Medicare benefit and coverage package and coverage policy. These initiatives undertake to develop more and better information regarding the clinical effectiveness of items and services as well as the outcomes of medical interventions by harnessing the results of effectiveness and outcomes research, including comparative effectiveness research, which studies the effectiveness of different options to treat a medical condition for a defined set of patients. These initiatives also aim to disseminate such information widely to permit maximal use by health care providers and to empower patients to improve their own health. These initiatives, especially when considered together with the ACA’s expansion of the Medicare benefits and coverage package to include preventive care and case management services, reflect a forward-looking approach to covering and reimbursing preventive care and other health care items and services based upon patient-outcomes-oriented evidence showing clinical effectiveness. This same forward-looking approach is also reflected in the Medicare program’s coverage with evidence development (“CED”) activities in which the Medicare program grants coverage conditioned on data collection that will help to

healthy individuals from becoming unhealthy; (2) secondary prevention, which are measures designed to prevent conditions from developing among individuals with preconditions for expensive illnesses; and (3) tertiary prevention, which are measures designed to manage the illnesses of sick individuals effectively so as to reduce cost and promote health. See id. at 38.


As applied in the health care sector, an analysis of comparative effectiveness is simply a rigorous evaluation of the impact of different options that are available for treating a given medical condition for a particular set of patients. Such a study may compare similar treatments, such as competing drugs, or it may analyze very different approaches, such as surgery and drug therapy. The analysis may focus only on the relative medical benefits and risks of each option, or it may also weigh both the costs and the benefits of those options.

Id.
develop evidence showing the effectiveness of interventions, treatments, and medications. These initiatives also lay the groundwork for more expansion of benefits and coverage and additional refinement of coverage decisions as more and better outcomes-related information develops and as evidence of intervention effectiveness grows.

Fifth, the ACA initiatives that expanded the Medicare benefits and coverage package to include additional preventive care services and that increased funding and programs directed at developing and disseminating information regarding the effectiveness of medical treatments and services built upon prior legislative initiatives approved by both Democrats and Republicans. The ACA’s expansion of coverage to additional preventive care services continues a legislative trend to extend Medicare benefits beyond the traditional coverage and reimbursement model in which providers are reimbursed for providing medically necessary diagnostic and treatment services to patients during episodes of illness. Over the last decade and a half, both Democrats and Republicans in Congress and the White House have adopted such legislative initiatives and extended the coverage of preventive care services. Likewise, over the last decade, both Democrats and Republicans in Congress and the White House have approved legislative initiatives aimed at developing evidence regarding the effectiveness of medical interventions and preventive services and disseminating such information. Thus, these two sets of initiatives in the ACA may properly be counted among a number of other initiatives adopted over the last decade and a half that have extended benefits and coverage with the goal of preventing illness and disease and that have sought to develop better evidence regarding health interventions. Additionally, by leaving the established Medicare coverage standard and the coverage decision-making processes unchanged, the ACA tacitly accepted the reforms to the Medicare decision-making processes (including administrative refinements to the national coverage determinations (“NCDs”) processes) made during the decade preceding the enactment of the ACA, which were the product of both Democrat and Republican efforts. Consequently, whatever one thinks about the wisdom and constitutionality of other reform initiatives in the ACA, the silence of Congress regarding the Medicare coverage decision-making processes and its initiatives related to preventive care and care management services and research regarding the effectiveness of health interventions do not depart from, but rather build upon prior legislative initiatives that have had broad Democrat and Republican support.

This Article examines the ACA initiatives that expanded Medicare benefits and coverage and have implications for Medicare coverage policy and decision-making. The ACA initiatives addressed in this Article have undertaken to improve the quality of care, increase access to care, and reduce the costs of the Medicare program without displacing
or fundamentally altering the traditional Medicare coverage standard, adopting cost-effectiveness analysis or cost-conscious considerations, or using “the blunt instruments of supply controls or rationing.”

The approach taken by Congress in the ACA of covering additional prevention and case management services, developing outcomes-related information, and disseminating the best medical and scientific evidence of clinical effectiveness continues to offer some hope for improving the quality and efficiency of care for Medicare beneficiaries, providing better data to inform Medicare coverage decisions, and helping to control the cost of the Medicare program without undertaking the more controversial policy of considering cost and cost effectiveness in the coverage-determination processes. This Article contends that this approach will find wider support among lawmakers, constituents, and interested parties than using supply controls, rationing, and cost effectiveness in Medicare coverage policy and decision-making. Consequently, this Article recommends that Congress and the agency that

Technology has been identified as a key culprit in the relentless escalation in health care spending. There have been a variety of proposals over the past forty years to manage technology diffusion, including controlling the supply of technology or limiting use through rationing. More recently, the debate about cost control has been linked to enhancing value, not by controlling supply but by changing the behavior of providers and consumers through the use of evidence.

See also id. 15 See infra Section VI. In addition to being controversial and politically untenable, statutory authority for CMS to use cost effectiveness in the coverage determination process appears to be lacking. See Fox, supra note 7; see also Jacqueline Fox, The Hidden Role of Cost: Medicare Decisions, Transparency and Public Trust, 79 U. CIN. L. REV. 1, 14 (2010).

Given the structure of the Medicare Act, where coverage decisions are still limited to determining what is “reasonable and necessary,” CMS has not had the power to follow the private sector in changing its decision-making process to take cost into account. Absent specific legislative authority to make such resource allocation decisions, the legality of CMS doing so is questionable.

administrators Medicare persist in refusing to make cost-effectiveness considerations part of the policy and processes, continue to premise coverage determinations on evidence of medical effectiveness, and explore further expansion of the Medicare benefits and coverage package as additional information regarding the effectiveness of preventive services becomes available.

This Article proceeds as follows. First, it outlines in general terms the various aspects of the Medicare program and its administration, and it places the Medicare coverage standard in its historical context. Second, it examines legislative and administrative initiatives to reform and refine Medicare coverage policy and decision-making processes. Third, it discusses the expansion of the Medicare benefits and coverage package to include preventive services prior to the enactment of and in the ACA. Fourth, it studies legislative initiatives enacted both prior to and in the ACA that seek to develop and enhance the availability of evidence showing clinical effectiveness, and it considers the implications of these efforts for Medicare coverage policy and decision-making. Fifth, it analyzes the approach taken in the ACA and recommends maintaining the focus of Medicare coverage policy and decisions on medical effectiveness rather than cost effectiveness or other cost-conscious considerations.

II. The Medicare Program and the Coverage Standard

A. The Medicare Program

Congress established the Medicare and Medicaid programs in the Social Security

A literal reading of the Medicare Act reveals that there is nothing that expressly bars Medicare from performing a cost-effectiveness analysis, only that Medicare is barred from paying for services that are not “reasonable and necessary.” The current interpretation of the Medicare Act, however, is that Medicare is barred from making decisions about coverage based on cost, because it is required by law to provide whatever medical services are deemed “reasonable and necessary,” regardless of the cost.

Id.

16 See infra Section II.A.
17 See infra Section II.B.
18 See infra Section III.
19 See infra Section IV.
20 See infra Section V.
21 See infra Section VI.
Amendments of 1965. To appreciate the various Medicare coverage-related initiatives in the ACA that are discussed in this Article, it is helpful to begin by considering certain aspects of the Medicare program including program administration, eligibility, benefits, coverage, reimbursement, and funding.

1. Medicare Program Administration

The Centers for Medicare & Medicaid Services (“CMS”), which was known as the Health Care Financing Administration (“HCFA”) until 2001, is an operational division within the United States Department of Health and Human Services (“HHS”). CMS is responsible for administering the Medicare program, as well as the federal portions of the Medicaid program and the Children’s Health Insurance Program (“CHIP”). CMS includes six centers and various offices that oversee the Medicare and


Medicaid programs and CHIP.  

2. **Medicare Eligibility**  

Congress designed the Medicare program as a federally-funded health insurance program to protect several classes of beneficiaries. Eligibility for Medicare benefits is typically linked to eligibility for Social Security benefits and does not depend on financial need. The first class of beneficiaries includes individuals who have paid Medicare payroll taxes and are 65 years of age and older and who are eligible for Social Security or railroad retirement benefits, or who have held Medicare-qualified government employment. These individuals are automatically eligible for Medicare when they reach the age of 65. Medicare benefits are also available to spouses and former spouses who qualify for the Social Security program as dependents when they reach the age of 65. The second class of beneficiaries includes individuals under the age of 65 years with certain disabilities. Those individuals who are eligible for Social Security or railroad retirement benefits on the basis of disability may receive benefits through the Medicare program after they have been eligible for disability benefits for at least twenty-four months. The third class includes individuals under the age of 65 with end-stage renal (kidney) disease. Individuals who are eligible for benefits under the Social Security program and have end-stage renal disease may receive benefits from the Medicare program after they have waited three months.

3. **Medicare Benefits**

The Medicare program currently has four parts that provide the structure for scattered sections of 42 U.S.C.).

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26 See Overview CMS Leadership, Ctrs. for Medicaid & Medicare Servs., http://www.cms.gov/CMSLeadership/ (last updated May 31, 2011). See infra Section V.B.1, for additional discussion of centers and offices within CMS.  
28 42 U.S.C. § 426(a)-(b).  
29 Id. § 426(a)(1); see also id. § 1395c.  
30 Id. § 426(a).  
31 Id.  
32 Social Security Act § 226, 42 U.S.C. § 426(b) (2006); see also id. § 1395c.  
33 Id. § 426(b). Individuals who have been medically determined to have amyotrophic lateral sclerosis (ALS or “Lou Gehrig’s disease”) are not required to wait the twenty-four-month period. Id. § 426(h).  
34 Id. § 426-1(a); see also id. § 1395c.  
35 Id. § 426-1(a)-(b).
benefits (i.e., the items and services included in the Medicare benefits bundle) and coverage (i.e., the benefits for which Medicare will pay). Parts A and B are the two original parts of the Medicare program from when it was created in 1965. Congress designed Parts A and B, the so-called “fee-for-service” parts of the Medicare program, after the blueprint of the hospitalization benefits afforded by the standard Blue Cross plan and the medical services benefits plan offered to federal workers by the Aetna insurance company.

Part A provides hospital insurance benefits to cover the costs of hospital, related post-hospital, home health, and hospice care services. Medicare beneficiaries are automatically entitled to Part A benefits. The Medicare statute specifies that Part A covers the following categories of benefits: (1) inpatient hospital services or inpatient critical access hospital services for up to a certain number of days during any spell of illness; (2) post-hospital extended care services (in a skilled nursing facility) for up to one hundred days during any spell of illness and, with some limitations, extended care services; (3) home health services and post-institutional home health services furnished during a home health spell of illness; and (4) hospice services.

Part B is the supplementary medical insurance program for those eligible for Part A, and participation in this part of Medicare is voluntary. The Medicare statute specifies that Part B includes the following benefits for enrollees: (1) medical and other health services furnished by physicians and other providers; (2) home health services; (3) outpatient physical therapy services and outpatient occupational therapy services; (4) rural health clinic services and federally qualified health center services; (5) comprehensive outpatient rehabilitation facility services; (6) facility services furnished in

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37 HENRY J. AARON & JEANNE M. LAMBREW, reforming medicare: options, tradeoffs, and opportunities 12, 152 n.1 (2008); Fox, supra note 7, at 594-95. For additional discussion of the plans that provided the blueprint for Parts A and B, see infra Section II.B.
39 Id. § 1395d(a)(1). Medicare Part A will cover “up to 150 days during any spell of illness minus one day for each day of such services in excess of 90 received during any preceding spell of illness.” Id.
40 Id. § 1395d(a)(2).
41 Id. § 1395d(a)(3).
42 Id. § 1395d(a)(4), (d)(1).
connection with surgical procedures performed in an ambulatory surgical center or a physician’s office; (7) durable medical equipment; (8) outpatient critical access hospital services; (9) prosthetic devices and orthotics and prosthetics furnished by a provider; and (10) partial hospitalization services provided by a mental health center.\textsuperscript{45}

In 1982, Congress expanded the managed care option (Part C) of the Medicare program,\textsuperscript{46} which was restructured in 1997 to become the Medicare+Choice program, and again in 2003 to become the Medicare Advantage program.\textsuperscript{47} Part C provides the services covered by Parts A and B (and often Part D) through Medicare-approved private managed care plans.\textsuperscript{48} Medicare Advantage plans are managed and administered by private organizations (such as health maintenance organizations and preferred provider organizations) that contract with the HHS Secretary through CMS, and beneficiaries enrolled in Parts A and B who live in a service area of a Medicare Advantage plan and do not have end-stage renal disease are eligible to enroll.\textsuperscript{49}

In 2003, Congress created Part D, the prescription drug benefit.\textsuperscript{50} Medicare beneficiaries may obtain prescription drug coverage by enrolling in a separate private prescription drug plan in addition to enrolling in traditional fee-for-service Medicare under Parts A and B, or by enrolling in a Part C Medicare Advantage managed care plan that includes prescription drug coverage.\textsuperscript{51}

\textsuperscript{45} Id. § 1395k(a).
\textsuperscript{48} 42 U.S.C. §§ 1395w-21 to -29.
4. Medicare Coverage

The Social Security Act does not provide a comprehensive list of specific items and services that are eligible for coverage in the Medicare program. Instead, the act lists categories of items and services and authorizes the HHS Secretary (along with regional or local Medicare contractors) to determine the items and services within the specified categories that the Medicare program will cover.\textsuperscript{52} The Medicare statute excludes from coverage expenses incurred for a range of items and services, such as most dental care, cosmetic surgery, routine eye examinations, eyeglasses, hearing aids, and items and services provided outside of the United States.\textsuperscript{53} The most significant exclusion in the Medicare statute relates to expenses incurred for items or services that are not reasonable and necessary.\textsuperscript{54} The statute provides that “no payment may be made under part A or part B . . . for any expenses incurred for items or services . . . which . . . are not reasonable and necessary for the diagnosis or treatment of illness or injury or to improve the functioning of a malformed body member.”\textsuperscript{55} The Medicare statute does not define the term “reasonable and necessary” or specify criteria for making coverage determinations.\textsuperscript{56} However, the Medicare statute creates exceptions to the exclusion for items and services that are not reasonable and necessary, and thus it does not preclude payment for expenses incurred for certain items and services that do not meet this “reasonable and necessary” standard. Among these exceptions are certain vaccinations; mammography screening, pap smear and pelvic exam screening, glaucoma screening,

\textsuperscript{52} Medicare Program; Revised Process for Making Medicare National Coverage Determinations, 68 Fed. Reg. 55,634, 55,635 (Sept. 26, 2003).
\textsuperscript{53} See 42 U.S.C. § 1395y(a)(2)-(25). Among the expenses incurred for items or services that are excluded from coverage are the following: items and services for which the individual has no legal obligation to pay; personal comfort items; routine physical checkups (except the initial examination); orthopedic shoes; custodial care (except in the case of hospice care); and routine foot care (such as cutting or removing corns or calluses, trimming nails, and other routine hygienic care). \textit{Id.}
\textsuperscript{54} See Goodman v. Sullivan, 891 F.2d 449, 450 (2d Cir. 1989) (citing 42 U.S.C. §§ 1395y(a)(1)(A) & 1395hh(a), Medicare Part B Carrier’s Manual, Coverage Issues Appendix; Medicare Part B Intermediary Letter, No. 77-7, (\textit{cited in Decision of Medicare Hearing Officer (No. 8801301001) (May 11, 1988)})). The Medicare statute does not expressly exclude experimental, investigational, or unproven treatments or diagnostic methods not generally accepted in the medical profession. \textit{Id.} at 850. However, the statute does exclude from coverage all items and services not reasonable and necessary for the diagnosis or treatment of illness or injury, and the HHS Secretary has, pursuant to her authority to prescribed rules, prohibited payment for such treatment and methods. \textit{Id.}
\textsuperscript{55} 42 U.S.C. § 1395y(a)(1)(A).
\textsuperscript{56} See Sandra J. Carnahan, \textit{Medicare’s Coverage with Study Participation Policy: Clinical Trials or Tribulations?}, 7 YALE J. HEALTH POL’Y L. & ETHICS 229, 236 (2007).
prostate cancer and colorectal cancer screening, cardiovascular screening, diabetes screening, and abdominal aortic aneurysm ultrasound screening; initial preventive physical examinations; and kidney disease education services. Thus, the basic Medicare coverage standard by which CMS determines whether the Medicare program will cover and pay for any particular item or service includes three components: (1) whether the item or service falls within or is classified in a specific benefit category in the Medicare statute; (2) whether any statutory exclusion from coverage applies; and (3) whether the item or the service is reasonable and necessary to diagnose or treat illness or injury or to improve the function of a malformed body member.

CMS and Medicare administrative contractors may develop, at the national level or the local level, coverage determinations for particular items or services, or they may decide claims on a case-by-case basis. Coverage decisions may involve ordinary, well-established treatments and services, as well as new medical technologies and treatments. Because of differences in the provision of items and services and in the applicable reimbursement systems, coverage questions are more likely to arise under Part B than under Parts A, C, and D.

With some items and services, CMS may decide to develop a coverage determination at the national level, and such national coverage determinations (“NCDs”) are decisions by the HHS Secretary regarding whether “a particular item or service is covered nationally.” An NCD may grant, limit, or deny coverage for an item

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57 42 U.S.C. § 1395y(a)(1)(B)–(O). Also among these are hospice care; clinical care items and services with respect to certain research and experimentation; certain home health services; and drugs and biologics furnished under certain circumstances. Id.
60 See GRINSTED, supra note 11, at 2.
or service, and it applies nationally for all Medicare beneficiaries who meet the criteria for coverage. NCDs are typically issued as CMS program instructions, and once an NCD is published in a CMS program instruction, it binds all Medicare contractors, as well as quality improvement organizations, program safeguard contractors, and administrative law judges in the claims appeal process. Accordingly, Medicare contractors apply NCDs when reviewing claims for items and services addressed by NCDs. Between 1999 and 2007, CMS made 119 NCDs.

In the absence of national coverage policy, regional or local Medicare administrative contractors make determinations of coverage as to items and services. The vast majority of coverage decisions are made on the local level by clinicians who work with the Medicare administrative contractors that process Medicare claims. Such local coverage determinations ("LCDs") are decisions by contractors to cover particular items or services on a contractor-wide basis under the "reasonable and necessary" standard in section 1862(a)(1)(A) of the Social Security Act.

5. Medicare Reimbursement/Payment

Reimbursement concerns the amount that the Medicare program will pay for covered items and services. In the Medicare program, most covered items and services are now paid for on a prospective and administered price basis. The transition from reimbursement based upon incurred costs and charges to reimbursement based upon an administered price basis began in 1983 when Congress adopted a prospective payment.

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67 Social Security Act § 1869, 42 U.S.C. § 1395H(f)(2)(B) (2006). It should also be noted that NCDs do “not include a determination of what code, if any, is assigned to a particular item or service covered” or “a determination with respect to the amount of payment made for a particular item or service so covered.” Id.; see also CTRS. FOR MEDICARE & MEDICAID SERVS., supra note 62, § 13.1.1.
system for hospitals, and it progressed with a revised payment system for physician services in 1989 and other prospective systems for most other providers and services by 2000.69

6. Medicare Funding

The Medicare program is funded by a combination of trust funds, dedicated payroll taxes, general revenues, premiums, deductibles, and co-insurance. Part A is funded through compulsory payroll taxes paid by employers, employees, and self-employed individuals and deposited into the Federal Hospital Insurance Trust Fund in the Treasury of the United States.70 Part A beneficiaries also pay deductibles for inpatient hospital services and co-insurance for inpatient hospital and extended care services.71 Part B is funded through general federal tax revenues, and Part B beneficiaries also pay monthly premiums, annual deductibles, and twenty percent co-insurance for most services (such as outpatient hospital services, ambulatory surgical care, clinical diagnostic services, outpatient mental health services, and until recently preventive care services) and equipment.72 Congress created the Federal Supplementary Medical Insurance Trust Fund for the purpose of funding Part B.73 Like Part B, Part D is also funded through a mixture of general tax revenues, monthly premiums, annual deductibles, and co-insurance, as well as state payments for beneficiaries dually enrolled in Medicare and Medicaid.74 Part D funds are deposited into and paid from the Medicare Prescription Drug Account contained within the Federal Supplementary Medical Insurance Trust Fund.75 Part C is not separately funded; consequently, the two trust funds for Parts A and B as well as monthly premiums fund Part C.76 Medicare beneficiaries enrolled in Parts A and B may also purchase Medicare supplement insurance (“Medigap”) from private insurance companies to help cover deductibles and co-insurance.77

70 42 U.S.C. § 1395t(a).
71 Id. § 1395e.
72 Id. §§ 1395j, 1395l(a)—(b), 1395r, 1395s, 1395t, 1395w.
74 Id. §§ 1395w-102(b)(1), 1395w-113(a), 395w-113(c), 395w-114.
75 Id. § 1395w-116(a).
76 Id. § 1395w-24(b)-(c).
77 Id. § 1395ss.
B. The “Reasonable and Necessary” Standard and Medicare Coverage

When the Medicare program was created in 1965, the relatively recent rise of private health insurance plans provided the bulk of the nation’s collective experience with health insurance. Before the advent of health insurance in the United States, patients paid out of their own pockets for most health care services and treatment on a fee-for-service basis. However, during the Depression era, as patients struggled to afford health care services and as hospitals and physicians experienced a shortage of patients to treat, health insurance emerged as a mechanism for financing health care in the United States. In 1929, the first Blue Cross plan developed in Texas when Baylor University Hospital contracted with some school teachers to provide room, board, and other services for a monthly fee. Gradually, other hospitals and groups of employees developed similar prepaid care arrangements, and soon larger Blue Cross plans organized by hospital associations at the state level became available. Physicians followed with Blue Shield plans that initially provided in-patient surgical services, but then added a wider range of medical services. Thus, the Blue Cross (hospital services) and Blue Shield (physician services) plans, typically established as nonprofit organizations, were developed by hospitals and physicians as a means of financing health care.

The Blue Cross and Blue Shield plans expanded throughout the country, and commercial insurance companies soon entered the market. As “service benefit” plans, the Blue Cross and Blue Shield plans directly and fully paid hospitals and physicians for the services rendered. Commercial insurers offered “indemnity” plans that would indemnify or reimburse insureds for payments they had made to providers for the services received. As contracts for insurance, health insurance plans provided coverage for broad categories of services, such as hospital, physician, and diagnostic services, and

80 Bovbjerg et al., supra note 78, at 143.
81 Id.
82 Id.
83 FURROW ET AL., supra note 79, § 9-1.
84 See Bovbjerg et al., supra note 78, at 143 (discussing how commercial insurance companies commenced).
85 See id.; see also FURROW ET AL., supra note 79, § 9-1.
86 See Bovbjerg et al., supra note 78, at 143; see also FURROW ET AL., supra note 79, § 9-1.
with time, additional services were included in the bundle. Under these plans, hospitals and physicians received generous retroactive fee-for-service payment for the services they rendered that they had deemed medically necessary, and thus coverage decisions largely turned on the medical judgment of the physician who directed the delivery of services. By the 1960s, the number of insured had increased dramatically, and the costs of medical services began to escalate. Private health plans then began to include vaguely worded exclusions and other restrictions in their policies to better manage the growing costs of health care. Accordingly, plans excluded “experimental,” “investigational,” “cosmetic,” and “convenience” services, and they restricted coverage to “medically necessary” services. Based upon these exclusions and restrictions, health insurers increasingly conducted retrospective reviews to ensure the appropriateness of treatments and services provided, and consequently, health insurance plans came to defer less to the judgment of physicians, whom insurers believed were responsible for the dramatic rise in health care costs based upon their utilization of high-cost technology and their provision of in-patient services.

In this context, the Medicare program was born in 1965. With the enactment of the Medicare program statute, President Lyndon B. Johnson and a Democrat-controlled Congress prevailed over opposition presented by Republicans and the physician establishment to provide a national health insurance program for the aged in the United States. As originally enacted, the Medicare program included a hospital insurance program (Part A) and a supplementary medical insurance program for physician services and other items and services typically provided on an outpatient basis (Part B), and thus the Medicare program resembled Blue Cross Blue Shield service benefit plans. In advance of the statute’s passage, what would become known as

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88 See Bovbjerg et al., supra note 78, at 143, 152.
89 Id. at 145-48. Approximately two-thirds of Americans had health insurance coverage by 1960. See id. at 146.
90 Bovbjerg et al, supra note 78, at 150. The average hospital expense per day more than doubled between 1950 and 1960. Id. at 148.
91 Sage, supra note 87, at 605.
92 Id. at 605-06.
93 Id.
94 Many good accounts of the history of the Medicare legislation, program, and coverage policy are available. See, e.g., Fox, supra note 7, at 584-609; Grinstead, supra note 11, at 1-16; Kinney, supra note 69, at 1462-71.
95 Fox, supra note 7, at 585, 587-88; Kinney, supra note 69, at 1465-66.
96 See Kinney, supra note 69, at 1463-64; Fox, supra note 7, at 588.
Medicare Part A had been the focus of considerable public and legislative discussion, but Part B was an eleventh hour addition to the legislation.97 To allay the concerns of the physician establishment that the federal government would control medical practices, the legislation began with the following clear directive prohibiting federal interference:

Nothing in [the Medicare program statute] shall be construed to authorize any Federal officer or employee to exercise any supervision or control over the practice of medicine or the manner in which medical services are provided, or over the selection, tenure, or compensation of any officer or employee of any institution, agency, or person providing health services; or to exercise any supervision or control over the administration or operation of any such institution, agency, or person.98

Although the Medicare statute created two trust funds and provided for the collection of payroll taxes, deductibles, and premiums to fund Medicare as a nationwide program, the program was designed to be administered through private insurers operating on a regional or statewide basis that had experience with determining benefits and processing claims.99 Consequently, regionalism and regional differences in coverage have been an aspect of the Medicare program from the beginning.100

Considering the reliance of Congress on existing Blue Cross Blue Shield plans for the design of the Medicare program, it comes as no surprise that Congress established a coverage standard in the Medicare program statute that was similar to the standards used in private health insurance plans at the time. The Medicare statute specified that the program would pay for those categories of items and services that are

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97 See Fox, supra note 7, at 589.
98 Social Security Act § 1801, 42 U.S.C. § 1395 (2006). This statutory section is the very first section of the Medicare program statute. Id.
99 Grinstead, supra note 11, at 3-4. The House Report on the bill that ultimately became the Medicare program statute stated:

The committee believes that medical benefits under the supplementary program in Part B should be administered by the private sector. Private insurers, group health plans, and voluntary medical insurance plans have great experience in reimbursing physicians. Administration of other benefits under Part B would be handled as is found most efficient and convenient to beneficiaries and persons providing health services.

100 Grinstead, supra note 11, at 4.
within the scope of benefits of Parts A and B. However, the Medicare statute prohibited payment “under part A or part B for any expenses incurred for items or services [] which . . . are not reasonable and necessary for the diagnosis or treatment of illness or injury or to improve the functioning of a malformed body member.” As originally enacted, the Medicare statute did not cover services such as preventive care, cosmetic surgery, routine checkups, or dental services, or items such as personal comfort items and eyeglasses. Congress adopted the reasonable and necessary standard and the exclusions (with some modifications) from an Aetna Life & Casualty insurance policy that federal employees had available to them at the time. The Aetna policy provided the following exclusion: “Charges listed on this and the following page are not allowable: Charges for services and supplies . . . [n]ot reasonably necessary for treatment of pregnancy, illness, or injury, or to improve the functioning of a malformed body member.” Since its enactment, the Medicare statute has provided little guidance regarding how the standard should be interpreted.

As enacted, Parts A and B of the Medicare program followed the fee-for-service payment methods practiced by private health insurance plans and provided generous reimbursement to hospital and physician providers participating in the program. These payment methods helped to attract providers to the program, but they also contributed to overutilization of health care services, promoted provider inefficiencies, and produced dramatic increases in the prices and costs of health care, especially as

103 42 U.S.C. § 1395y(a); Fox, supra note 7, at 589-90.
104 Fox, supra note 7, at 593-94.
105 Id. at 594 (quoting Aetna Life & Casualty, Government-Wide Indemnity Benefit Plan: United States Civil Service Commission (as revised on Jan. 1, 1966)).
106 Id. at 591-95 (arguing that the standard may have been understood to mean that the reimbursement rate was to be reasonable and in line with customary charges and that the item or service was necessary as determined by the treating physician). Some insight into the meaning of the reasonable and necessary standard may be gleaned from the first section of the Medicare program statute, which prohibits federal interference with the practice of medicine or the manner in which medical services are provided. Social Security Act § 1801, 42 U.S.C. § 1395 (2006). Additionally, the structure of the provision provides some clues as “not reasonable and necessary” modifies “items or services.” Hays v. Sebelius, 589 F.3d 1279, 1282-83 (D.C. Cir. 2009). The D.C. Circuit held that the Medicare statute unambiguously forecloses the determination of a regional Medicare contractor to reimburse a particular drug only up to the price of its least costly alternative and that the statute requires that Medicare pay for covered items or services at a statutorily prescribed rate. Id. at 1281-83. The court found that the phrase “reasonable and necessary” modifies “items or services,” not “expenses” as the HHS Secretary had argued. Id. at 1282-83.
107 Fox, supra note 7, at 591; Kinney, supra note 69, at 1466.
providers increasingly used expensive medical technologies.\textsuperscript{108} Since the implementation of the Medicare program, the rising costs of the program and the seeming inability to bring costs under control have remained a persistent concern, leading to some significant changes in the program, such as the various Medicare managed care efforts and the prospective payment systems and fee schedules.\textsuperscript{109} They have also inspired some to call for rationing of care and explicit consideration of cost and cost effectiveness in the Medicare coverage decision-making processes.\textsuperscript{110}

III. The Refinement of the Medicare Coverage Determination Processes Prior to the ACA

A. The Administrative Journey Toward Formal National Medicare Coverage Decision-Making Processes

The beginning point on the journey toward national coverage policy and decision-making processes in the Medicare program is the coverage standard established at the program’s inception.\textsuperscript{111} Over a period of more than three decades, the Medicare coverage decision-making processes were transformed from informal to formal processes.\textsuperscript{112} All along the way, the great majority of coverage decisions have been made at the local level.\textsuperscript{113} However, the increased use of new medical procedures, devices, and other technologies, coupled with some inconsistencies among local coverage decisions, manifested a need for the Medicare program to develop national coverage policy.\textsuperscript{114} In the early 1980s, the Health Care Financing Administration (“HCFA”), which at the time administered the Medicare program, utilized an informal committee of HCFA physicians to review medical literature, consult with medical experts, and make national coverage decisions.\textsuperscript{115} The HCFA also requested technology assessments from the Public Health

\begin{itemize}
\item \textsuperscript{108}Kinney, \textit{supra} note 69, at 1466-67.
\item \textsuperscript{109}Fox, \textit{supra} note 7, at 595, 603-09.
\item \textsuperscript{111}See \textit{supra} Section II.B; see also Grinstead, \textit{supra} note 11, at 5-14; Kinney, \textit{supra} note 69, at 1471-82.
\item \textsuperscript{112}Kinney, \textit{supra} note 69, at 1471-72.
\item \textsuperscript{113}Carnahan, \textit{supra} note 56, at 236-37; Kinney, \textit{supra} note 69, at 1471.
\item \textsuperscript{114}Kinney, \textit{supra} note 69, at 1471-72.
\item \textsuperscript{115}Id. at 1472.
\end{itemize}
Service when the complexity or controversial nature of issues so warranted. In 1987, the HCFA issued a notice regarding its procedures for making Part B coverage decisions, and in 1989, it published a proposed rule to establish generally applicable criteria and procedures for its coverage decisions and its determination of whether specific items or services are reasonable and necessary under the Medicare statute. This proposed rule never became a final rule.

The HCFA subsequently reformed its internal review process and began to use a Technical Advisory Committee, which was composed of the medical directors of Medicare contractors. In 1998, the United States General Accounting Office concluded that the HCFA’s Technical Advisory Committee violated the Federal Advisory Committee Act, and the HCFA thereafter issued a notice announcing the establishment of the Medicare Coverage Advisory Committee (“MCAC”). The HCFA assigned MCAC the tasks of reviewing and evaluating medical literature, reviewing technical assessments, and examining data and information and the effectiveness and appropriateness of medical items and services that are covered or eligible for coverage. MCAC then provided technical advice to the HHS Secretary and the HCFA Administrator regarding whether particular items and services are reasonable and necessary under the Medicare statute. MCAC was to consist of 120 members, who were to have expertise in clinical and administrative medicine, biologic and physical sciences, public health administration, health care data and information management and analysis, health care economics, medical ethics, and other related professions.

In 1999, the HCFA issued a notice announcing the processes it would use to make national coverage decisions for specific items and services and its intention to streamline the national coverage decision-making processes and increase public

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\[116\] Id.
\[117\] Medicare Program; Procedures for Medical Services Coverage Decisions; Request for Comments, 52 Fed. Reg. 15,560, 15,560 (Apr. 29, 1987).
\[119\] See infra text accompanying note 126.
\[120\] Kinney, infra note 69, at 1475.
\[121\] Id.
\[123\] Id. In the Notice, the HCFA Administrator also announced the HHS Secretary’s signing of the MCAC charter, which was to end two years later unless the Secretary renewed the charter. Id. The notice also invited nominations for members of the committee.
\[124\] Id. The members serve overlapping four-year terms. Id.
participation. The HCFA also explained that it had decided not to adopt the rule it had proposed on January 29, 1989. The HCFA’s reforms to the processes represented a significant transformation and formalization of the Medicare national coverage decision-making processes. The reforms included procedures for initiation of a review process by formal requests, time frames for review, review-related procedures involving internal review and referrals to MCAC or for an external technology assessment, announcements of national coverage decisions, and procedures for revisiting a decision.

B. The Medicare, Medicaid, and SCHIP Benefits Improvement and Protection Act of 2000

In the Medicare, Medicaid, and SCHIP Benefits Improvement and Protection Act of 2000 (“BIPA”), Congress reformed the coverage determination and appeals processes of the Medicare program. The BIPA established separate processes for individual beneficiaries to dispute denials of coverage and to appeal NCDs and LCDs.

Among the reforms to the appeal process for coverage denials was a mandate that the HHS Secretary promulgate regulations governing initial determinations by the Secretary or Medicare contractors regarding benefits under Parts A and B. The act imposed deadlines for making initial determinations and provided for redeterminations by Medicare contractors, after which beneficiaries could appeal seeking reconsideration of initial determinations by qualified independent contractors and a hearing by the HHS Secretary followed by judicial review. Under the act, qualified independent

126 Id. at 22,620.
127 Id. at 22, 621-24.
129 Id. Section 521 of BIPA revised the Medicare appeals process governing review of claims challenging coverage denials, and section 522 revised the Medicare national and local coverage determinations process. Id. See generally Eleanor D. Kinney, Medicare Beneficiary Appeals Processes, in GUIDE TO MEDICARE COVERAGE DECISION-MAKING AND APPEALS (Eleanor D. Kinney ed., 2002) (providing a thoughtful review of BIPA’s reforms to the Medicare beneficiary appeals process).
130 Id. § 521 (codified as amended at 42 U.S.C. § 1395ff(a)-(b)).
131 Id. § 521 (codified as amended at 42 U.S.C. § 1395ff(b)).
contractors must have sufficient training and expertise in medical science and must conduct reconsiderations pursuant to specific requirements. When “an initial determination is made with respect to whether an item or service is reasonable and necessary for the diagnosis or treatment of illness or injury (under section 1862(a)(1)(A)),” the qualified independent contractor must consider “the facts and circumstances of the initial determination by a panel of physicians or other appropriate health care professionals” in its review. If an initial determination results in a denial, a reconsideration decision by a qualified independent contractor must be “based on applicable information, including clinical experience and medical, technical, and scientific evidence.” Additionally, the BIPA specified that NCDs are binding on qualified independent contractors in making reconsideration decisions, that LCDs must be considered but are not binding in making reconsideration decisions, and that when no NCD or LCD applies, qualified independent contractors must base their reconsideration decisions on applicable information, including clinical experience and medical, technical, and scientific evidence. The reconsideration decisions of qualified independent contractors must be in writing and provide detailed explanations of their decisions as well as discussions of the pertinent facts and applicable regulations. When a reconsideration decision determines whether an item or service is reasonable and necessary, the qualified independent contractor must explain the medical and scientific rationale for its decision. Following reconsideration by a qualified independent contractor, a Medicare beneficiary was permitted to obtain a hearing by the HHS Secretary. In this hearing process, an administrative law judge (“ALJ”) conducts a hearing on the qualified independent contractor’s reconsideration decision and issues a decision, which is reviewable by the Departmental Appeals Board (“DAB”) of the Department of Health and Human Services. Following review by the Secretary, a beneficiary was authorized to seek judicial review.

The BIPA’s reforms to the NCD and LCD processes included providing definitions of national and local coverage determinations. The BIPA defined NCDs as

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132 Id. § 521 (codified as amended at 42 U.S.C. § 1395ff(c)).
133 Id. § 521 (codified as amended at 42 U.S.C. § 1395ff(c)(3)(B)(i)).
135 Id. § 521 (codified as amended at 42 U.S.C. § 1395ff(c)(3)(B)(ii)).
136 Id. § 521 (codified as amended at 42 U.S.C. § 1395ff(c)(3)(E)).
137 Id.
138 Id. § 521 (codified as amended at 42 U.S.C. § 1395ff(d)).
139 Id. § 521 (codified as amended at 42 U.S.C. § 1395ff(d)(1)-(2)).
determinations by the HHS Secretary “with respect to whether or not a particular item or service is covered nationally” in the Medicare program, but the act specified that NCDs do not include coding determinations or determinations regarding amounts that will be paid for covered items or services.\footnote{Id. § 522(a) (codified at 42 U.S.C. § 1395ff(f)(1)(B)).} The BIPA defined LCDs as determinations by Medicare administrative contractors (or fiscal intermediaries or carriers) under Part A or Part B “respecting whether or not a particular item or service is covered on an intermediary- or carrier-wide basis under such parts, in accordance with [the reasonable and necessary standard in the Medicare program statute].”\footnote{Id. § 522(a) (codified at 42 U.S.C. § 1395ff(f)(2)(B)).} Congress mandated the following of the Secretary in NCD decision-making:

[T]he public is afforded notice and opportunity to comment prior to implementation by the Secretary of the determination; meetings of advisory committees established under section 1114(f) [of the Social Security Act] with respect to the determination are made on the record; in making the determination, the Secretary has considered applicable information (including clinical experience and medical, technical, and scientific evidence) with respect to the subject matter of the determination; and in the determination, provide a clear statement of the basis for the determination (including responses to comments received from the public), the assumptions underlying that basis, and make available to the public the data (other than proprietary data) considered in making the determination.\footnote{Id. § 522(b) (codified at 42 U.S.C. § 1395y(a)(22)).}

The BIPA authorized individuals who are entitled to benefits under Part A or enrolled under Part B to request that the Secretary make a determination when the Secretary has not issued a national coverage or noncoverage determination regarding a particular type or class of items or services.\footnote{Id. § 522(a) (codified at 42 U.S.C. § 1395ff(f)(4)-(5)).} The BIPA mandated the Secretary to take one of the following actions within ninety days of receiving a request for an NCD: (1) issue an NCD, with or without limitations; (2) issue a national noncoverage determination; (3) issue a determination that neither an NCD nor a national noncoverage determination is appropriate; or (4) issue a notice indicating that the Secretary’s review is not complete, what steps remain in the review process, and when the review will be completed and a decision issued.\footnote{Id. § 522(a) (codified at 42 U.S.C. § 1395ff(f)(4)(A)).} Under the act, if the Secretary were to fail to take timely action on a request, the Secretary was deemed to have issued a

In the BIPA, Congress specified separate administrative and judicial review procedures for NCDs and LCDs. \footnote{Id. § 522(a) (codified at 42 U.S.C. §1395ff(f)(1)(A)(i), (iii)).} With NCDs, the DAB of HHS, not an ALJ, provides review.\footnote{Id. § 522(a) (codified at 42 U.S.C. § 1395ff(f)(1)(A)(v)).} When a complaint is filed, the DAB reviews the record and may permit discovery and allow evidence to be taken to evaluate the reasonableness of the determination, and it may consult with appropriate scientific and clinical experts.\footnote{Id. § 522(a) (codified at 42 U.S.C. § 1395ff(f)(1)(A)(iv)).} The Secretary is to implement the DAB’s decision within thirty days of its receipt.\footnote{Id. § 522(a) (codified at 42 U.S.C. § 1395ff(f)(2)(A)(i)(I), (II)).} Additionally, the DAB’s decision is the final agency action and subject to judicial review.\footnote{Id. § 522(a) (codified at 42 U.S.C. § 1395ff(f)(2)(A)(iv)).} With LCDs, an ALJ of the Social Security Administration provides review.\footnote{Id. § 522(a) (codified at 42 U.S.C. § 1395ff(f)(2)(A)(ii)).} When a complaint is filed, the ALJ reviews the record and may permit discovery and allow evidence to be taken to evaluate the reasonableness of the determination, and the ALJ may consult with appropriate scientific and clinical experts.\footnote{Id. § 522(a) (codified at 42 U.S.C. § 1395ff(f)(2)(A)(iii)).} The aggrieved party may have the ALJ’s decision reviewed by the DAB,\footnote{Id. § 522(a) (codified at 42 U.S.C. § 1395ff(f)(2)(A)(iii)).} and the Secretary is to implement the decision of the ALJ or the DAB within thirty days of its receipt.\footnote{Id. § 522(a) (codified at 42 U.S.C. § 1395ff(f)(2)(A)(v)).} A decision of the DAB is the final agency action and subject to judicial review.\footnote{Id. § 522(c) (codified at 42 U.S.C. § 1314(i)).}

To ensure the openness and transparency of the NCD process, Congress imposed requirements on the process followed by a Medicare advisory committee.\footnote{Medicare, Medicaid, and SCHIP Benefits Improvement and Protection Act of 2000, § 522(a), Pub. L. No. 106-554, § 522(a), 114 Stat. 2763 (2006) (codified as amended at 42 U.S.C. § 1395ff(f)(4)(B))).} Congress mandated that any advisory committee appointed to advise the Secretary on matters related to the interpretation, application, or implementation of the exclusions from coverage provisions of the Medicare program statute (section 1862(a)(1)) must permit full participation by nonvoting members in committee deliberations and provide nonvoting members access to all information and data that are made available to voting members.\footnote{Id. § 522(a) (codified at 42 U.S.C. § 1395ff(f)(2)(A)(iv)).}
members, with some specified exceptions.  

In 2002, CMS issued a notice announcing that the tasks of MCAC continued to include reviewing and evaluating medical and scientific materials and advising the HHS Secretary and the CMS Administrator regarding whether adequate evidence exists to determine whether specific medical items and services are reasonable under the Medicare program statute. Additionally, MCAC was reduced to a maximum of 100 members who were to have varied expertise as specified in the original notice and charter. Aspects of the committee, including its name and structure, have since been changed.


In the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (“MMA”), Congress continued its reforming efforts as to the NCD and LCD processes. The MMA required the HHS Secretary to develop guidance documents regarding the factors considered in making an NCD regarding whether an item or service is reasonable and necessary and to make these factors publicly available. Congress imposed the following timeframes for decisions on requests for NCDs: (1) in the case of a request that does not require an external technology assessment or deliberation from MCAC, the decision must be made no later than six months after the date of the request; or (2) in the case of a request that requires an external technology assessment or MCAC deliberation and in which a clinical trial is not requested, the decision on the request must be made no later than nine months after the date of the

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159 Medicare Program; Renewal and Amendment of the Charter of the Medicare Coverage Advisory Committee (“MCAC”), 67 Fed. Reg. 79,109 (Dec. 27, 2002). The notice announced renewal and amendment of the MCAC charter and invited nominations for members of the committee. Id.
160 Id. The 100 appointed members are drawn from areas of clinical and administrative medicine, public health administration, physical and biological sciences, healthcare economics, medical ethics, health management and data analysis, along with other similar medical professions. See id.
161 See infra notes 199 and 235 and accompanying text.
163 See id. § 731(a)(1)(B) (codified at 42 U.S.C. § 1395y(f)(1)).
request. At the end of the relevant period, the Secretary must make a draft of the proposed decision publicly available through the CMS website and allow a thirty-day period for public comment on the draft decision. Within sixty days of the end of the thirty-day public comment period, the Secretary must: (1) make a final decision; (2) include in the final decision summaries of the public comments received and responses to the comments; (3) make available to the public the clinical evidence and other data used in making the final decision when the decision differs from the recommendations of MCAC; and (4) when a final decision grants the request for an NCD, assign a temporary or permanent code (whether existing or unclassified) and implement the coding change. Additionally, when a request for an NCD is not reviewed by MCAC, the Secretary must “consult with appropriate outside clinical experts.” The MMA also required the Secretary to develop a plan to evaluate new LCDs to decide which “should be adopted nationally and to what extent greater consistency can be achieved among local coverage determinations,” to mandate consultation among Medicare administrative contractors (or fiscal intermediaries and carriers) in the same area on all new LCDs within their area, and to facilitate the dissemination of information among Medicare administrative contractors to reduce duplication.

In the MMA, Congress also established the Council on Technology and Innovation within CMS. This council, which is to be composed of senior CMS staff and clinicians and chaired by an Executive Coordinator for Technology and Innovation, was assigned the duties of coordinating the activities of the various CMS components in developing and implementing coverage, coding, and payment policy related to new technologies and procedures and facilitating information exchange on new technologies between CMS and other entities involved in making coverage, coding, and payment decisions.

D. The Further Development of the NCD Process by CMS

In response to congressional direction, CMS has formalized the NCD process and issued guidance regarding the factors it considers in making NCDs. The formal

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164 See id. § 731(a)(1)(B) (codified at 42 U.S.C. § 1395y(b)(2)).
165 See id. § 731(a)(1)(B) (codified at 42 U.S.C. § 1395y(b)(3)(A),(B)).
166 See id. § 731(a)(1)(B) (codified at 42 U.S.C. § 1395y(b)(3)(C)).
167 See id. § 731(a)(1)(B) (codified at 42 U.S.C. § 1395y(b)(4)).
169 See id. § 942(a)(5) (codified at 42 U.S.C. § 1395ee(b)(1)).
170 See id. § 942(a)(5) (codified at 42 U.S.C. § 1395ee(b)(2),(3)).
171 See Guidance for the Public, Industry and CMS Staff; Factors CMS Considers in Opening a National
process for requesting and receiving an NCD includes three basic steps: (1) initiation; (2) review; and (3) completion.\(^{172}\)

1. The Initiation Step

At the initiation step, a formal request for an NCD is made.\(^{173}\) A request may come from internal sources, such as CMS staff or agency personnel, or from external sources, such as Medicare beneficiaries, health care providers, medical device manufacturers, suppliers of products, medical professional associations, health plans, developers of new medical technologies, or other parties.\(^{174}\) Informal contacts and inquiries do not qualify as a formal request; rather, a complete, formal request that meets certain requirements is necessary for the official opening of an NCD.\(^{175}\) With external requestors, CMS encourages preliminary discussions and meetings with CMS to consider issues such as documentation, available data, and applicable benefit categories, and to ensure that all relevant evidence is submitted to CMS in a timely manner.\(^{176}\) For a complete, formal request to be “received” by CMS, it must meet certain conditions: (1) a formal request and supporting documentation must be submitted electronically; (2) the request must be identified as a “formal request for an NCD”; (3) the request must state the benefit category or categories of the Medicare program to which the item or service is believed to apply; and (4) the supporting documentation must include a full compilation of the supporting medical and scientific information currently available that

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\(^{172}\) See CMS, NCD Opening Guidance, supra.

\(^{173}\) See id. (explaining that a “formal request” includes an electronically submitted, self-titled “formal request for an NCD” letter, a statement indicating the benefit category or categories of the Medicare program requested and all medical or scientific documentation that may support the medical benefits).

\(^{174}\) Id.

\(^{175}\) Id.

\(^{176}\) Id.
shows medical benefits. With an external request, CMS conducts an initial review to determine whether it is a complete, formal request and whether adequate supporting evidence exists.

During the initiation step, a modified process applies to internally generated requests. An internal request for an NCD regarding a new item or service, an existing item or service that has been substantially modified, or a new use of a covered product may be generated in the following circumstances: when the new technology represents a substantial clinical advance that is likely to result in significant health benefit if the technology is diffused rapidly to all patients for whom it is indicated; when rapid diffusion of the technology is likely to have a significant programmatic effect on the Medicare program and Medicare-related public policies; or when significant uncertainty exists regarding health benefits, patient selection, or facility and staffing requirements associated with the new technology. With an existing technology that is already in use, an internal request may be generated in the following circumstances: when significant questions have arisen about the health benefits of currently covered items or services, especially for Medicare beneficiaries, and these questions are supported by CMS’s internal review of data; when changes to current policies may be warranted based upon new evidence or re-interpretation of previously available evidence; when local coverage policies are inconsistent or conflict with each other to the detriment of beneficiaries; or when program integrity concerns (such as wide variation in billing practices or potential for fraud) have arisen under current national or local policies. CMS has explicitly stated that the cost of a particular technology and cost effectiveness do not factor into (indeed, are “not relevant” to) its consideration regarding whether to make an NCD, whether the technology improves health outcomes, or whether the technology should be covered through an NCD. CMS has indicated that it will endeavor to give the public advance notice regarding potential topics and allow stakeholders to suggest additional topics.

177 Id.
178 See CMS, NCD Opening Guidance, supra note 171.
179 See id. (explaining that requests are sometimes internally generated for the purpose of developing an NCD that would benefit a Medicare beneficiary’s safety and health).
180 Id.
181 Id.
182 Id.
183 Id.
2. The Review Step

The review step begins with CMS's formal acceptance or receipt of an NCD request.\(^{184}\) CMS opens the NCD when it posts the request and a “tracking sheet” on the CMS coverage website, announcing its review of the NCD request and permitting interested parties to monitor the review process.\(^{185}\) The statutory timeframes then become applicable, and CMS proceeds with its review to determine whether the particular item or services meets the statutory requirements.\(^{186}\)

CMS staff often performs internal technology assessments ("TAs"), which are systematic reviews and evaluations of relevant data and evidence (including medical and scientific articles) to inform CMS staff regarding whether an item or service is reasonable and necessary.\(^{187}\) If an NCD request does not require an external TA or review by MCAC, CMS must post a draft decision memorandum no later than six months after its acceptance of the formal NCD request.\(^{188}\) If an NCD request requires an external TA or MCAC review, CMS must post the proposed decision no later than nine months after its acceptance of the request.\(^{189}\) External TAs and MCAC reviews supplement the NCD process and CMS staff review.\(^{190}\)

CMS has issued guidance indicating the factors it considers in commissioning an external TA.\(^{191}\) TAs evaluate scientific and clinical evidence regarding the performance characteristics, safety, efficacy, effectiveness, outcomes, appropriateness, and economic

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\(^{184}\) See CMS, NCD Opening Guidance, supra note 171.

\(^{185}\) Id.

\(^{186}\) Id.

\(^{187}\) Id.


\(^{189}\) Id.


impacts of technology. CMS may commission a TA to assist it in determining whether a particular technology is reasonable and necessary and in identifying areas in which further evidence development is necessary. In its guidance document, CMS has explicitly stated that cost is not a factor in its review or decision to cover particular technologies.

CMS has identified the following conditions that inform its decision to commission a TA: when an extensive body of evidence makes it difficult for CMS staff to complete an internal TA in the statutory period; when the complexity or conflicting nature of available medical and scientific literature suggest the desirability of an independent assessment; when independent analysis of the medical and scientific literature would be helpful because of significant differences in expert opinion regarding that evidence; when CMS staff lack the unique technical or clinical expertise to perform the review; when the review requires the use of specialized methods; when the topic will be referred to MCAC for review; or when unpublished, but relevant non-proprietary data may be collected and analyzed. When CMS concludes that it needs an external TA to supplement its internal TA, CMS may obtain an external TA from an entity that has experience in TA methodology and evidence-based medicine. CMS has an agreement with the Agency for Healthcare Research and Quality (“AHRQ”) to acquire TA reports, and the AHRQ may conduct the TA in-house, select an evidence-based practice center, or utilize another qualified entity. Even when CMS has obtained an external TA, it may refer the issue (along with the completed TA) to MCAC for further review and evaluation.

CMS has also issued guidance regarding the factors it considers in deciding whether to refer a topic to the Medicare Evidence Development and Coverage Advisory Committee (“MedCAC”), which is the new name for MCAC. CMS has issued a

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192 Id.
193 Id.
194 Id.
195 Id.
196 Id.
197 CMS, External TA Guidance, supra note 191.
198 Id.
notice reiterating that MedCAC’s responsibilities include reviewing and evaluating medical literature, reviewing technology assessments, and examining data and information on the effectiveness and appropriateness of specific medical items and services for coverage purposes under the Medicare program in order to advise CMS in making NCDs.\textsuperscript{200} In the notice, CMS indicated an expansion of the range of expertise on the committee—in addition to the other expertise and background earlier identified for representation on the committee, MedCAC would also include authorities in patient advocacy and other related professions such as epidemiology and biostatistics and methodology of trial design.\textsuperscript{201} The notice also divided committee membership to include a maximum of eighty-eight members as standard voting members and twelve as nonvoting members.\textsuperscript{202} Additional changes to the charter included giving MedCAC responsibility for advising CMS as part of its coverage with evidence development ("CED") activity and formalizing a permanent role for patient advocates on the committee to represent beneficiary/patient perspectives.\textsuperscript{203}

MedCAC is an advisory committee that reviews and evaluates medical and scientific literature and TAs, examines additional data and information on the effectiveness and appropriateness of items and services under review, and provides independent guidance and expert advice.\textsuperscript{204} CMS refers a topic to MedCAC for review under the following circumstances: (1) when significant controversy exists among experts regarding the medical benefit of an item or service, the level of competence of providers the facilities require, or some other significant consideration affecting whether the item or service is “reasonable and necessary”; (2) when existing published studies

\textit{Guidance}. Soon after issuing the guidance document, CMS issued a notice announcing the renewal of the MCAC charter, the renaming of MCAC as MedCAC, and the issuance of its MedCAC referral guidance document. \textit{See Medicare Program; Renewal and Renaming of the Medicare Coverage Advisory Committee (MCAC) to Medicare Evidence Development Coverage Advisory Committee (MedCAC) and a Request for Nominations for Members for the Medicare Evidence Development & Coverage Advisory Committee, 72 Fed. Reg. 3853, 3853 (Jan. 26, 2007).} In its notice, CMS stated that the MedCAC referral guidance document was issued in keeping with section 731 of the MMA and intended as part of CMS’s effort to develop “a more open, transparent, and understandable national coverage process.” \textit{Id.} at 3854. The notice also invited nominations for members. \textit{Id.}

\textsuperscript{200} \textit{See Medicare and Medicaid Programs; Reapproval of Deeming Authority of the Accreditation Association for Ambulatory Health Care, Inc. for Medicare Advantage Health Maintenance Organizations and Local Preferred Provider Organizations, 72 Fed. Reg. 3854 (Jan. 26, 2007).}

\textsuperscript{201} \textit{Id.}

\textsuperscript{202} \textit{Id.} Six of the twelve nonvoting members are representatives of consumer interests, and six are representative of industry interests. \textit{Id.}

\textsuperscript{203} \textit{See infra} Section III. E.

\textsuperscript{204} CMS, \textit{MedCAC Referral Guidance, supra} note 199.
contain methodological flaws and do not meet the “reasonable and necessary” standard; (3) when available research has not addressed policy relevant questions or diseases, conditions, or special needs of Medicare beneficiaries; (4) when available published studies manifest conflicting results; (5) when additional expert review of the methods used in external TAs is desirable; (6) when greater public input and comments on the effectiveness of an item or service could be obtained through the MedCAC process; (7) when the general public finds a technology controversial; (8) when future NCDs would benefit from the presentation, public discussion, and clarification afforded by the MedCAC process; (9) when dissemination of a technology may have a major effect on the Medicare program or beneficiaries; and (10) when the NCD process would be better informed by deliberation that includes patient advocate and broader social perspectives. MedCAC’s role extends beyond providing expert advice related to coverage decisions on items or services and includes addressing broad, significant issues related to coverage policy development.

MedCAC meets publicly approximately six times a year to review evidence, hear testimony, deliberate about the quality of evidence, vote on questions, and make recommendations. Thirteen to fifteen members of MedCAC serve at any one meeting. Notice of its meetings is published in advance of meetings, and public participation is permitted. Additionally, feedback and comments from the public and stakeholders may be provided through the CMS website, and the materials distributed to MedCAC members are made available on the CMS website.

3. The Completion Step

At the completion step, CMS posts a draft decision memorandum on its website that outlines the intention of CMS to issue an NCD, a national non-coverage determination, or a determination that an NCD or a non-coverage determination is not appropriate at the time. The draft decision memorandum is not an NCD; rather, it

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205 Id.
206 Id.
207 Id.
208 Id.
209 Id.
210 CMS, MedCAC Referral Guidance, supra note 199.
announces the intention of CMS to issue policy.\textsuperscript{212} The draft decision memorandum informs the interested parties of CMS’s analysis of the scientific and clinical literature, provides background regarding its decision-making process, and explains the rationale for the determination.\textsuperscript{213} Once the draft decision memorandum is posted, the public has thirty days to make comments, and then CMS has sixty days to complete its final decision memorandum and implementation instructions.\textsuperscript{214} An NCD is a formal implementation instruction provided to the Medicare administrative contractors that specifies whether they are to pay, not pay, or pay only when certain conditions are met, and the Medicare contractors then implement the NCD locally and may develop LCDs or policies to supplement the NCD (as long as the LCDs or policies do not conflict with the NCD).\textsuperscript{215} CMS has established procedures governing reconsideration and review of NCDs as well as LCDs.\textsuperscript{216}

Although CMS’s Council on Technology and Innovation is not an official participant in the NCD process, it plays a role in coordinating the NCD process and coverage issues with coding and payment issues addressed by other components of CMS.\textsuperscript{217} The council works to streamline and make more transparent the coding and payment processes, improve the quality of medical decisions, and accelerate patient access to effective new treatments.\textsuperscript{218} Likewise, the council promotes better evidence development and supports better decisions by physicians providing and patients receiving Medicare-covered services.\textsuperscript{219}

\textbf{E. The Coverage with Evidence Development NCD Process}

In 2005 and 2006, CMS developed a process to govern a class of NCDs that conditions payment on the development and capture of additional patient data to supplement standard claims data, and it issued guidance regarding coverage with evidence development ("CED") NCDs.\textsuperscript{220} According to CMS, the purpose of CED is

\textsuperscript{212} Medicare Program; Revised Process for Making Medicare National Coverage Determinations, 68 Fed. Reg. at 55,639.
\textsuperscript{213} Id.
\textsuperscript{214} Id.
\textsuperscript{215} Id. at 55,635, 55,640.
\textsuperscript{217} CMS, NCD Opening Guidance, supra note 171.
\textsuperscript{219} Id.
\textsuperscript{220} CTRS. FOR MEDICARE & MEDICAID SERVS., NATIONAL COVERAGE DETERMINATIONS WITH
“to generate data on the utilization and impact of the item or service evaluated in the NCD” so that the Medicare program is able to (1) “document the appropriateness of use of that item or service in Medicare beneficiaries under current coverage,” (2) “consider future changes in coverage for the item or service,” and (3) “generate clinical information that will improve the evidence base on which providers base their recommendations to Medicare beneficiaries regarding the item or service.”

CMS has identified a range of principles to guide its application of CED. NCDs requiring CED are to occur within transparent and open NCD processes, and CMS is not to use CED when other forms of coverage are justified by available evidence. CED is to expand access to technologies and treatments for beneficiaries and lead to evidence development complementary to existing medical evidence, but it is not to duplicate or replace the Food and Drug Administration’s authority to ensure the safety, efficacy, and security of drugs, biological products, and devices or assume the National Institutes of Health’s role in fostering, managing, or prioritizing clinical trials. Additionally, CMS’s application of CED is to be consistent with federal laws, regulations, and patient protections.

CED includes two separate subclasses: coverage with appropriateness determination (“CAD”) and coverage with study participation (“CSP”). CMS understands Medicare’s coverage of the two different CED subclasses to be authorized by different statutory provisions. According to CMS’s interpretation of the Medicare statute, coverage of CAD is authorized under section 1862(a)(1)(A) of the Social Security Act, and coverage of CSP is authorized under section 1862(a)(1)(E).


221 CMS, CED Guidance, supra note 220.
222 Id.
223 Id.
the addition of the CED process, the following range of coverage decisions is possible pursuant to the NCD process:

(1) No change in coverage. The current coverage, whether national or local, remains unchanged.

(2) Non-coverage. The medical evidence is inadequate to determine that the particular item or service is reasonable and necessary under section 1862(a)(1)(A), and coverage is not allowed.

(3) Coverage without special conditions. The medical evidence is adequate to determine that the particular item or service is reasonable and necessary under section 1862(a)(1)(A) for all Medicare beneficiaries, but this coverage is rare.

(4) Coverage with special conditions. The medical evidence is adequate to determine that the particular item or service is reasonable and necessary under section 1862(a)(1)(A) but only under one or more of the following circumstances:

(a) The item or service is covered only for patients with specific clinical or demographic characteristics;

(b) The item or service is covered only when provided by physicians and/or facilities that meet specific criteria; or

(c) The item or service is covered only when specific data are submitted in addition to claims data to demonstrate that the item or service was provided as specified in the NCD.

(5) Coverage with study participation conditions. Coverage of the item or service under section 1862(a)(1)(E) is permitted only when the item or service is provided within a setting in which there is a pre-specified process for gathering additional data and in which that process provides additional protections and safety measures for beneficiaries, such as the protections and measures afforded in certain clinical trials.226

\[226\] See CMS, CED Guidance, supra note 220.
Coverage decision (4)(c) is CAD, and coverage decision (5) is CSP, the two subclasses of CED.227

With CAD, CMS is able to determine based upon the available evidence that the item or service is reasonable and necessary under section 1862(a)(1)(A), but CMS concludes that additional clinical evidence that is not routinely available on claims forms is needed to ensure that the item or service is being provided to appropriate patients in the manner specified in the NCD.228 Thus, with CAD, the evidence is adequate to make the reasonable and necessary determination, but coverage only extends to items or services for patients who are included in the data collection.229 CMS has identified several circumstances that could lead to an NCD requiring CAD as a condition of coverage: when the newly covered item or service should be restricted to patients with specific conditions and criteria or for use by providers with specific training or credentials; when clinical thought leaders express concern that opportunities for misuse of the item or service are substantial; or when the NCD significantly changes how providers manage patients utilizing the newly covered item or service.230

With CSP, CMS concludes that the evidence is not adequate to determine that a particular item or service is reasonable and necessary under section 1862(a)(1)(A), but it determines that coverage of the particular item or service is appropriate under section 1862(a)(1)(E), which permits CMS to work jointly with the AHRQ and to pay for the clinical costs of the research.231 The Medicare statute authorizes the AHRQ to conduct and support research with respect to “the outcomes, effectiveness, and appropriateness of health care services and procedures in order to identify the manner in which diseases, disorders, and other health conditions can most effectively and appropriately be prevented, diagnosed, treated, and managed clinically.”232 Thus, the CSP subclass authorizes coverage for patients enrolled in a clinical research study that is conducted under section 1862(a)(1)(E) and in a setting where patients are protected, safety and monitoring measures are in place, and clinical expertise is ensured.233 CMS has identified a range of circumstances in which a CSP/NCD may be appropriate. For instance, a CSP/NCD may be appropriate when available evidence is based upon

227 See id.
228 See id.
229 See id.
230 See id.
231 See CMS, CED Guidance, supra note 220. Section 1862(a)(1)(E) explicitly references section 1142 of the Social Security Act, which describes the authority of the AHRQ. Id.
233 See CMS, CED Guidance, supra note 220.
rigorous and sound evaluations but outcomes relative to Medicare beneficiaries were not evaluated; when available evidence does not adequately address the risks and benefits to Medicare beneficiaries of off-label or other unanticipated uses of a drug, biological, service, or device; and when available evidence does not address specific patient subgroups or patients with disease characteristics that are highly prevalent among Medicare beneficiaries. Additionally, it may be appropriate when new applications of diagnostic services and devices are available but little or no published research is available to support a determination that such services or devices are reasonable and necessary. Another circumstance is when evidence is sufficient to determine that a particular item or service is reasonable and necessary for a subgroup of Medicare beneficiaries under specific clinical criteria and/or for providers with certain experience or credentials, but additional evidence is needed to determine whether the item or service is reasonable and necessary for other subgroups or providers.234

All of these reforms to and refinements of the Medicare coverage policy and decision-making processes discussed in this Section were implemented before the enactment of the ACA, and most of these reforms and refinements were made over a period of less than a decade between the late 1990s and early 2007.235 Both Democrat and Republican legislators and administrative actors contributed to these reforms. The ACA makes no changes to the fundamental Medicare coverage standard or these coverage decision-making processes. Thus, by leaving unchanged the policy and processes specified by earlier legislation that were amplified and extended by administrative action (including the CED innovation), Congress in the ACA implicitly gave its stamp of approval to the coverage policy and decision-making processes that had been developed.

On November 7, 2011, CMS issued a public solicitation for comments regarding CED.236 CMS indicated its interest in receiving public input in three areas: (1) the implementation of CED through NCDs or other avenues under Parts A and B; (2) the potential impact of CED on the Medicare program and its beneficiaries; and (3) the

234 See id.
suggested approach to CED to maximize the benefits to Medicare beneficiaries. CMS has removed the current CED guidance document from its website for this comment period, but it has indicated that CED remains in place during the comment period. In taking this action, CMS appears to be motivated by several concerns, including: the possibility that non-coverage decisions limit further evidence development; some internal lessons learned from its several years of experience with the current guidance document; the need to improve the process and develop a guidance document that aligns CED with changes in the health care system; and a desire to “mature CED so that it fulfills its potential as a mechanism that simultaneously reduces barriers for innovation and enables CMS to make better informed decisions that improve health outcomes for Medicare beneficiaries.” From the public solicitation notice, it appears that CMS will retain the CED process but that the process will undergo its own reformation and development.

IV. The Expansion of Medicare Benefits and Coverage Through Preventive Services

Over the last decade and a half, various pieces of federal legislation have expanded Medicare benefits and coverage to include a growing list of preventive services that were initially unavailable through the Medicare program. The ACA extends these efforts to make additional preventive services available to Medicare beneficiaries. These expansions of the Medicare benefit and coverage package were approved by both Democrat and Republican controlled Congresses and White Houses.

A. Pre-ACA Expansion of Prevention Services

In the Balanced Budget Act of 1997 (“BBA”), Congress introduced several preventive care initiatives for the Medicare program. The BBA authorized coverage of annual screening mammograms for women over the age of thirty-nine years and directed that no deductible requirement would apply to such services. It increased the frequency of covered screening pap smears, extended coverage to screening pelvic

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237 Id.
238 Id.
239 Id.
240 Balanced Budget Act of 1997, Pub. L. No. 105-33, §§ 4101-4108, 111 Stat. 251. Subtitle B (Prevention Initiatives) of Title IV (Medicare, Medicaid, and Children’s Health Provisions) of the BBA included these prevention efforts. Id. The BBA provisions discussed in this Section of the Article amended Title XVIII of the Social Security Act; however, this Article will reference only the provisions as codified in the United States Code.
241 Id. § 4101 (codified at 42 U.S.C. §§ 1395l(b)(5), 1395m(c)(1)(C), 1395m(c)(2)(A)(iii)).
examinations with some frequency limitations, and suspended the deductible requirement for such services.\textsuperscript{242} The act also authorized coverage of prostate cancer screening tests for men over the age of fifty within prescribed frequency limitations,\textsuperscript{243} and coverage of colorectal screening for purposes of early detection of colorectal cancer (and screening colonoscopy for individuals at high risk of colorectal cancer) with specified frequency and payment limitations.\textsuperscript{244} In the BBA, Congress directed the HHS Secretary to request that the National Academy of Sciences, in conjunction with the United States Prevention Services Task Force, analyze whether preventive care or other benefits provided to Medicare beneficiaries should be expanded or modified and consider the short-term and long-term benefits and costs to the Medicare program of any such expansion or modification.\textsuperscript{245}

In 2000, the BIPA enhanced some of the preventive care benefits available to Medicare beneficiaries.\textsuperscript{246} It authorized biennial (as opposed to triennial) screening pap smear diagnostic laboratory tests for early detection of cervical or vaginal cancer and screening pelvic examinations (along with clinical breast examinations).\textsuperscript{247} It approved annual glaucoma screenings for individuals at high risk for glaucoma, individuals with a family history of glaucoma, and individuals with diabetes.\textsuperscript{248} The BIPA also extended coverage of screening colonoscopies to individuals with average risk of colorectal cancer but limited the frequency of such covered services.\textsuperscript{249} Additionally, the act authorized payment for screening mammograms conducted within prescribed frequency limitations.\textsuperscript{250}

In 2003, the MMA extended coverage to additional preventive services.\textsuperscript{251} To
promote health and detect disease and to provide education, counseling, and referral for screening and other preventive services, the act authorized coverage of initial preventive physical examinations performed no later than six months after the date when an individual’s first coverage period begins under Part B. The MMA also extended coverage to cardiovascular screening blood tests and diabetes screening tests administered within prescribed frequency limitations.

Other federal statutes enacted after the MMA extended coverage to additional preventive services. The Deficit Reduction Act of 2005 authorized coverage of (and directed that the Part B deductible not apply to) ultrasound screenings for abdominal aortic aneurysms for individuals who are referred for such services as a result of their initial preventive physical examinations, who have not previously received this screening, and whose families have histories of the disease or condition or who manifest risk factors regarding the disease or condition. The Deficit Reduction Act provided that the Part B deductible requirement does not apply to colorectal cancer screenings.

B. ACA Expansion of Preventive Services

Title IV of the ACA put forward a deliberate effort to advance prevention, wellness, and health promotion practices. This effort reflects a policy to promote

addressed several preventive services although they are not reasonable and necessary for the diagnosis or treatment of illness or injury or to improve the functioning of a malformed body member. See Medicare Prescription Drug, Improvement, and Modernization Act of 2003 §§ 611-14.

252 Medicare Prescription Drug, Improvement, and Modernization Act of 2003 § 611(a)-(b), (d) (codified at 42 U.S.C. §§ 1395x(s)(2)(W), 1395y(a)(1)(K), 1395x(ww)).

253 See Medicare Prescription Drug, Improvement, and Modernization Act of 2003 § 612(a)-(c) (codified as amended at 42 U.S.C. §§ 1395x(s)(2)(Y), 1395x(xx), 1395y(a)(1)(L)) (discussing coverage of cardiovascular screening blood tests); see MMA § 613(a)-(c) (codified at 42 U.S.C. §§ 1395x(s)(2)(Y), 1395x(yy), 1395y(a)(1)(M)) (describing coverage of diabetes screening tests).


255 Deficit Reduction Act of 2005 § 5113 (codified at 42 U.S.C. § 1395l(b)(8)).


257 Title IV (Prevention of Chronic Disease and Improving Public Health) includes the following subtitles: Subtitle A, Modernizing Disease Prevention and Public Health Systems; Subtitle B, Increasing Access to Clinical Preventive Services; Subtitle C, Creating Healthier Communities;
prevention throughout the United States in order to improve the health status of individuals and reduce costs. Additionally, it extends Medicare coverage to evidence-based preventive services and encourages beneficiaries to receive additional prevention services, take steps to reduce their risk factors, and improve self-management.

1. Select Prevention Initiatives for the General Population

The ACA called for the President to establish the National Prevention, Health Promotion and Public Health Council within the HHS to coordinate and lead the federal effort in prevention, wellness, and health promotion practices, the public health system, and integrative health care. The ACA assigned the following duties to this council: developing a national strategy for improving health status and reducing the incidence of preventable illness and disability; making recommendations regarding the most pressing health issues and policy changes necessary to achieve wellness, health promotion, and public health goals; proposing evidence-based models, policies, and innovative approaches for promoting transformative models of prevention, integrative health, and public health; and establishing processes for public input.

The ACA also called on the President to establish the Advisory Group on Prevention, Health Promotion, and Integrative and Public Health within the HHS to develop policy and program recommendations and to advise the National Prevention, Health Promotion and Public Health Council on lifestyle-based chronic disease prevention and management, integrative health care practices, and health promotion. The advisory group is to be a diverse body composed of non-federal members from licensed health professions.

Subtitle D, Support for Prevention and Public Health Innovation; and Subtitle E, Miscellaneous Provisions. Patient Protection and Affordable Care Act of 2010 §§ 4001-4402. The ACA provisions discussed in this Section of the Article amended portions of the Public Health Service Act and the Social Security Act; however, this Article will reference only the provisions as codified in the United States Code.


259 Id. § 4001(d)(2)-(6).

260 Id. §§ 4001(d)(1), 4001(3).
including integrative health practitioners.\textsuperscript{261}

The ACA established the Prevention and Public Health Fund, which is to be administered by the HHS Secretary, to invest in prevention and public health programs, promote health, and restrain the growth rate of both private and public sector health care costs.\textsuperscript{262} Appropriations to this fund were authorized, beginning with $500 million for fiscal year 2010 and incrementally increasing to $2 billion for fiscal year 2015 and subsequent fiscal years.\textsuperscript{263}

The ACA required the AHRQ Director to convene an independent Preventive Services Task Force to review scientific evidence related to the effectiveness, appropriateness, and cost-effectiveness of clinical preventive services for the purpose of pursuing two ends: (1) developing recommendations for the health care community; and (2) updating clinical preventive recommendations for individuals and entities that deliver clinical services.\textsuperscript{264} In developing recommendations, the task force is to consider clinical preventive best practice recommendations from a range of public agencies and private entities.\textsuperscript{265} The members of the task force are to be independent and insulated from political pressure.\textsuperscript{266}

The ACA called for a health education and outreach campaign to raise public awareness of health improvement across the life span.\textsuperscript{267} The HHS Secretary is charged with planning and implementing a national public-private partnership to spearhead the effort to disseminate information that, among other things, describes the importance of utilizing preventive services to promote wellness, reduce health disparities, and mitigate chronic disease, promotes the use of recommended preventive services, encourages healthy behaviors to prevent chronic diseases, and explains the preventive services covered under health plans.\textsuperscript{268} Through the CDC Director, the Secretary is to implement a science-based media campaign on health promotion and disease prevention

\textsuperscript{261} Id. § 4001(f)(2).
\textsuperscript{262} Patient Protection and Affordable Care Act of 2010 § 4002(a) (codified at 42 U.S.C. § 300u-11).
\textsuperscript{263} Id. § 4002(b).
\textsuperscript{264} Id. § 4003(a) (codified as amended at 42 U.S.C. § 299b-4(a)(1)).
\textsuperscript{265} Id. § 4003(a) (codified as amended at 42 U.S.C. § 299b-4(a)(2)). These included the AHRQ, the NIH, the CDC, the IOM, medical associations, patient groups, and scientific societies. Id. § 4003(a) (codified as amended at 42 U.S.C. § 299b-4(a)(1)).
\textsuperscript{266} Id. § 4003(a) (codified as amended at 42 U.S.C. § 299b-4(a)(6)).
\textsuperscript{267} Patient Protection Affordable Care Act of 2010 § 4004(a) (codified as amended at 42 U.S.C. § 300u-12(a)).
\textsuperscript{268} Id.
and to disseminate health promotion and disease prevention information to health care providers.\textsuperscript{269} The Secretary is to develop and maintain two Internet websites. The first is for health care providers and consumers, and it is to provide science-based information on guidelines for nutrition, regular exercise, obesity reduction, smoking cessation, and chronic disease prevention.\textsuperscript{270} The second is for individuals, and it is to provide a personalized prevention plan tool that incorporates up-to-date scientific evidence regarding disease prevention and enables individuals to determine their risk of developing five leading diseases and obtain personalized suggestions for preventing these diseases.\textsuperscript{271}

2. \textit{Additional Prevention Services Coverage in the Medicare Program}

The ACA also expanded the federal effort to promote prevention and wellness and advance health promotion practices by extending Medicare coverage to certain prevention services, including personalized prevention plan services and annual wellness examinations.\textsuperscript{272} Under the act, Medicare beneficiaries are eligible to receive initial preventive physical examinations during the twelve-month period after the date when their Part B coverage begins, and they are eligible to receive personalized prevention plan services each subsequent year as long as they have not received their initial preventive physical examination or personalized prevention plan services within the preceding twelve-month period.\textsuperscript{273} In providing personalized prevention plan services, health care professionals create a plan for an individual that includes a health risk assessment.\textsuperscript{274} The assessment is to be completed prior to or as part of the same visit, and the plan takes into account the results of the health risk assessment and other elements.\textsuperscript{275} These other elements may include the individual’s medical and family history; the individual’s current providers, suppliers, and prescribed medications; the

\begin{itemize}
\item[\textsuperscript{269}] Id. § 4004(e), (c) (codified as amended at 42 U.S.C. §§ 300u-12(e), (c)).
\item[\textsuperscript{270}] Id. § 4004(d) (codified as amended at 42 U.S.C. § 300u-12(d)).
\item[\textsuperscript{271}] Id. § 4004(f) (codified as amended at 42 U.S.C. § 300u-12(f)). Up to $500 million may be spent on this education and outreach initiative. Id. § 4004(h) (codified as amended at 42 U.S.C. § 300u-12(h)).
\item[\textsuperscript{272}] The act added this coverage by amending the definition of “medical and other health services” in the Medicare statute to include personalized prevention plan services. Patient Protection and Affordable Care Act of 2010 § 4103(a)(1) (codified as amended at 42 U.S.C. § 1395x(s)(2)). Additionally, the act provides a detailed definition for the personalized prevention plan service. Id. § 4103(b) (codified as amended at 42 U.S.C. § 1395x(hhh)).
\item[\textsuperscript{273}] Id. § 4103(b) (codified as amended at 42 U.S.C. § 1395x(hhh)(4)(G)).
\item[\textsuperscript{274}] Id. § 4103(h) (codified as amended at 42 U.S.C. § 1395x(hhh)(1), (3)). Among the health care professionals contemplated here are physicians, physician assistants, nurse practitioners, and other medical professionals or teams of medical professionals under physician supervision. Id.
\item[\textsuperscript{275}] Id.
\end{itemize}
individual’s height, weight, body mass index, blood pressure, and other routine measurements; and the individual’s cognitive impairments.\textsuperscript{276} They may also include a screening schedule for the next five to ten years based upon the recommendations of the United States Preventive Services Task Force, the individual’s health status and screening history, and the covered age-appropriate preventive services; a list of risk factors and conditions for which primary, secondary, or tertiary prevention interventions are recommended or underway; and a list of treatment options and their associated risks and benefits.\textsuperscript{277} Additionally, other elements may include the provision of personalized health advice and referral to health education and preventive counseling services or programs to reduce identified risk factors and improve self-management or to community-based lifestyle interventions to reduce health risks and promote self-management and wellness.\textsuperscript{278} The ACA directed the Secretary to issue guidance identifying the elements that are to be provided as part of a beneficiary’s first visit for personalized prevention plan services and setting up a yearly schedule for the provision of elements after this first visit.\textsuperscript{279}

The ACA required the HHS Secretary to establish publicly available guidelines for health risk assessments to identify chronic diseases, injury risks, modifiable risk factors, and urgent health needs that may be furnished in various settings and through various means.\textsuperscript{280} The Secretary is also required to establish standards for interactive telephonic or web-based programs used to furnish health risk assessments, and to develop and make publicly available a health risk assessment model.\textsuperscript{281} The Secretary is to ensure that health risk assessments are accessible to beneficiaries, support beneficiaries in the completion of health risk assessments, and develop educational aids to assist beneficiaries and providers in understanding that health risk assessments must be completed prior to or at the same time as the provision of personalized prevention

\textsuperscript{276} Id. § 4103(b) (codified as amended at 42 U.S.C. § 1395x(hhh)(2)(A)-(D)).
\textsuperscript{277} Patient Protection and Affordable Care Act of 2010 § 4103(b) (codified as amended at 42 U.S.C. § 1395x(hhh)(2)(E)). For definitions of these three varieties of prevention, see supra note 12.
\textsuperscript{278} Patient Protection and Affordable Care Act of 2010 § 4103(b) (codified as amended at 42 U.S.C. § 1395x(hhh)(2)(F), (G)). It may also include any other elements determined appropriate by the HHS Secretary.
\textsuperscript{279} Id. § 4103(b) (codified as amended at 42 U.S.C. § 1395x(hhh)(4)(H)).
\textsuperscript{280} Id. § 4103(b) (codified as amended at 42 U.S.C. § 1395x(hhh)(4)(A)). Such means through which a health risk assessment may be furnished included an interactive telephonic or web-based program, an encounter with a health care professional through community-based prevention programs, or any other means deemed appropriate by the Secretary, that maximized accessibility and ease of use by beneficiaries. \textit{Id.}
\textsuperscript{281} Patient Protection and Affordable Care Act of 2010 § 4103(b) (codified as amended at 42 U.S.C. § 1395x(hhh)(4)(B), (C)).
plan services.\textsuperscript{282} The ACA required the Secretary to encourage the use of health information technology and authorized her to experiment with the use of personalized technology to assist beneficiaries with self-management and compliance with provider recommendations to improve their health status.\textsuperscript{283}

Under the ACA, the Medicare program covers all costs of personalized prevention plan services, and consequently beneficiaries pay no coinsurance for these services.\textsuperscript{284} This also applies to personalized prevention plan services provided by hospital outpatient departments.\textsuperscript{285} Additionally, any deductible is waived as to these services.\textsuperscript{286} Excluded from payment are personalized prevention plan services performed more frequently than the ACA authorized.\textsuperscript{287}

3. Removal of Barriers to Preventive Services

The ACA removed barriers to preventive services in the Medicare program. The act defined preventive services as (1) screening and preventive services described in section 1861(ww)(2) of the Social Security Act, (2) initial preventive physical examinations, and (3) personalized prevention plan services.\textsuperscript{288} For initial preventive physical examinations and screening and preventive services recommended with a grade of A or B by the United States Preventive Services Task Force for any indication or population that are appropriate for the individual, the ACA provided that the Medicare program would pay one hundred percent of the lesser of the actual charge for the services or the amount determined under the applicable fee schedule.\textsuperscript{289} Likewise, when hospital outpatient departments furnish such appropriate and recommended preventive services, the Medicare program will pay for the services.\textsuperscript{290} Consequently, coinsurance amounts for these preventive services are waived, as are deductibles as to these services.

\textsuperscript{282} Id. § 4103(b) (codified as amended at 42 U.S.C. § 1395x(hhh)(4)(D), (E)).
\textsuperscript{283} Id. § 4103(b) (codified as amended at 42 U.S.C. § 1395x(hhh)(4)(F)).
\textsuperscript{284} Id. § 4103(c)(1) (codified as amended at 42 U.S.C. § 1395l(a)(1)(X)).
\textsuperscript{285} Id. § 4103(c)(3)(B) (codified as amended at 42 U.S.C. § 1395l(a)(2)(H)).
\textsuperscript{286} Id. § 4103(c)(4) (codified as amended at 42 U.S.C. § 1395l(b)(10)).
\textsuperscript{287} Patient Protection and Affordable Care Act of 2010 § 4103(d)(1) (codified as amended at 42 U.S.C. § 1395y(a)(1)(P)).
\textsuperscript{288} Id. § 4104(a)(3) (codified as amended at 42 U.S.C. § 1395x(ddd)(3)). Excluded from the screening and preventive services described in § 1861(ww)(2) of the Social Security Act was an electrocardiogram. Id.
\textsuperscript{289} Id. § 4104(b)(1) (codified as amended at 42 U.S.C. § 1395l(a)(1)).
\textsuperscript{290} Id. § 4104(b)(2)(B) (codified as amended at 42 U.S.C. § 1395l(a)(2)) (setting forth the amounts to be paid from the Federal Supplementary Medical Insurance Trust Fund for benefits).
and colorectal cancer screening tests.291

4. Evidence-Based Coverage of Preventive Services

The ACA authorized the HHS Secretary to modify Medicare coverage of screening and preventive services, as long as any modifications are consistent with the recommendations of the United States Preventive Services Task Force and the services included in initial preventive physical examinations.292 The Secretary may also specify that no payment be made for screening and preventive services that have not received a grade of A, B, C, or I by the task force.293 The ACA expressly provided that the authority granted to the Secretary to modify coverage of screening and preventive services may not be construed to affect coverage of diagnostic or treatment services in the Medicare program statute.294

As a consequence of the extensions of Medicare benefits and coverage in the ACA and earlier legislation, a wide range of preventive services is now covered, and Medicare beneficiaries can reap the health and other benefits from receiving these services. Notably, Congresses controlled by both Democrats and Republicans passed the pieces of legislation that expanded Medicare benefits and coverage to include additional prevention services, and both a Republican President and two Democrat Presidents signed these pieces of legislation into law.

V. Health Care Quality, Efficiency, and Evidence Development Initiatives

Over the last decade, Congress has approved a range of initiatives to improve the quality and efficiency of health care and to develop more and better evidence to support treatment decisions and coverage policy development. These include initiatives in the ACA and earlier legislation.

291 Patient Protection and Affordable Care Act of 2010 § 4104(c) (codified as amended at 42 U.S.C. § 1395l(b)(1)) (providing the payment of benefits’ deductible provision).
292 Id. § 4105(a) (codified as amended at 42 U.S.C. § 1395m(n)(1)).
293 Id. § 4105(a) (codified as amended at 42 U.S.C. § 1395m(n)(1)). The task force assigns one of five letter grades (A, B, C, D, or I) to each of its recommendations. Grade Definitions, U.S. PREVENTIVE SERVICES TASK FORCE, http://www.uspreventiveservicestaskforce.org/uspstf/grades.htm (last visited Jan. 5, 2012). Each grade has an associated definition that also includes the task force’s assessment regarding the level of certainty that the recommendation will provide a net benefit. See id. With each grade, the task force also indicates whether a service is recommended. See id.
294 Patient Protection and Affordable Care Act of 2010 § 4105(b).
A. Pre-ACA Initiatives Regarding Outcomes Evidence and Comparative Effectiveness Research


In the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (“MMA”), Congress initiated a federal effort to develop comparative effectiveness research. In the interest of improving the quality, effectiveness, and efficiency of health care delivered in the Medicare, Medicaid, and CHIP programs, Congress assigned the HHS Secretary acting through the AHRQ Director the following duties:

[C]onduct and support research to meet the priorities and requests for scientific evidence and information identified by such programs with respect to—

(i) the outcomes, comparative clinical effectiveness, and appropriateness of health care items and services (including prescription drugs); and

(ii) strategies for improving the efficiency and effectiveness of such programs, including the ways in which such items and services are organized, managed, and delivered under such programs.

The Secretary was authorized to conduct or support “research, demonstrations, evaluations, technology assessments, or other activities, including the provision of technical assistance, scientific expertise, or methodological assistance.” The Secretary was also authorized to conduct and support research to improve methods of

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296 Id. § 1013(a)(1)(A) (codified at 42 U.S.C. § 299b-7(a)(1)(A)) (setting forth Congress’ goal of improving the level of health care provided in governmental programs).

297 Id. § 1013(a)(1)(A) (codified at 42 U.S.C. § 299b-7(a)(1)(A)). The AHRQ is an agency within the Department of Health and Human Services that supports, conducts, and disseminates research aimed at improving access to care and the outcomes and quality of health care services. Id.

disseminating information.\textsuperscript{299} The MMA authorized the appropriation of funds to pursue this effort.\textsuperscript{300}

The MMA directed the Secretary to establish a process for developing priorities to guide research, demonstrations, and evaluation activities and an initial list of research priorities regarding health care items and services.\textsuperscript{301} In implementing the process for developing priorities, the Secretary was to ensure broad and ongoing consultation with stakeholders in identifying research priorities to support and improve the Medicare, Medicaid, and CHIP programs and to ensure that research activities are responsive to the identified priorities.\textsuperscript{302} The MMA authorized the Secretary, in identifying priorities, to include items and services that impose high costs on the Medicare, Medicaid, and CHIP programs, that may be underutilized or overutilized, and that may significantly improve the prevention, treatment, or cure of diseases and conditions that impose high direct or indirect costs.\textsuperscript{303}

Under the act, the Secretary was directed to evaluate and synthesize available scientific evidence regarding the comparative clinical effectiveness, outcomes, and appropriateness of health care items and services on the priorities list; identify areas in which existing evidence is insufficient; disseminate the research findings as well as evaluations and syntheses in easily understandable form and readily accessible formats; and work with public and private entities to promote the development of new scientific knowledge.\textsuperscript{304} The MMA required that all scientific evidence, and the methodologies employed, be publicly available and subject to evaluation and replication.\textsuperscript{305} The Secretary was required to identify options for collaborating with public and private entities to provide more timely information regarding the outcomes and quality of patient care and to accelerate the adoption of innovation and quality improvement in the

\textsuperscript{299} Id. § 1013(c) (codified at 42 U.S.C. § 299b-7(c)).
\textsuperscript{300} Id. § 1013(e) (codified at 42 U.S.C. § 299b-7(e)) (authorizing appropriation of $50 million for fiscal year 2004 and additional amounts for subsequent fiscal years).
\textsuperscript{301} Id. § 1013(a)(2)(A)-(B) (codified at 42 U.S.C. § 299b-7(a)(2)(A)-(B)) (requiring the HHS Secretary to develop principles to guide the activities undertaken under section (a) within six months of the date of enactment).
\textsuperscript{302} Id. § 1013(a)(2)(C)(i), (iii) (codified at 42 U.S.C. § 299b-7(a)(2)(C)(i), (iii)) (describing the requirements of the process for developing priorities to guide the activities under the section (a) undertaken by the HHS Secretary).
\textsuperscript{304} Id. § 1013(a)(3)(A), (C) (codified at 42 U.S.C. § 299b-7(a)(3)(A), (C)).
\textsuperscript{305} Id. § 1013(a)(3)(D) (codified at 42 U.S.C. § 299b-7(a)(2)(D)).
Medicare, Medicaid, and CHIP programs. Although the AHRQ Director was prohibited from mandating national standards of clinical practice or quality health care standards, the MMA directed that the research, evaluation, and communication activities “reflect the principle that clinicians and patients should have the best available evidence upon which to make choices in health care items and services, in providers, and in the health care delivery systems, recognizing that patient subpopulations and patient and physician preferences may vary.” The MMA also prohibited the CMS Administrator from using data obtained through this initiative to withhold coverage of prescription drugs.

On this statutory foundation, the AHRQ established the Effective Health Care Program to fund individual researchers, research centers, and academic organizations to work with the AHRQ to produce effectiveness research for clinicians, consumers, and policymakers. This program also reviews and synthesizes scientific evidence, generates new scientific evidence and analytic tools, compiles research findings, and translates the findings into various formats. Funding was also authorized for this program.


The American Recovery and Reinvestment Act of 2009 (“ARRA”) expanded the federal comparative effectiveness research effort by appropriating to the HHS Secretary $1.1 billion for comparative effectiveness research, which was appropriated in two parts. First, the ARRA appropriated $700 million for healthcare research and quality programs, of which $400 million was to be transferred to the National Institutes of Health (“NIH”) to conduct or support comparative effectiveness research. The remaining $300 million was for the AHRQ to use in its healthcare

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306 Id. § 1013(a)(6)(A)-(B) (codified at 42 U.S.C. § 299b-7(a)(6)(A)-(B)).
307 Id. § 1013(b)(1)(A), (2) (codified at 42 U.S.C. § 299b-7(b)(1)(A), (2)).
308 Medicare Prescription Drug, Improvement, and Modernization Act of 2003 § 1013(d) (codified at 42 U.S.C. § 299b-7(d)).
310 Id. In 2005, this program received an appropriation of $15 million, and in 2008, Congress increased the size of the appropriation to $30 million. Id.
312 Id. at 176-77. Congress intended the $700 million appropriation to carry out Titles III and IX of the Public Health Service Act, Part A of Title XI of the Social Security Act, and § 1013 of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003. Id. at 176-77.
313 Id. at 176-77. The funds transferred to the NIH were for purposes of research under § 301
research and quality programs, and this funding enhanced the comparative effectiveness research effort of the Effective Health Care Program of the AHRQ.

Second, the ARRA appropriated an additional $400 million to the HHS Secretary to be allocated at the Secretary’s discretion. Congress intended the Secretary to use this funding to “accelerate the development and dissemination of research assessing the comparative effectiveness of health care treatments and strategies” through comparative effectiveness research and outcomes-related data collection and use efforts. Thus, this funding was to be used for research efforts that “conduct, support or synthesize research that compares the clinical outcomes, effectiveness, and appropriateness of items, services, and procedures that are used to prevent, diagnose, or treat diseases, disorders, and other health conditions.” This funding was also to be used for outcomes-related data collection and use efforts that “encourage the development and use of clinical registries, clinical data networks, and other forms of electronic health data that can be used to generate or obtain outcomes data.” The ARRA required the Secretary to enter into a contract with the Institute of Medicine (“IOM”) to produce a report for Congress and the Secretary and provide recommendations on the national priorities for comparative effectiveness research conducted or supported with this funding appropriation. In selecting activities to receive this funding and in making grants and contracts with public and private entities to achieve the purposes associated with the appropriation, the Secretary was required to consider the IOM recommendations as well as recommendations of the Federal Coordinating Council for Comparative Effectiveness Research. The ARRA assigned the Secretary the duties of publishing information regarding grants and contracts awarded pursuant to the act, disseminating research findings that result from these grants and contracts to clinicians, patients, and the general public, and ensuring that funding recipients offer opportunities for public comment on the research.

and Title IV of the Public Health Services Act. Id. at 177.


317 Id.

318 Id.

319 Id.

320 Id. The report was to be completed by June 30, 2009. 123 Stat. at 177.


322 Id.
report to Congress on their use of the funding and the research activities.323

The ARRA established the Federal Coordinating Council for Comparative Effectiveness Research (“Federal Coordinating Council”) to “foster optimum coordination of comparative effectiveness and related health services research conducted and supported by relevant Federal departments and agencies.”324 The goal behind this initiative was to reduce duplicative efforts and encourage coordinated and complementary use of resources.325 Congress assigned the council the following duties: (1) assisting the federal government in coordinating the conduct and support of comparative effectiveness research and related health services research; and (2) advising the President and Congress on (a) strategies related to comparative effectiveness research infrastructure needs within the federal government and (b) organizational expenditures for such research by federal departments and agencies.326 Under the ARRA, the President, acting through the HHS Secretary, appointed members to the council, which was to be composed of no more than fifteen members, at least half of which were to be physicians or other experts with clinical expertise.327 The act required that council members be senior federal officers or employees with responsibility for health-related programs, including members from several specific agencies: the AHRQ; the CMS; the NIH; the Office of the National Coordinator for Health Information Technology; the Food and Drug Administration; the Veterans Health Administration within the Department of Veterans Affairs; and the office within the Department of Defense responsible for management of the Department of Defense Military Health Care System.328 The Secretary was authorized to make available to the council up to $4 million for staff and administrative support.329 The ARRA called upon the council to submit an initial report and annual reports to the President and Congress.330 The initial

323 Id. at 178.
324 Id. § 804(b) (codified at 42 U.S.C. § 299b-8 (2011)) (outlining the duties of the council including, advising the President and Congress as well as assisting other offices and agencies in coordinating and conducting research).
325 Id. § 804(b).
327 Id. § 804(d).
328 Id. § 804(d)(2). The ARRA established the Office of the National Coordinator for Health Information Technology within the Department of Health and Human Services to lead the effort to develop “a nationwide health information technology infrastructure that allows for the electronic use and exchange of information.” Id. § 13101; see also id. at 230-34.
329 See id. § 804(f). The Secretary is permitted to make available to the Council for staff and administrative support no more than one percent of the total funds granted for comparative effectiveness research in the Act. American Recovery and Reinvestment Act of 2009 § 804(f).
330 See id. § 804(e). On June 30, 2009, the Federal Coordinating Council submitted its Report to
report was due no later than June 30, 2009, and was to describe existing federal comparative effectiveness research activities and provide recommendations for research conducted or supported from funds appropriated under the ARRA for comparative effectiveness research.\textsuperscript{331} The ARRA explicitly directed that the council was not authorized to “mandate coverage, reimbursement, or other policies for any public or private payer” and that no reports or recommendations of the council could be construed as a mandate or clinical guideline for payment, coverage, or treatment.\textsuperscript{332}

B. ACA Initiatives Regarding Health Care Quality and Efficiency in the Medicare Program

The ACA included a range of initiatives to improve health care quality and efficiency, and several of these have important implications for the Medicare program and coverage policy.\textsuperscript{333}

1. The Center for Medicare and Medicaid Innovation and the Restructuring of CMS

a. The Center for Medicare and Medicaid Innovation

In the ACA, Congress sought to transform the health care delivery system by, among other things, encouraging the development of new patient care models that will affect the Medicare program.\textsuperscript{334} The ACA created the Center for Medicare and the President and the Congress. See FEDERAL COORDINATING COUNCIL FOR COMPARATIVE EFFECTIVENESS RESEARCH, REPORT TO THE PRESIDENT AND CONGRESS (June 30, 2009), available at http://www.hhs.gov/recovery/programs/cer/cerannualrpt.pdf.


\textsuperscript{332} Id. § 804(g).


\textsuperscript{334} Subtitle A (Transforming the Health Care Delivery System) of Title III (Improving the Quality and Efficiency of Health Care) of the PPACA initiates programs to link payment to quality outcomes in the Medicare program, to develop a national strategy to improve health care
Medicaid Innovation ("CMI") within CMS to “test innovative payment and service delivery models to reduce program expenditures . . . while preserving or enhancing the quality of care furnished to individuals.” 335 The CMI tests new models in clinical care, integrated care, and community health as well as innovative approaches to paying for care with the twin goals of enhancing the quality of health and health care while reducing cost through improvement of health outcomes. 336 In selecting new service delivery and payment models, the HHS Secretary is directed to give preference to those models that improve the coordination, quality, and efficiency of health care services. 337 In developing and testing new models of service delivery and innovative approaches to payment, the CMI is to consult with other federal agencies and clinical and analytical experts who have expertise in medicine and health care management. 338 The center also disseminates information regarding effective care delivery and payment models. 339

Under the ACA, two phases of testing are contemplated—an initial phase of testing models (Phase I), and an expanded phase of testing (Phase II). 340 In Phase I, the CMI tests service delivery and payment models to determine the effect of models on health care quality and Medicare and Medicaid program expenditures. 341 Models selected for testing are to include those that evidence suggests will address the needs of defined populations in which deficits in care lead to poor clinical outcomes or potentially avoidable expenditures. 342 In selecting models, the CMI may consider factors such as whether a model includes a regular process for monitoring and updating patient care plans; places beneficiaries, family members, and other informal care givers at the center of care teams; coordinates care over time and across settings by utilizing technology (such as electronic health record and patient-based remote monitoring systems); provides for close relationships among various care providers; relies on a team-based approach to interventions; and permits providers to share information with

patients, caregivers, and other providers on a real time basis. For Phase I testing, the ACA requires the HHS Secretary to terminate or modify the design and implementation of any model unless the Secretary determines, after testing has begun, that the model is expected to result in one of the following three outcomes: (1) improve the quality of care without increasing spending; (2) reduce spending without reducing the quality of care; or (3) improve the quality of care and reduce spending. The Secretary is to evaluate each model, analyzing the quality of care furnished under the model, especially with reference to patient-level outcomes and patient-centeredness criteria, and changes in spending, and the Secretary is to make the results of her evaluation publicly available.

The ACA identified various possible models (“opportunities”) for Phase I testing. One involved promoting practice and payment reform in primary care through the use of patient-centered medical homes and the transition of payment from fee-for-service based reimbursement to comprehensive or salary-based payment. Another two models involved direct contracts with groups of providers to promote innovative care delivery and care coordination between providers that transition providers away from fee-for-service reimbursement and toward salary-based payment. Several models related to beneficiaries with chronic conditions: coordinating care by utilizing geriatric assessments and comprehensive care plans; coordinating care through health information technology-enabled provider networks that include care coordinators, a chronic disease registry, and home tele-health technology; establishing community-based health teams to support small-practice medical homes by assisting primary care practitioners with chronic care management services (including patient self-management); and funding home health providers who cooperate with interdisciplinary teams in offering chronic care management services. In the area of cancer care, another model called for aligning payment incentives with nationally recognized, evidence-based guidelines in the areas of treatment planning and follow-up care.

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343 Id. §§ 3021(a), 10306 (codified as amended at 42 U.S.C. § 1315a(b)(2)(C)). Additional factors to consider in selecting models include whether a model provides for in-person contact with beneficiaries and whether a model demonstrates effective linkages with other public or private sector payers. See 42 U.S.C. 1315a(b)(2)(C)(i)-(vii).
344 Patient Protection and Affordable Care Act of 2010 § 3021(a) (codified as amended at 42 U.S.C. § 1315a(b)(3)(B)).
345 Id. § 3021(a) (codified as amended at 42 U.S.C. § 1315a(b)(4)(A)-(B)).
346 Id. § 3021(a).
planning. Yet another model warranting testing involved developing a collaborative of high-quality, low-cost health care institutions that (1) develop, document, and disseminate best practices and proven care methods, (2) implement these practices and methods to show further improvements in quality and efficiency, and (3) assist other health care institutions in employing such practices and methods. Two models involved innovations in inpatient and outpatient care: providing inpatient care at local hospitals with electronic monitoring by specialists based at integrated health systems; and permitting beneficiaries to access outpatient services without requiring physicians to refer or establish care plans for the services when another provider furnishes the services.

In Phase II, the HHS Secretary is permitted, based upon his or her Phase I evaluation of a model and through notice and comment rulemaking, to expand the duration and the scope of a model or a demonstration project under section 1866C of the Social Security Act if the Secretary determines that an expansion is expected to reduce spending without reducing the quality of care or to improve the quality of patient care without reducing spending and if the Chief Actuary of CMS certifies that such expansion would reduce (or not result in any increase in) net spending for the program. Expansion of models are also conditioned on the Secretary determining that any expansion would not deny or limit the coverage or provision of benefits for program beneficiaries. The ACA mandated that the Secretary maintain a focus upon twin goals of improving health care quality and reducing spending in deciding whether to expand a model or demonstration project.

The ACA authorized the HHS Secretary, solely for purposes of testing innovative service delivery and payment models, to waive requirements in the Medicare program statute “as may be necessary.” The ACA prohibits administrative and judicial review of the selection of models for testing or expansion; the selection of organizations, sites, or participants to test selected models; the elements, parameters, scope, and duration of models; the termination or modification of the design and implementation of any model; and determinations to expand the duration and the scope

350 Id. § 3021(a) (codified as amended at 42 U.S.C. § 1315a(b)(2)(B)(xii)).
351 Id. § 3021(a) (codified as amended at 42 U.S.C. § 1315a(b)(2)(B)(xv)).
352 Id. § 3021(a) (codified as amended at 42 U.S.C. § 1315a(b)(2)(B)(xvi)-(xvii)) .
353 Id. §§ 3021(a), 10306(4)(A)-(B) (codified as amended at 42 U.S.C. § 1315a(c)).
354 Id. § 10306(4)(B) (codified as amended at 42 U.S.C. § 1315a(c)).
355 Patient Protection and Affordable Care Act of 2010 § 10306(4)(A)(ii) (codified as amended at 42 U.S.C. § 1315a(c)).
356 Id. § 3021(a)(1), (d)(1) (codified as amended at 42 U.S.C. § 1315a(d)(1)).
of any model. The act appropriated $5 million for fiscal year 2010 for Phase I activities, $10 billion for fiscal years 2011 to 2019, and $20 billion for each subsequent ten-year period beginning with fiscal year 2020. For each fiscal year after fiscal year 2010, at least $25 million must be made available for Phase I evaluation. In the ACA, Congress has required the Secretary to submit reports at least every other year regarding activities with respect to models, testing, expansion, and recommendations for legislative action.

b. The New Structure of CMS

The creation of the Center for Medicare and Medicaid Innovation afforded the HHS Secretary an opportunity to modify the structure of CMS to “align similar functions under common executive leadership” with a shared “consistent vision,” to permit the establishment of a Center for Program Integrity, and to strengthen the focus of CMS on beneficiary services and strategic planning. In this restructuring, which has implications for Medicare coverage policy, the Secretary reorganized the Center for Medicare, the Center for Medicaid, CHIP and Survey & Certification, the Center for Strategic Planning, the Center for Program Integrity, and the Office of External Affairs and Beneficiary Services, and she established the Center for Program Integrity. Several organizations within CMS remained unchanged: the Office of Equal Opportunity and Civil Rights; the Office of Legislation; the Office of the Actuary; the Office of Clinical Standards and Quality; and the Office of Strategic Operations and Regulatory Affairs, which was renamed the Office of Executive Operations and Regulatory Affairs and later returned to its former name.

Three of these centers in particular are integral to the administration of the

357 Id. § 3021(d)(2) (codified as amended at 42 U.S.C. § 1315a(d)(2)).
358 Id. § 3021(f)(1)(A)-(C) (codified as amended at 42 U.S.C. § 1315a(f)(1)).
359 Id. § 3021(f)(2) (codified as amended at 42 U.S.C. § 1315a(f)(2)).
360 Id. § 3021(g) (codified as amended at 42 U.S.C. § 1315a(g)).
362 Medicare Program, supra note 361, at 14176.
363 Id.; see Medicare Program; Statement of Organization, Functions, and Delegations, 75 Fed. Reg. 82,405 (Dec. 30, 2010).
Medicare program. The Center for Medicare plays a central role in formulating, coordinating, implementing, and evaluating national Medicare program policies and operations.\textsuperscript{364} This center also identifies and proposes alterations to Medicare programs and policies based upon changes or trends in the health care industry, program objectives, and needs of Medicare beneficiaries.\textsuperscript{365} Additionally, it manages and oversees the four parts of the Medicare program, and it also oversees budgetary and performance issues.\textsuperscript{366} The Center for Medicare looks over CMS’s interactions and collaborations with stakeholders regarding the Medicare program, and it communicates with these stakeholders to understand their perspectives and disseminate policies, guidance, and materials to ensure best practices in the health care industry.\textsuperscript{367} This center’s role includes developing and implementing a comprehensive strategic plan that includes objectives and measures to ensure that the Medicare program achieves its mission and goals and can meet future challenges.\textsuperscript{368}

The Center for Program Integrity, the establishment of which was a specific purpose mentioned by the HHS Secretary in restructuring CMS,\textsuperscript{369} promotes the integrity of the Medicare and Medicaid programs and CHIP by conducting provider/contractor audits and policy reviews, identifying and monitoring program vulnerabilities, and providing support and assistance to states.\textsuperscript{370} It also interacts and collaborates with federal and state enforcement agencies involved in detecting, deterring, monitoring, and combating fraud and abuse and taking action against unlawful activity.\textsuperscript{371}

The Center for Strategic Planning formulates, designs, and coordinates long-term strategic plans and future program policy and proposals for CMS.\textsuperscript{372} This center identifies, evaluates, and reports emerging trends in health care delivery and financing, their effects upon the programs administered by CMS, and their implications for policy development and planning.\textsuperscript{373} It collaborates with other CMS components in designing, coordinating, and conducting research, demonstrations, analyses, and special studies, and

\textsuperscript{364} Medicare Program, supra note 361, at 14177.
\textsuperscript{365} Id.
\textsuperscript{366} Id.
\textsuperscript{367} Id.
\textsuperscript{368} Id.
\textsuperscript{369} See Medicare Program, supra note 361.
\textsuperscript{371} Id.
\textsuperscript{372} Id.
\textsuperscript{373} Id.
in evaluating the results to understand their impact on beneficiaries, providers, plans, health care programs and financing, and states.\textsuperscript{374}

Another center within CMS, the Center for Medicaid, CHIP and Survey & Certification, oversees state programs and national program policies and operations related to Medicaid, CHIP, Survey, and Certification and the Clinical Laboratory Improvement Act.\textsuperscript{375} More recently, the CMS Administrator established the Center for Consumer Information and Insurance Oversight within CMS.\textsuperscript{376} This new center leads a national effort to set and enforce standards for health insurance that promote fair and reasonable practices to ensure affordable, quality health care coverage.\textsuperscript{377} In addition to implementing, monitoring compliance with, and enforcing new rules under the ACA governing the insurance industry and insurance markets, such as the rules prohibiting rescissions and pre-existing condition exclusions for children, this center develops and implements policies and rules governing the insurance exchanges and oversees the operation of exchanges.\textsuperscript{378} It also provides consumers relevant information on health insurance coverage.\textsuperscript{379} The HHS Secretary has also established a Federal Coordinated Health Care Office to ensure more effective integration of benefits under the Medicare and Medicaid programs for individuals who are eligible for both programs ("dual-eligibles").\textsuperscript{380}

For the Medicare and Medicaid programs and CHIP, the CMS Office of Clinical Standards and Quality administers and oversees quality, clinical, and medical science issues and policies.\textsuperscript{381} This office leads and coordinates the development and implementation of an agency-wide approach to measuring and promoting quality, directs the agency’s priority-setting process for clinical quality improvement, coordinates quality-related activities with entities outside CMS, and identifies and develops best

\textsuperscript{374}Id.
\textsuperscript{377}Id.
\textsuperscript{378}Id.
\textsuperscript{379}Id.
\textsuperscript{380}Statement of Organization, Functions, and Delegation of Authority, 75 Fed. Reg. 82,405 (Dec. 30, 2010). The ACA called upon the Secretary to establish this office. \textit{See} Patient Protection and Affordable Care Act of 2010 § 2602.
practices and techniques in quality improvement. It also monitors quality, evaluates the success of interventions, and carries out the Health Care Quality Improvement Program for the programs CMS administers. The office also prepares the scientific and clinical basis for and recommends approaches to quality-related medical review activities of carriers and payment policies. The Office of Clinical Standards and Quality is the organization within CMS responsible for developing the scientific, clinical, and procedural basis for and recommending to the CMS Administrator decisions regarding coverage of new and established technologies and services. Within the office, the Coverage and Analysis Group develops national Medicare coverage policy and oversees Medicare administrative contractors to ensure compliance with the local coverage determination process. The Coverage and Analysis Group includes two divisions—the Division of Items and Devices and the Division of Medical and Surgical Services—that are involved in more specialized determinations related to drugs, non-implantable devices, and laboratory and diagnostic testing and surgical procedures and implantable devices, respectively. The group also includes the Division of Operations and Information Management that surveys industry developments to keep the Coverage and Analysis Group informed regarding new and developing treatments and technologies. The Division of Operations and Information Management oversees the Medicare Evidence Development & Coverage Advisory Committee (“MedCAC”) and the public notice and comment processes. This office also coordinates activities of CMS’s Technology Advisory Committee (“TAC”) and acts as liaison with other HHS components regarding the safety and effectiveness of technologies and services.

2. The Independent Payment Advisory Board

The ACA established an Independent Payment Advisory Board to “reduce the per capita rate of growth in Medicare spending.” The advisory board is to develop

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382 Id.
383 Id.
384 Id.
385 Id.
387 Id.
388 Id.
390 Patient Protection and Affordable Care Act of 2010 § 3403(a)(1) (codified as amended at 42 U.S.C. § 1395kkk(a)-(b)). Section 10320 changed the name of the advisory board from the
proposals to reduce the growth rate, but its proposals may not recommend rationing health care, raising revenues or Medicare beneficiary premiums, increasing Medicare beneficiary cost-sharing, or otherwise restricting benefits or modifying eligibility criteria.391 The board is to be comprised of a wide array of experts in financing and delivering health care and must include physicians and other health professionals, experts in pharmaco-economics or prescription drug benefit programs, employers, third-party payers, and individuals “skilled in the conduct and interpretation of biomedical, health services, and health economics research and expertise in outcomes and effectiveness research and technology assessment.”392

3. The Center for Quality Improvement and Patient Safety in the Agency for Health Care Research and Quality

In the ACA, Congress sought to improve the quality of health care by undertaking additional research related to the health care delivery system and by providing technical assistance for quality improvement,393 and these efforts will indirectly benefit the Medicare program over time. This initiative in the ACA was intended to enable the AHRQ Director “to identify, develop, evaluate, disseminate, and provide training for innovation 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.”394 The Center for Quality Improvement and Patient Safety, which is part of the AHRQ, was assigned an array of functions.395 First, the

“Independent Medicare Advisory Board” to the “Independent Payment Advisory Board.” Id. § 10320(b).

391 Id. § 3403 (codified as amended at 42 U.S.C. § 1395kkk). Under the act, the advisory board is to include a recommendation to reduce Medicare payments under Parts C and D. See id. In its proposals, the advisory board should, among other things, make extending Medicare solvency a priority; include recommendations for improving delivery systems and health outcomes by promoting integrated care, care coordination, prevention and wellness, and quality and efficiency improvement; target reductions to sources of excess cost growth; consider the effects on beneficiaries of changes to provider payments; and consider the unique needs of dual-eligibles. See id.


393 Subtitle F (Health Care Quality Improvements) of Title III (Improving the Quality and Efficiency of Health Care) of the PPACA includes several provisions intended to improve health care quality. Patient Protection and Affordable Care Act of 2010 §§ 3501-11. Section 3501 of the PPACA amends Part D of Title IX of the Public Health Service Act by adding a new Subpart II (Health Care Quality Improvement Programs). Patient Protection and Affordable Care Act of 2010 § 3501 (codified as amended at 42 U.S.C. §§ 299B-33 to 299B-37).

394 Patient Protection and Affordable Care Act of 2010 § 3501.

395 Id.
center is to use research from a wide range of disciplines such as epidemiology, health services, biostatistics, clinical research, and health informatics in conducting its work.396 Second, it is to develop best practices for quality improvement practices in the delivery of health care services and to change processes of care and redesign systems used by providers that will lead to intended health outcomes, improved patient safety, and reduced medical errors.397 Third, the center is to identify providers that consistently deliver high-quality, efficient care services and employ best practices that may be used effectively in other health care settings.398 Fourth, the center is to evaluate strategy-related and methodology-related research, evidence, and knowledge for improving health care delivery and translating such information rapidly and effectively into practice.399 Fifth, the center is to create strategies for improving quality that could result from reduced variations in health care delivery and to study and improve those organizational, human, and other causative factors that contribute to specific quality improvement and patient safety strategies.400 Sixth, another of the center's functions is to provide for the development of detailed and adaptable best practices in health care services delivery.401 Seventh, the center is to provide for the funding of activities of those organizations that have expertise in improving health care services delivery and to build capacity to lead quality and safety efforts through education, training, and mentoring programs.402 Additionally, the ACA requires the center to coordinate its activities with activities conducted by CMS's Center for Medicare and Medicaid Innovation.403

The act also assigned the center specific functions related to research. The center is directed to support “research on health care delivery system improvement and the development of tools to facilitate adoption of best practices that improve the quality, safety, and efficiency of health care delivery services.”404 Center-supported research is to address the priorities set forth in the national strategic plan, identify areas in which evidence is insufficient to identify strategies and methodologies, address concerns identified by health care institutions and providers, and reduce preventable morbidity, mortality, and associated costs by building capacity for patient safety research.405

396 Id.
397 Id.
398 Id.
399 Id.
400 Patient Protection and Affordable Care Act of 2010 § 3501.
401 Id.
402 Id.
403 Id.
404 Id.
405 Id.
research is also to support the discovery of processes for the reliable, safe, efficient, and responsive delivery of health care and draw upon discoveries from both clinical research and comparative effectiveness research. The center is to allow communication of research findings and to translate evidence into practice recommendations that may be adapted to different settings, and it is to identify and mitigate hazards by studying adverse events as well as to sponsor both systematic reviews of and new research into practices that improve the quality, safety, and efficiency of health care delivery. The act required the AHRQ Director to make the center’s research findings publicly available through multiple media and other appropriate formats and the HHS Secretary to ensure that the center’s research findings and results are made available to the Office of the National Coordinator of Health Information Technology. The AHRQ Director was also required to identify and regularly update a priorities list of processes or systems that are to be the focus of the center’s research and dissemination activities and to take into consideration concerns such as the cost of federal health programs.

The ACA also authorized the appropriation of funding to the center. Through the center, the AHRQ Director awards both technical assistance grants and contracts and implementation grants and contracts to eligible entities so that they will understand, adapt, and implement models and practices related to health care delivery system improvement, especially as concerns the quality, safety, and efficiency of health care delivery services. The act requires application processes for technical assistance awards and implementation awards and mandates that eligible entities secure matching funds. The AHRQ Director must evaluate the performance of entities that receive grants and contracts and determine whether to renew specific grants and contracts.

C. ACA Initiatives Regarding Comparative Clinical Effectiveness Research and the Patient-Centered Outcomes Research

The ACA advances a number of initiatives in the area of patient-centered outcomes research. These initiatives do not have a direct application to the Medicare

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407 Id.
408 Id. For information regarding the creation and purpose of this office, see supra note 328.
409 Patient Protection and Affordable Care Act of 2010 § 3501.
410 Id.
411 Id.
412 Id.
413 Id.
414 Title VI of the PPACA, which is entitled “Transparency and Program Integrity,” includes a
program but will have an impact over time by providing evidence that will inform coverage determinations.

1. The Patient-Centered Outcomes Research Institute

The ACA authorized the establishment of a nongovernmental, nonprofit Patient-Centered Outcomes Research Institute (“PCOR Institute”) to develop and fund comparative effectiveness research.\(^{415}\) Congress established the institute as a tax-exempt organization under the Internal Revenue Code.\(^{416}\) Congress intended the PCOR Institute to play a central role in generating, gathering, synthesizing, and disseminating evidence regarding the effectiveness of medical interventions so that those involved in making health decisions have the best information available. The ACA stated the purpose of the institution in clear terms: it is “to assist patients, clinicians, purchasers, and policy-makers in making informed health decisions” by advancing: (1) “the quality and relevance of evidence concerning the manner in which diseases, disorders, and other

Subtitle D that is addressed to patient-centered outcomes research. Patient Protection and Affordable Care Act of 2010 §§ 6301, 6302. This subtitle includes two sections, § 6301 (Patient-Centered Outcomes Research) and § 6302 (Federal Coordinating Council for Comparative Effectiveness Research). Id. § 6301 (codified as amended at 42 U.S.C. § 1320e). Section 6301(a) adds a new Part D (Comparative Clinical Effectiveness Research) to Title XI of the Social Security Act. Id. § 3601. The new Part D includes three new sections (§1181 (Comparative Clinical Effectiveness Research), § 1182 (Limitations on Certain Uses of Comparative Clinical Effectiveness Research), and § 1183 (Trust Fund Transfers to Patient-Centered Outcomes Research Trust Fund)). Id. § 3601 (codified as amended at 42 U.S.C. § 1320e, e-1, e-2). Section 6301(b) of the PPACA adds a new § 937 to Title IX of the Public Health Service Act (42 U.S.C. § 299 et seq.). Id. § 6301(b) (codified as amended at 42 U.S.C. § 299b-37). Section 6301(c) of the PPACA amends Part D of Title XI of the Social Security Act by adding § 1182. Id. § 6301(c) (codified as amended at 42 U.S.C. § 1320e-1). Section 6301(d) of the PPACA amends Part D of Title XI of the Social Security Act by adding § 1183. Id. § 6301(d) (codified as amended at 42 U.S.C. § 1320e-2). Section 6301(e) of the PPACA amends Subchapter A of Chapter 98 of the Internal Revenue Code by adding a new § 9511 and amends Chapter 34 of the Internal Revenue Code by adding a new Subchapter B (Insured and Self-Insured Health Plans) that has three new statutory sections. Id. § 6301(e) (codified as amended at I.R.C. §§ 4375-77). Section 6301(f) of the PPACA adds a new paragraph at the end of Subsection 501(f) of the Internal Revenue Code of 1986. Id. § 6301(f) (codified as amended at I.R.C. § 501(f)(1986)). In response to fierce public opposition to comparative effectiveness research (CER) that appeared to link the CER initiative with a reform proposal to reimburse physicians for counseling patients on end-of-life issues, this initiative was placed in Title VI of the PPACA instead of Title III of the act, and the term “patient-centered outcomes research” was used instead of the term “comparative effectiveness research.” McDonough, supra note 7, at 221-23.

\(^{415}\) Patient Protection and Affordable Care Act of 2010 § 6301(a) (codified as amended at 42 U.S.C. § 1320e(b)(1)).

\(^{416}\) Id. § 6301(f) (codified as amended at I.R.C. § 501(f)(4)).
health conditions can effectively and appropriately be prevented, diagnosed, treated, monitored, and managed through research and evidence synthesis that considers variations in patient subpopulations; and (2) “the dissemination of research findings with respect to the relative health outcomes, clinical effectiveness, and appropriateness of the medical treatments, services, and items described in subsection (a)(2)(B).”

The activities of the PCOR Institute are to focus on the results of comparative clinical effectiveness research, which is “research evaluating and comparing health outcomes and the clinical effectiveness, risks, and benefits of 2 or more medical treatments, services, and items.” Congress intended a broad scope for such comparative clinical effectiveness research, for the term “medical treatments, services, and items” encompasses “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.”

This new institute replaced the Federal Coordinating Council for Comparative Effectiveness Research, the institution established by the American Recovery and Reinvestment Act of 2009, which was terminated upon the enactment of the PPACA.

The ACA assigned a number of duties to the PCOR Institute. First, the institute is to identify and adopt national research priorities and to establish, adopt, and update a research project agenda to address the priorities. In identifying priorities, the institute is to consider a broad range of factors including: disease incidence, prevalence, and burden; gaps in evidence related to clinical outcomes; and practice variations and health disparities related to delivery and outcomes of care. Priorities are also to be set

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417 Id. § 6301(a) (codified as amended at 42 U.S.C. § 1320e(c)).
419 Patient Protection and Affordable Care Act of 2010 § 6301(a) (codified as amended at 42 U.S.C. § 1320e(a)(2)(B)).
420 Id. § 6302 (codified as amended at 42 U.S.C. 299b-8). For additional information regarding the Federal Coordinating Council for Comparative Effectiveness Research, see supra Section V.A.2.
421 Patient Protection and Affordable Care Act of 2010 § 6301(a) (codified as amended at 42 U.S.C. § 1320e(d)(1), (d)(9)).
422 Id. § 6301(a).
based upon the possibilities for developing new evidence to improve patient health and well-being and quality of care, to affect national health care expenditures related to health care treatment, strategy, or health conditions and patient needs, outcomes, and preferences, and to influence patients and clinicians in making informed health decisions.\footnote{Id. § 6301(a) (codified as amended at 42 U.S.C. § 1320e(d)(1)(A)).}

Second, the PCOR Institute is to adopt and carry out the research project agenda pursuant to the methodological standards adopted by a methodology committee.\footnote{Id. § 6301(a) (codified as amended at 42 U.S.C. § 1320e(d)(2)(A), (a)(d)(9)).} Among the methods to be used in carrying out the agenda are systematic reviews and assessments of existing and future research and evidence (including original research) as well as primary research conducted through randomized clinical trials, molecularly informed trials, and observational studies.\footnote{Id. § 6301(a)(d)(2)(A) (to be codified as amended at 26 U.S.C. § 1320e).} To carry out the agenda, the institute is to enter into contracts to manage funding and conduct research with federal agencies as well as with academic, private sector, and other research institutions, but the institute must give preference to research conduct by the AHRQ and the NIH.\footnote{Patient Protection and Affordable Care Act of 2010 § 6301(a) (codified as amended at 42 U.S.C. § 1320e(d)(2)(B))).} Contracts must comply with various conditions related to transparency, conflicts of interest, methodological standards, publication in peer-reviewed journals or other publications, public dissemination of information, and data use requirements of the institute.\footnote{Id. § 6301(a) (codified as amended at 42 U.S.C. § 1320e(d)(3)).} The institute is to review and update evidence periodically and to design research projects to account for differences in effectiveness among various subpopulations and differences among treatment modalities.\footnote{Id. § 6301(a) (codified as amended at 42 U.S.C. § 1320e(d)(3)).}

Third, the ACA directed the HHS Secretary to provide data collected by CMS under the Medicare, Medicaid, and CHIP programs and to provide the PCOR Institute access to the data networks so it can perform its duties.\footnote{Id. § 6301(a) (codified as amended at 42 U.S.C. § 1320e(d)(1)(A)).} The act also authorized the institute to request and obtain data (such as clinical databases and registries) from public and private entities, but the act required the institute to comply with applicable laws and regulations governing the release and use of data (such as those applicable to confidentiality and privacy).\footnote{Id. § 6301(a) (codified as amended at 42 U.S.C. § 1320e(d)(3)).}

Fourth, the institute is authorized to appoint permanent or ad hoc expert
advisory panels to assist in identifying research priorities, establishing the research project agenda, conducting randomized clinical trials, advising on research questions and design, and answering technical questions. Expert advisory panels are to be comprised of individuals representing a wide range of interests and expertise, including clinicians, patients, and researchers (especially those with expertise in evidence-based medicine and integrative health and primary prevention strategies).\textsuperscript{431} Fifth, the institute is to support and help to facilitate the participation of patient and consumer representatives on the governing board and expert advisory panels.\textsuperscript{432}

Sixth, the ACA tasked the PCOR Institute with establishing a standing methodology committee, which is to be composed of no more than fifteen members who have expertise in various fields of science.\textsuperscript{433} The methodology committee is to develop and improve the science and methods of comparative clinical effectiveness by developing and updating methodological standards for research and a translation table that the governing board can reference in determining the research methods best suited to address specific research questions.\textsuperscript{434} The methodology committee may consult and contract with public and private research institutions that have relevant expertise, and it may consult stakeholders.\textsuperscript{435} The committee also reports and provides recommendations to the governing board.\textsuperscript{436}

Seventh, the PCOR Institute is to ensure a bias and conflict of interest free peer-review process for primary research to ensure scientific integrity and adherence to methodological standards.\textsuperscript{437} Eighth, within ninety days after the conduct or receipt of research findings, the institute is to release research findings to clinicians, patients, and the general public and to note limitations and additional research needs.\textsuperscript{438} Research findings are to be communicated in a manner that is comprehensible and useful to patients and providers in making health care decisions, but they may not include practice guidelines, coverage recommendations, payment, policy recommendations, or

\textsuperscript{431} Id. § 6301(a) (codified as amended at 42 U.S.C. § 1320e(d)(4)).
\textsuperscript{432} Patient Protection and Affordable Care Act of 2010 § 6301(a) (codified as amended at 42 U.S.C. § 1320e(d)(5)).
\textsuperscript{433} Id. § 6301(a) (codified as amended at 42 U.S.C. § 1320e(d)(6)(A)-(B). Committee membership also includes the directors of the AHRQ and NIH or their designees. Id.
\textsuperscript{434} Id. § 6301(a) (codified as amended at 42 U.S.C. § 1320e(d)(6)(C)).
\textsuperscript{435} Id. § 6301(a) (codified as amended at 42 U.S.C. § 1320e(d)(6)(D)).
\textsuperscript{437} Id. §6301(a) (codified as amended at 42 U.S.C. § 1320e(d)(7)).
\textsuperscript{438} Id. § 6301(a) (codified as amended at 42 U.S.C. § 1320e)
information that would violate privacy or confidentiality interests.439 Ninth, the ACA directs the institute to adopt, by majority vote, the national research priorities, the research project agenda, the methodological standards, and the peer-review process.440 Tenth, the institute is to report annually to Congress and the President regarding its activities, research priorities, methodological standards, and administrative activities, as well as the individuals who contributed to any peer-review process and other relevant information.441

The ACA mandated a public comment period prior to the adoption of the national research priorities, the research project agenda, the methodological standards, the peer-review process, and the release of draft findings with respect to systematic reviews of existing research and evidence.442 The PCOR Institute must take steps to ensure transparency regarding its research priorities, its research findings, and its performance of its duties and to make publicly accessible information contained in research findings, processes and methods for conducting research, links to industry, research protocols, comments received, and institute proceedings.443

The PCOR Institute is directed by a board of governors that includes the directors of the AHRQ and the NIH (or their designees), as well as nineteen members representing various groups of stakeholders including patients and health care consumers; physicians and providers; private payers; pharmaceutical, device, and diagnostic manufacturers or developers; quality improvement or independent health service researchers; and the federal or state governments.444 Thus, Congress intended that the governing board include members reflecting a wide range of perspectives and collectively possessing expertise in various clinical health sciences.445

439 Id. §§ 6301(a), 10602(2) (codified as amended at 42 U.S.C. § 1320e(d)(8)).
440 Patient Protection and Affordable Care Act of 2010 § 6301(a) (codified as amended at 42 U.S.C. § 1320e(d)(9)).
441 Id. § 6301(a) (codified as amended at 42 U.S.C. § 1320e(d)(10)). The institute is also to report regarding its research agenda and budget for the following year. Id.
442 Id. § 6301(a) (codified as amended at 42 U.S.C. § 1320e(h)(1)).
443 Id. § 6301(a) (codified as amended at 42 U.S.C. § 1320e(h)(2), (3)).
444 Id. §§ 6301(a), 10602 (codified as amended at 42 U.S.C. § 1320e(f)(1)).
445 Id. § 6301(a) (codified as amended at 42 U.S.C. § 1320e(f)(2)). Board members receive compensation and serve staggered terms of six years. Id. § 6301(a) (codified as amended at 42 U.S.C. § 1320e(f)(3) & (5)). A chairperson and a vice-chairperson preside over the board and the board may employ an executive director and other personnel and engage experts and consultants to assist in the performance of institute duties. Patient Protection and Affordable Care Act of 2010 § 6301(a) (codified as amended at 42 U.S.C. § 1320e(f)).
2. The Dissemination of Research Findings and the Building of Comparative Clinical Effectiveness Research Capacity

As part of the patient-centered outcomes research initiative, the ACA has provided for the dissemination of research findings and the expansion of the capacity to conduct comparative clinical effectiveness research.\textsuperscript{446} The act directs the AHRQ’s Office of Communication of Knowledge Transfer to disseminate broadly the research findings published by the PCOR Institute and other government-funded research relevant to comparative clinical effectiveness research.\textsuperscript{447} The act has assigned the office the tasks of creating informational tools that organize and disseminate research findings for health care providers, patients, payers, and policy makers and of developing a publicly available research database that collects and holds government-funded evidence and research.\textsuperscript{448} The office is to disseminate these findings to and to receive feedback from physicians, healthcare providers, patients, vendors of health information that provide clinical decision support, professional associations, and federal and private health plans.\textsuperscript{449} The act directs the AHRQ to build capacity for comparative clinical effectiveness research by, among other things, establishing a grant program for training researchers in comparative clinical effectiveness research methodology and directs the HHS Secretary to provide for the coordination of relevant federal health programs to build data capacity for such research by developing such means as clinical registries and health outcomes research data networks.\textsuperscript{450}

3. The Limitations on the Authority of the PCOR Institute and Certain Uses of Comparative Clinical Effectiveness Research

The ACA has limited the authority of the PCOR Institute as to health insurance coverage and reimbursement policy and the use of comparative clinical effectiveness research. The act states that nothing in section 1181 of the Social Security Act (the section in Title XI of the act that addresses patient-centered outcomes research and the PCOR Institute) “shall be construed . . . to permit the [PCOR] Institute to mandate coverage, reimbursement, or other policies for any public or private payer.”\textsuperscript{451} Additionally, nothing in section 1181 may be construed to prevent the HHS Secretary

\textsuperscript{446} Id. § 6301(b) (codified as amended at 42 U.S.C. § 299b-37).
\textsuperscript{447} Id.
\textsuperscript{448} Id.
\textsuperscript{449} Id.
\textsuperscript{450} Id.
\textsuperscript{451} Patient Protection and Affordable Care Act of 2010 § 6301(a) (codified as amended at 42 U.S.C. § 1320e(j)(1)(A)).
“from covering the routine costs of clinical care received by an individual entitled to, or enrolled for, benefits” in the Medicare, Medicaid, or CHIP programs when the “individual is participating in a clinical trial and such costs would otherwise be covered under [one of these programs] with respect to the beneficiary.”

The ACA has not prohibited the HHS Secretary from using evidence and findings developed through this initiative in making Medicare coverage determinations, but it requires that any use of such evidence and findings be “through an iterative and transparent process which includes public comment and considers the effect on subpopulations.” The ACA has directed that nothing in section 1181 may be construed (1) to supersede or modify the coverage of items or services in the Medicare program that the Secretary determines are reasonable and necessary, or (2) to authorize the Secretary to deny coverage of items or services in the Medicare program solely on the basis of comparative clinical effectiveness research. The ACA does, however, prohibit the Secretary from using evidence or findings from comparative clinical effectiveness research under section 1181 of the Social Security Act in determining Medicare coverage, reimbursement, or incentive programs “in a manner that treats extending the life of an elderly, disabled, or terminally ill individual as of lower value than extending the life of an individual who is younger, nondisabled, or not terminally ill,” or “in a manner that precludes, or with the intent to discourage, an individual from choosing a health care treatment based on how the individual values the tradeoff between extending the length of their life and the risk of disability.” The Secretary is not prohibited from using evidence or findings from comparative clinical effectiveness research under section 1181 in determining Medicare coverage, reimbursement, or incentive programs based upon a comparison of the difference in the effectiveness of alternative treatments in extending an individual’s life due to an individual’s age, disability, or terminal illness, or based upon a comparison of the difference in the effectiveness of alternative health care treatments in extending an individual’s life due to that individual’s age, disability, or terminal illness. The ACA prohibits the PCOR Institute from using “a dollars-per-quality adjusted life year (or similar measure that discounts the value of a life because of an individual’s disability) as a threshold to

452 Id. § 6301(a) (codified as amended at 42 U.S.C. § 1320e(j)(1)(B)).
453 Id. § 6301(c) (codified as amended at 42 U.S.C. § 1320e-1(a)).
454 Id. § 6301(c) (codified as amended at 42 U.S.C. § 1320e-1(b)).
455 Id. § 6301(c) (codified as amended at 42 U.S.C. § 1320e-1(c)(1)).
456 Id. § 6301(c) (codified as amended at 42 U.S.C. § 1320e-1(d)(1)).
457 Id. § 6301(c) (codified as amended at 42 U.S.C. § 1320e-1(c)(2)).
458 Id. § 6301(c) (codified as amended at 42 U.S.C. § 1320e-1(d)(2)).
establish what type of health care is cost effective or recommended.” Similarly, the Secretary is prohibited from utilizing “an adjusted life year (or such a similar measure) as a threshold to determine coverage, reimbursement, or incentive programs” in the Medicare program.

4. The Funding of the Patient-Centered Research Institute and Its Activities

The ACA makes provision for the funding of the PCOR Institute and its activities. The act establishes the Patient-Centered Outcomes Research Trust Fund (“PCOR Trust Fund”) in the Treasury of the United States, and it makes the Secretary of the Treasury the trustee of the fund. The act authorizes appropriations to the trust fund from the general fund of the Treasury in the following amounts: $10 million for fiscal year 2010; $50 million for fiscal year 2011; $150 million for fiscal year 2012; and $150 million plus an amount received from excise fees imposed under the act, for each fiscal year beginning with fiscal year 2013 and ending with fiscal year 2019. The act imposes excise fees upon specified health insurance and self-insured plans, but it exempts from excise fees certain governmental insurance and medical assistance programs such as the Medicare, Medicaid, and CHIP programs. The act also authorizes the HHS Secretary to transfer to the PCOR Trust Fund amounts from the Hospital Trust Fund and the Supplementary Medical Insurance Trust Fund.

Starting in fiscal year 2010 and continuing in subsequent fiscal years, the PCOR Institute is authorized to use the funds available in the PCOR Trust Fund to carry out its mission without any further appropriation by Congress. From the PCOR Trust Fund, the Treasury Secretary, as the trustee, is required to provide for the transfer of twenty

459 Id. § 6301(c) (codified as amended at 42 U.S.C. § 1320e-1(e)).
460 Id. § 6301(c) (codified as amended at 42 U.S.C. § 1320e-1(i)).
461 See id. § 6301. Several paragraphs in section 6301 relate to the funding of the PCOR Institute: subsections 6301(a), (d), (e), and (f). Section 6301(a) adds section 1181 to Title XI of the Social Security Act. Section 6301(d) adds section 1183 (Trust Fund Transfers to Patient-Centered Outcomes Research Trust Fund) to the end of Part D of Title XI of the Social Security Act. Section 6301(e)(1) adds section 9511 (Patient-Centered Outcomes Research Trust Fund) to Subchapter A of Chapter 98 of the Internal Revenue Code of 1986. Section 6301(e)(2) adds a new Subchapter B (Insured and Self-Insured Plans), which includes sections 4375 (Health Insurance), 4376 (Self-Insured Health Plans), and 4377 (Definitions and Special Rules), to Chapter 34 of the Internal Revenue Code of 1986.
462 Id. § 6301(e)(1).
463 Id. § 6301(e)(2). These excise fees are treated as taxes. Id.
464 Id. § 6301(e)(2)(A). These excise fees are treated as taxes. Id.
465 Id. § 6301(d), (e) (codified as amended at 42 U.S.C. §§ 1320e-2) 6301(e).
466 Id. § 6301(a), (e).
percent of the amounts appropriated or credited to the fund for each fiscal year beginning in 2011 and ending in 2019 to the HHS Secretary to disseminate the research findings of the PCOR Institute and to build capacity for comparative clinical effectiveness research.\textsuperscript{467}

Thus, the ACA built upon earlier federal efforts in the MMA of 2003 and the ARRA of 2009. What started as an interest in improving the quality, effectiveness, and efficiency of health care provided through the Medicare, Medicaid, and CHIP programs has now expanded to much broader federally-led initiatives to improve the quality, effectiveness, and efficiency of health care throughout the United States. However, all along the way, the interest of Congress has not simply been improving the quality, effectiveness, and efficiency of health care. It has also been to control the costs of health care, and the effects of these broad federal initiatives will undoubtedly be felt on public and private health spending.\textsuperscript{468}

VI. Analysis and Conclusion

This Article has examined several initiatives in the ACA that affect Medicare benefits and coverage or that will have an impact on Medicare benefits and coverage over time. It has noted that this major piece of federal health care and health insurance reform legislation did not reform the Medicare coverage policy and decision-making processes. Indeed, in the ACA, Congress did not directly address Medicare coverage

\textsuperscript{467} Id. § 6301(e)(1) (adding section 9511(d)(2)(A) to Subchapter A of Chapter 98 of the Internal Revenue Code of 1986). Amounts transferred under this provision remain available until expended. \textit{See} Patient Protection and Affordable Care Act of 2010 6301(e)(1). Of the amounts transferred for research findings dissemination and capacity building, eighty percent is to be distributed to the Office of Communication and Knowledge Transfer of the AHRQ, and twenty percent to the HHS Secretary. \textit{Id.}

\textsuperscript{468} MCDONOUGH, supra note 7, at 220.

U.S. interest in a new, federally led [comparative effectiveness research] effort grew in the first decade of the new century as burgeoning health costs reemerged as a national concern and as reports of the politicization of difficult and expensive coverage decisions grabbed media attention. For example, a controversy in 2003 about whether Medicare should cover an aggressive and expensive lung operation for patients with emphysema grabbed the attention of U.S. Senate Finance Committee staffer Shawn Bishop, who perceived weaknesses in the government’s ability to make sound judgments on these difficult controversies.

\textit{Id.}
decision-making processes, and several reasons may be cited for this. First, Congress had already reformed the Medicare coverage decision-making processes, and CMS had already responded to legislative mandates and reforms by developing and refining the NCD and LCD processes and providing guidance documents to inform the public, beneficiaries, and stakeholders regarding the factors CMS considers in making NCDs. Second, the well-established Medicare coverage standard has been part of the Medicare statute since the inception of the program, and no fundamental adjustment to that standard was necessary. Third, any wide-scale reforms to Medicare coverage policy and the coverage decision-making processes, especially if such reforms were to introduce cost and cost-effectiveness considerations into coverage decisions regarding items and services, would likely have drawn even more vigorous opposition and jeopardized passage of the ACA. Fourth, Congress could focus on other initiatives.

469 See supra Sections III.B, III.C (discussing the BIPA and the MMA).
470 See supra Section III.D, III.E (discussing the development of the NCD process by CMS and the CED NCD process).
471 See supra Section II.B (discussing the “reasonable and necessary” standard and Medicare coverage).
472 The controversial nature of the debate over cost-effectiveness in coverage and reimbursement decisions has been noted by others:

In the health reform legislation, Congress rejected using cost-effectiveness analyses to aid Medicare coverage and reimbursement decisions. In particular, it wanted to stay away from the metric called quality-adjusted life-years (QALYs)—which is used by England’s and Wales’ National Institute for Health and Clinical Excellence (NICE)—to define health outcomes as part of cost-effectiveness determinations.

... During the debate over national health reform in the United States, the notion of weighing QALYs and costs as part of the calculus for deciding whether to cover treatments became a political minefield. Critics associated the metric with “rationing”—that is, with explicit decisions to withhold certain types of care from patients because they were too costly. As a result, the final language of the Affordable Care Act forbids the government from using QALYs and other cost-effectiveness estimates “as a threshold to determine coverage, reimbursement, or incentive programs” under Medicare.

The government is also forbidden from making decisions on “coverage, reimbursement, or incentive programs” under Medicare “in a manner that treats extending the life of an elderly, disabled, or terminally ill individual as of lower value than extending the life of an individual who is younger, nondisabled, or not terminally ill.”

Health Affairs, Health Policy Brief: Comparative Effectiveness Research, 3-4 (Oct. 8, 2010), available
that have the potential to reduce Medicare program costs while at the same time developing better evidence regarding the outcomes of health care interventions, improving the quality and efficiency of health care, and promoting the health of Medicare beneficiaries.

This Article has identified two classes of initiatives in the ACA that offered this potential. The first involved expanding coverage of preventive and care management services and helping seniors to obtain such services, take steps to prevent illness, and improve their health status. The second involved efforts to improve the quality and efficiency of health care, develop more and better evidence regarding the clinical effectiveness of health care interventions, and disseminate information to providers and patients so that better health care decisions are made. Congress has appropriated substantial funding for both of these initiatives.

These federal initiatives will not, however, yield quick results. Much remains to be learned about the impact of preventive services on costs and beneficiary health in the Medicare program. Additionally, although clinical comparative effectiveness research


One commentator has explained:

Criticism of the ACA for not specifying the precise mechanisms and the detailed reductions in spending miss the institutional strategy that reformers pursued to avoid fueling a political backlash against the government’s expanded role in restraining spending by Medicare and private payers. Reformers refrained from spelling out clear, immediate costs to be borne by well-organized stakeholders based on the calculation that this would unify and greatly intensify their opposition and risk a broader backlash against “big government.”

Lawrence R. Jacobs, *America’s Critical Juncture: The Affordable Care Act and Its Reverberations*, 36 J. HEALTH POL’Y & L. 625, 628 (2011) (citing LAWRENCE R. JACOBS & THEDA SKOCPOL, *HEALTH CARE REFORM AND AMERICAN POLITICS* (2010)). Jacobs and Skocpol have argued that, in order for health care reform to come to fruition, liberal Democrats in Congress, who favored governmental expansion, were willing to give up some battles so that some sort of legislation passed. See JACOBS & SKOCPOL, supra, at 63.

473 Two authors have noted the potential offered by preventive measures:

Interventions [that] both increase health and reduce costs are easily justified and widely supported. Unfortunately, interventions of this type are relatively rare. There have been many hundreds of cost-effectiveness studies over the past half century of interventions ranging from pharmaceuticals to case management to self-management, and most interventions tend to both improve health and increase costs. In a review of studies of prevention
measures reporting a cost-effectiveness ratio, [Joshua T. Cohen, Peter J. Neumann, and Milton C. Weinstein] report that less than one in five studies find that prevention reduces costs. Instead, the vast majority of studies find that prevention increases costs and provides some benefit . . . Yet, the tantalizing potential remains for reforms that improve health and reduce costs.


[T]he evidence does not support the commonly accepted idea that prevention always, or even usually, reduces medical costs—although it sometimes does. Most preventive interventions add more to medical costs than they save, at the same time that they improve health.

But even that statement needs to be made more specific. Preventive interventions need to be evaluated individually. Some . . . may be good investments almost regardless of how they are applied—they bring additional good health at a very reasonable cost. Other interventions are good investments when used selectively—targeted at those people who benefit most from them—but not such good investments when used for more broadly defined groups of people.

Id. at 8. The challenge of realizing costs savings from preventive services has been described as follows:

Many of the standard preventive measures fail to reduce spending . . . The reason that prevention rarely reduces costs is because the cost savings associated with early treatment or detection (or disease avoidance) are typically far less than the costs associated with the direct cost of the preventive service, costs associated with adverse reactions to the preventive services, costs associated with follow-up treatment and testing for those with a positive screen, and the cost of unrelated illnesses that occur late in life.

This is not to say that prevention is a bad idea. As a result of the efforts to reduce chronic illness, there has been a marked decrease in the number of Medicare beneficiaries who are disabled. This can help in health care spending because the disabled tend to be more costly than those without disabilities. However, health care costs among nondisabled Medicare beneficiaries have
builds upon outcomes research that has been ongoing for some time, the comparative effectiveness research initiative has entered a new phase with the financial and institutional support put forward in the ACA. However, the long-term impact on Medicare program costs and health care spending is unknown. Thus, it will take some

been increasing much more quickly than health care costs among the disabled. This may well reflect the costliness of efforts to prevent beneficiaries with potentially disabling conditions from becoming actually disabled. While this may be a justifiable use of societal resources, it does increase Medicare costs.

Atherly & Yang, supra, at 80-81. Although “some evidence does suggest that there are opportunities to save money and improve health through prevention . . . [s]weeping statements about the cost-saving potential of prevention . . . are overreaching” Cohen, Neumann, & Weinstein, supra, at 661. Additionally, “[w]hether any preventive measure saves money or is a reasonable investment despite adding to costs depends entirely on the particular intervention and the specific population in question,” and the “focus on prevention as a key source of cost savings in health care also sidesteps the question of whether such measures are generally more promising and efficient than the treatment of existing conditions.” Id. at 661-62; see also Louise B. Russell, Preventing Chronic Disease: An Important Investment, but Don’t Count on Cost Savings, 28 HEALTH AFFAIRS 42 (2009) (arguing that instead of debating whether prevention or treatment saves money, the focus should be on the most cost-effective ways to improve population health); Louise B. Russell, Prevention Will Reduce Medical Costs: A Persistent Myth, THE HEALTH CARE COST MONITOR (June 17, 2009), available at http://healthcarecostmonitor.thehastingscenter.org/louiserussell/a-persistent-myth/; Health Care and the Budget: Issues and Challenges for Reform: CBO Testimony Before the Committee on the Budget (2007) (statement of Peter R. Orszag), available at http://www.cbo.gov/ftpdocs/82xx/doc8255/06-21-HealthCareReform.pdf.

Prevention is often worth doing because it brings better health. But with prevention, as with treatment, better health comes at a higher price most of the time. The best medical care is based on the best evidence. Health reform will be most likely to succeed when it, too, is based on the best evidence. That evidence shows that spending more on prevention is not the way to control health care costs.

Russell, Prevention Will Reduce Medical Costs, supra.

474 Supporters of comparative effectiveness research contend that such research will save money or at least ensure better value for the money spent. See Health Affairs, supra note 472, at 4.

Despite the language in the Affordable Care Act that restricts the use of cost-effectiveness analysis in Medicare’s coverage decisions, backers of comparative effectiveness research say it could lead to making better use of the nation’s health care dollars. If there’s more clarity about which treatments work best—and for which types of patients—there’s potential for shifting money to those interventions and away from less effective treatments.

Id. Health care savings from the comparative effectiveness research initiatives will depend on a number of factors, such as whether “physicians and other health care providers [will] change what they do for patients based upon [CER] findings,” how and what “patients and providers
time for these initiatives to have the desired effects of catching diseases early, preventing illness, developing research capacity, conducting research, evaluating data, disseminating information, translating evidence into improved clinical practices, improving health care decisions, elevating the health of Medicare beneficiaries, and perhaps reducing the costs of health care for the Medicare program. Positive outcomes from these initiatives will

[will] learn about the results,” whether “the research [will] be conducted openly and soundly enough that patients and providers will trust the outcomes,” and whether “private insurers and other payers [will] use the research findings to make decisions on whether to cover treatments, and how much to pay for them.” Id. at 1.

475 The ACA included many other initiatives that are more remote from Medicare coverage policy and decision making, such as efforts to reform Medicare payment and an initiative to improve the health of the segment of the United States population that is on the verge of Medicare eligibility. These initiatives will also have consequences for the Medicare program and reduce program costs, but they are beyond the scope of the subject treated in this Article. As to the long-term outcomes, especially as to health care costs, one commentator has observed:

Among many contested arguments involving the ACA, one of the most consequential is the question of the law’s impact on slowing the growth in overall health care spending over the next two decades. The ACA will undoubtedly slow the rate of growth in Medicare at least by the CBO-estimated $449 billion between 2010 and 2019. . . . Reductions in Medicare payments may, however, create pressure for even higher private health spending. Alternatively, it is also possible that the ACA innovations in Medicare and Medicaid may have positive spillover effects that will improve efficiency and also lower costs in the private health sector. And with so many changes occurring simultaneously, it will be challenging to tease the impact of any single intervention from the others.

. . .

Are there other innovations that could have been included in the ACA? And could any of the innovations have been structured to have a more effective and significant impact? Yes and yes. An example of the former would have involved permitting Medicare to pay physicians to provide end-of-life counseling to beneficiaries—a proposal dropped because of political attacks charging that Democrats were creating “death panels.” An example of the latter is the Patient Centered Outcomes Research Institute [], included in Title VI, which could have been structured to consider cost-effectiveness in addition to clinical effectiveness, which was not done for reasons similar to the end-of-life issue. The ACA took every idea on how to reduce health care spending, public and private, and pushed as far as the political system would tolerate in 2009 and 2010. Some of these innovations will fail, either completely or mostly. Some will succeed, far beyond the estimates calculated
only be realized over time, with some perhaps much time.

This Article has demonstrated that the initiatives in the ACA that extend Medicare coverage to additional preventive and care management services and that promote the development and dissemination of more and better evidence regarding clinical effectiveness and medical outcomes build upon legislative efforts sponsored and approved by both Democrats and Republicans over the last decade and a half. Thus, bipartisan support has backed initiatives in the BBA, the BIPA, the MMA, the ARRA, and the ACA that have expanded coverage of preventive services and encouraged the development of better evidence regarding the effectiveness of medical interventions. Consequently, the two sets of ACA initiatives highlighted in this Article are not departures from, but rather extensions of prior legislative efforts.

This Article has also highlighted that in drafting the ACA, Congress articulated clear policy that the focus in Medicare coverage decision making should remain, as the Medicare coverage standard directs, on medical and scientific evidence and that administrative efforts should be directed at developing better evidence, disseminating information, supporting better health care decisions, and providing quality health care to Medicare beneficiaries. Congress limited how evidence can be used in making coverage decisions, prohibited the use of quality adjusted life years and other such factors to set a threshold to determine coverage or reimbursement, and safeguarded against effectiveness evidence being used to diminish the value of the lives of the elderly, the disabled, and the terminally ill. Consequently, the ACA reflects congressional opposition to making cost and cost-effectiveness considerations part of the Medicare coverage decision-making process. CMS has also clearly stated that cost and cost effectiveness are not factors that it considers in making coverage determinations and that the decision-making process is evidence based. These initiatives in the ACA, considered together with other legislative initiatives over the last decade and a half, show that Congress believes more can be done to reform Medicare, improve the health care system and the health of Medicare beneficiaries, reduce costs, and adjust payments before resorting to blunt instruments such as explicit rationing of health care and considering cost effectiveness in Medicare coverage decision making.

Furthermore, the Medicare program would not keep faith with elderly and disabled Americans if it were directly to engage in rationing of health care services or

by the CBO. Some of these innovations will be altered by Congress in the coming years, and no one will know how they might have otherwise worked.

McDONOUGH, supra note 7, at 176, 178.
consider cost and cost effectiveness in making coverage decisions. Since the inception of the Medicare program, the Medicare coverage standard has focused coverage decision making and coverage policy on the reasonableness and the necessity of items and services based upon medical and scientific evidence, and lawmakers, administrators, providers, and beneficiaries are accustomed to this coverage standard. However, Congress has also found ways to expand the Medicare benefit and coverage package to include additional services (such as preventive care and care management services) that are warranted by medical and scientific evidence. This has permitted the Medicare program to honor the trust of America’s seniors and disabled. As the initiatives in the ACA and earlier legislation to provide additional preventive and care management services and to develop evidence regarding the effectiveness of medical interventions and patient outcomes bear fruit in the years to come, the established Medicare coverage standard and coverage decision-making processes, which result from the work of both Democrat and Republican lawmakers and administrators, will afford tested and reliable means for making coverage determinations based upon the best available evidence.