COMPARATIVE EFFECTIVENESS RESEARCH UNDER THE PATIENT PROTECTION AND AFFORDABLE CARE ACT: CAN NEW BOTTLES ACCOMMODATE OLD WINE?

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COMPARATIVE EFFECTIVENESS RESEARCH UNDER THE PATIENT PROTECTION AND AFFORDABLE CARE ACT: CAN NEW BOTTLES ACCOMMODATE OLD WINE?

By

Eleanor D Kinney, JD, MPH*

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ABSTRACT

The Patient Protection and Affordable Care Act (PPACA), as amended by the Health Care and Education Reconciliation Act of 2010, initiated comprehensive health reform for the health care sector of the United States. PPACA has some strategies for the American health care sector to make health care more efficient and effective. PPACA’s comparative effectiveness initiative and the establishment of the Patient-Centered Outcomes Research Institute are major strategies in this regard. This initiative is one of a long line of federal initiatives to address the rising costs of health care as well as obtain better value for health care expenditures. The key question is whether the governance and design features of the institute that will implement the initiative will enable it to succeed where other federal efforts have faltered. This article analyzes the federal government’s quest to ensure value for money expended in publically-funded health care programs and the health sector generally. The article will also analyze what factors contribute to the possible success or failure of the comparative effectiveness research initiative.
I. INTRODUCTION

The Patient Protection and Affordable Care Act (PPACA),\(^1\) as amended by the Health Care and Education Reconciliation Act of 2010,\(^2\) initiated comprehensive health reform for the health care sector of the United States. In addition to increasing access to health care coverage through expansion of public programs and reform of the private health insurance market, PPACA has several initiatives to improve the quality and control the cost of health care services.

To make the PPACA coverage expansions affordable, PPACA has some strategies for the American health care sector to make health care more efficient and effective. PPACA’s comparative effectiveness initiative is a major strategy in this regard. Congress intended the comparative effectiveness initiative to develop hard information about comparative effectiveness of different medical products and services. This initiative is one of a long line of federal initiatives to address the rising costs of health care as well as obtain better value for health care expenditures. The key question is whether the governance and design features of the institute that will implement the initiative will enable it to succeed where other federal efforts have faltered.

This article analyzes the federal government’s quest to ensure value for money expended in publically-funded health care programs and the health sector generally. First will be reviewed the origins of each initiative, the course of its implementation and the reasons for its ultimate success or failure. Second will an analysis of what factors contribute to the possible success or failure of the comparative effectiveness research initiative.

II. THE ROAD TO COMPARATIVE EFFECTIVENESS

The federal leadership in comparative effectiveness research is possible because of the infrastructure to support and assess research and in the National Institutes of Health (NIH) and the Food and Drug Administration (FDA). Following World War II, the federal government greatly expanded its commitment to biomedical research.\(^3\) An important result of this funding was the creation of academic medical centers throughout


the United States that collectively comprise perhaps the greatest research enterprise in the world. In the Drug Amendments of 1962, Congress established modern safety and efficacy regulation for pharmaceutical products, and then took up regulation for medical devices and technology with the Medical Device Amendments of 1976.

In 1965, Congress enacted, and the President signed, the Social Security Amendments of 1965 establishing the Medicare and Medicaid programs. These programs provided publicly funded health insurance coverage for the elderly, disabled and some poor. The inauguration of the Medicare and Medicaid programs transformed the federal role in health care by making the federal government responsible for paying for the health care of a significant portion of the US population.

A. Early Efforts at Technology Assessment

Shortly after implementation, the cost of the Medicare program greatly exceeded prior estimates. Similarly, Medicaid expenditures rose at unexpected levels putting great pressure on state budgets. Early on, social science researchers recognized the role of health insurance in health care cost inflation.

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8 See *Proposed Medicare Reimbursement Formula: Hearings before the Senate Comm. on Finance*, 89th Cong. ii (1966).


One cause of the cost inflation was the incredible medical advances following World War II. The development of pharmaceuticals and medical devices for the diagnosis and treatment of illness and injury has been monumental. Today, there are treatments and cures for cancer and other diseases that were virtually incurable only fifty years ago. Yet it soon became apparent that medical advances and new medical technology were major factors in the rising cost of medical care.

By the 1970s, many policy makers, scientists and other observers were concerned about the ability of government to make sound decisions on about new technology in general. In 1972, Congress enacted the Technology Assessment Act of 1972 and established the Congressional Office of Technology Assessment (OTA) to provide “unbiased information concerning the physical, biological, economic, social, and political effects” of technological applications. Over the years, OTA conducted numerous studies of health care technologies. In the mid-1990s, the Republican-controlled Congress declined to appropriate funding for OTA and it closed in 1996.

In the 1970s, on the theory that new medical technologies were a contributing factor in the escalating costs of medical care, the federal government undertook efforts to

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assess the effectiveness of new medical technologies.\textsuperscript{17} In 1978, Congress established the National Center for Health Care Technology within the Public Health Service.\textsuperscript{18} The Center was conduct and sponsor assessments of health care technologies and to coordinate such efforts within the US Department of Health, Education and Welfare (now the US Department of Health and Human Services (DHHS)).\textsuperscript{19} One function of the center was to evaluate ion technology for purposes of determining whether Medicare should cover the new technology.\textsuperscript{20} Opposed by the medical device industry and the American Medical Association,\textsuperscript{21} the Reagan Administration eliminated the center’s budget in 1982 and the center closed. DHHS continued its technology assessment activities in the Public Health Service through the Office of Health Technology Assessment (OHTA).\textsuperscript{22} Despite these setbacks for federal efforts at technology assessment, interest has remained in how to do medical technology assessment effectively.\textsuperscript{23}

\begin{itemize}
\item \textsuperscript{21} Id.
\end{itemize}
B. The Ascendency of Health Services Research

Health services research developed largely to explain and tame the cost inflation in health care services as well as to improve the quality of and access to health care services. In 1969, Congress established the National Center for Health Services Research and Development in the (then) Department of Health, Education and Welfare. Academy Health, the primary professional association for health services researchers, defines health services research as follows:

Health services research is the multidisciplinary field of scientific investigation that studies how social factors, financing systems, organizational structures and processes, health technologies, and personal behaviors affect access to health care, the quality and cost of health care, and ultimately our health and well-being. Its research domains are individuals, families, organizations, institutions, communities, and populations.

In the 1980s, spurred on by health services research indicating that little was known about whether expensive medical procedures were more efficacious than less expensive treatment approaches, medical researchers and third party payers promoted outcome measures as the appropriate indicators of quality in quality assurance and

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improvement activities.\textsuperscript{26} Health services researchers demonstrated that not all costly medical procedures are more effective than less costly care.\textsuperscript{27}

In addition, the Health Care Financing Administration (HCFA), the predecessor agency of the Centers for Medicare and Medicaid Services (CMS) which administers said programs, had a strong research function which conducted research and demonstrations under Title XI of the Social Security Act.\textsuperscript{28} In the mid-1980s, HCFA launched an aggressive program of research on outcomes of care that would serve as the basis of medical practice guidelines and even coverage policy for federal health insurance programs.\textsuperscript{29}

Extensive health services research has also demonstrated that physicians and other providers have tended to provide more healthcare than necessary.\textsuperscript{30} The work of Dr. John Wennberg and colleagues has demonstrated that variation in the practice of medicine is great with unexplained variation in services provided for the same conditions.\textsuperscript{31} Dr. Wennberg and colleagues have established the Dartmouth Atlas Project, which uses

\textsuperscript{26}ROBERT H. BROOK ET AL., QUALITY OF MEDICAL CARE ASSESSMENT USING OUTCOME MEASURES: AN OVERVIEW OF THE METHOD (1976); Robert H. Brook & Kathleen N. Lohr, Monitoring Quality of Care in the Medicare Program, 258 JAMA 3138 (1987); Paul M. Ellwood, Shattuck Lecture--Outcomes Management: A Technology of Patient Experience, 318 NEW ENG. J. MED. 1549 (1988).

\textsuperscript{27}See, e.g., David M. Eddy, Variation in Physician Practice: The Role of Uncertainty, 3 HEALTH AFF. 74 (1984); Robert H. Brook & Kathleen N. Lohr, Efficacy, Effectiveness, Variations, and Quality: Boundary-Crossing Research, 23 MED. CARE 710 (1985); David M. Eddy & John Billings, The Quality of Medical Evidence: Implications for Quality of Care, 7 HEALTH AFF. 19 (1988).


\textsuperscript{29}William L. Roper et al., Effectiveness in Health Care: An Initiative to Evaluate and Improve Medical Practice, 319 NEW ENG. J. MED. 1197 (1988); William L. Roper & Glenn M. Hackbarth, HCFA’s Agenda for Promoting High-Quality Care, 7 HEALTH AFF. 91 (1988).


\textsuperscript{31}See John E. Wennberg & John Gittelsohn, Small Area Variation in Health Care Delivery 182 SCIENCE 1102 (1973); John E. Wennberg & John Gittelsohn, Variations in Medical Care Among Small Areas, 246 SCIE. AM. 120 (1982); John E. Wennberg et al., Professional Uncertainty and the Problem of Supplier-Induced Demand, 16 SOC. SCI. & MED. 811 (1982).
Medicare data to analyze utilization of health care services in national, regional, and local markets, as well as individual hospitals and affiliated physicians.\(^{32}\) This body of research is an important inspiration for recent the comparative effectiveness research initiatives.

In the Omnibus Budget Reconciliation Act of 1989, Congress established the Agency for Health Care Policy and Research.\(^{33}\) The purpose of the agency was:

> [T]o enhance the quality, appropriateness, and effectiveness of health care services, and access to such services, through the establishment of a broad base of scientific research and through the promotion of improvements in clinical practice and in the organization, financing, and delivery of health care services.\(^{34}\)

The statute charges the Administrator, appointed by the Secretary of DHHS,\(^{35}\) with conducting and supporting research, demonstration projects, evaluations, training, guideline development, and dissemination of information, on health care services and systems for the delivery of such services.\(^{36}\) The subject matter of these activities is presented at Figure 1. The agency also had to give special attention to the delivery of health care services in rural areas and to low-income groups, minority groups, and the

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\(^{34}\) *OBRA ’89*, § 6103(a) (codified as amended Public Health Service Act § 901(b), 42 U.S.C. § 299(b)).

\(^{35}\) *OBRA ’89*, § 6103(a) (codified as amended Public Health Service Act § 901(c), 42 U.S.C. § 299(c)).

\(^{36}\) *OBRA ’89*, § 6103(a) (codified as amended Public Health Service Act § 902(b)(1-8), 42 U.S.C. § 299a(a)(1-8)).
The agency could also fund independent research centers in not-for-profit entities to conduct these activities. AHCPR also had important dissemination responsibilities.

AHCPR replaced the NCHSR and also assumed the technology assessment function of the Public Health Service. AHCPR had to promote the development and application of technology assessments through the activities listed in Figure 2. In specific technology assessments, AHCPR needed to consider “the safety, efficacy, and effectiveness, and, as appropriate, the cost-effectiveness, legal, social, and ethical implications, and appropriate uses of such technologies, including consideration of geographic factors.”

The administrator of AHCPR also had to make recommendations on whether the Medicare program should pay for specific medical technologies and/or any conditions and requirements attending reimbursement for the technology. In making these recommendations, AHCPR had to consider the “safety, efficacy, and effectiveness, and, as appropriate, the cost-effectiveness and appropriate uses of such technologies.” It is consequential that “cost-effectiveness” was a criterion for AHCPR technology assessments as this criterion has been so controversial in making Medicare coverage policy and in the current comparative effectiveness initiative.

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37 OBRA ’89, § 6103(a) (codified as amended Public Health Service Act § 902(b), 42 U.S.C. § 299a(b)).

38 OBRA ’89, § 6103(a) (codified as amended Public Health Service Act § 902(c), 42 U.S.C. § 299a(c)).

39 OBRA ’89, § 6103(a) (codified as amended Public Health Service Act § 903(a), 42 U.S.C. § 299a-1(a)).

40 OBRA ’89, § 6103(a) (codified as amended Public Health Service Act § 904, 42 U.S.C. § 299a-2).

41 OBRA ’89, § 6103(a) (codified as amended Public Health Service Act § 904(a), 42 U.S.C. § 299a-2(a)).

42 OBRA ’89, § 6103(a) (codified as amended Public Health Service Act § 904(b)(2), 42 U.S.C. § 299a-2(b)(2)).

43 OBRA ’89, § 6103(a) (codified as amended Public Health Service Act § 904(d), 42 U.S.C. § 299a-2(d)).

44 OBRA ’89, § 6103(a) (codified as amended Public Health Service Act § 904(d)(2), 42 U.S.C. § 299a-2(d)(2)).

45 See Section IV.B. infra.
OBRA ’89 establishes several other notable programs. Perhaps the most well know program is the Forum for Quality and Effectiveness in Health Care. Pursuant to procedures and requirements specified in the statute, the program director had to arrange for the development and periodic review of the following:

1. clinically relevant guidelines that may be used by physicians, educators, and health care practitioners to assist in determining how diseases, disorders, and other health conditions can most effectively and appropriately be prevented, diagnosed, treated, and managed clinically; and
2. standards of quality, performance measures, and medical review criteria through which health care providers and other appropriate entities may assess or review the provision of health care and assure the quality of such care.

The Forum was designed to facilitate guideline development through the convocation of expert panels and formal recognition of guidelines developed by other appropriate groups.

The second important program was the research program on Outcomes of Health Services and Procedures under Title XI of the Social Security Act. The program conducted and supported research on “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.” Research had to ensure that the needs and priorities of the Medicare and Medicaid programs were reflected in the procedures for developing treatment-specific or condition-specific practice guidelines for clinical treatments and conditions in forms appropriate for use in clinical practice.

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46 OBRA ’89, § 6103(a) (codified as amended Public Health Service Act §§ 911 & 912(b), 42 U.S.C. § 299b).
47 OBRA ’89, § 6103(a) (codified as amended Public Health Service Act § 913, 42 U.S.C. §§ 299b-1(b) & 299b-2).
48 OBRA ’89, § 6103(a) (codified as amended Public Health Service Act § 912(a), 42 U.S.C. § 299b-1(a)).
51 OBRA ’89 §6103(b) (codified as amended Social Security Act § 1142(a)(1)(A), 42 U.S.C. § 1320b–12(a)(1)(A)).
educational programs, and for reviewing quality and appropriateness of medical care. The program also had to conduct and support “evaluations of the comparative effects, on health and functional capacity, of alternative services and procedures utilized in preventing, diagnosing, treating, and clinically managing diseases, disorders, and other health conditions.”

Under this authority, HCFA established the interdisciplinary Patient Outcome Research Teams (PORTs), which evaluated specific procedures widely used by Medicare beneficiaries. The research program was also responsible for establishing initial medical practice guidelines for high volume Medicare services. Further CMS had to use these guidelines in the Medicare program to “improve the...

<table>
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<tr>
<th>Subject Matter of AHRQ Research and Activities</th>
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<tbody>
<tr>
<td><strong>Research Issues Addressed as Part of the Mission of AHRQ</strong></td>
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<tr>
<td>• The development and assessment of methods for enhancing patient participation in their own care and for facilitating shared patient-physician decision-making;</td>
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<tr>
<td>• The outcomes, effectiveness, and cost-effectiveness of health care practices, including preventive measures and long-term care;</td>
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<td>• Existing and innovative technologies;</td>
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<td>• The costs and utilization of, and access to health care;</td>
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<td>• The ways in which health care services are organized, delivered, and financed and the interaction and impact of these factors on the quality of patient care;</td>
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<tr>
<td>• Methods for measuring quality and strategies for improving quality; and</td>
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<tr>
<td>• Ways in which patients, consumers, purchasers, and practitioners acquire new information about best practices and health benefits, the determinants and impact of their use of this information;</td>
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<tr>
<th><strong>Required Subject Matter of AHRQ Activities</strong></th>
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<tr>
<td>• The quality, effectiveness, efficiency, appropriateness and value of health care services;</td>
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<tr>
<td>• Quality measurement and improvement;</td>
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<tr>
<td>• Outcomes, cost, cost-effectiveness, and use of health care services and access to such services</td>
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<tr>
<td>• Clinical practice, including primary care and practice-oriented research</td>
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<tr>
<td>• Health care technologies, facilities, and equipment;</td>
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<td>• Health care costs, productivity, organization, and market forces;</td>
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<tr>
<td>• Health promotion and disease prevention, including clinical preventive services;</td>
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<tr>
<td>• Health statistics, surveys, database development, and epidemiology; and</td>
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<td>• Medical liability.</td>
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52 OBRA ’89 §6103(b) (codified as amended Social Security Act § 1142(a)(1)(B), 42 U.S.C. § 1320b–12(a)(1)(B)).

53 OBRA ’89 §6103(b) (codified as amended Social Security Act § 1142(a)(2), 42 U.S.C. § 1320b–12(a)(2)).

54 See John E. Wennberg, *The More Things Change...: The Federal Government's Role In The Evaluative Sciences*, HEALTH AFF. (June 25, 2003), [http://content.healthaffairs.org/content/early/2003/06/25/hlthaff.w3.308.full.pdf](http://content.healthaffairs.org/content/early/2003/06/25/hlthaff.w3.308.full.pdf);

55 OBRA ’89 §6103(b) (codified as amended Social Security Act § 1142(a)(3)(A), 42 U.S.C. § 1320b-12)).
quality, effectiveness, and appropriateness of care” for Medicare beneficiaries. Its statutory mandate clearly envisioned visualized the development of guidelines that would be used by the Medicare programs and other third party payers to determine coverage of benefits and payment levels.

AHCPR had a very turbulent history, especially with the advent of Republican majorities in Congress in 1994. Following release of a controversial guideline for the treatment of low back pain, several members of Congress sought to terminate funding for AHCPR. Further, a manufacturer of devices used to treat low back pain sued the agency for alleged violations of the Federal Advisory Committee Act in connection with the Low Back Pain Panel that developed the guideline. Congress ultimately spared funding for the agency on the condition that the agency focused only on quality measurement and improvement in the future.

56 Id.


In the Health Care Research and Quality Act of 1999, Congress established the Agency for Healthcare Research and Quality (AHRQ) to replace the controversial AHCPR. The mission of the new agency was:

[T]o enhance the quality, appropriateness, and effectiveness of health services, and access to such services, through the establishment of a broad base of scientific research and through the promotion of improvements in clinical and health system practices, including the prevention of diseases and other health conditions.

The Agency’s mission is to promote health care quality improvement by conducting and supporting research that develops and presents scientific evidence regarding all aspects of health care. Specific research issues to be addressed in executing its mission are presented at Figure 3. AHRQ’s mission is also to support the synthesis and dissemination of available scientific evidence for use by patients, consumers, practitioners, providers, purchasers, policy makers, and educators, as well as to support initiatives to

<table>
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<th>Figure 4</th>
<th>MMA Comparative Effectiveness Mandates for AHRQ</th>
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<tr>
<td><strong>Activities Pertaining to AHRQ Comparative Effectiveness Research</strong></td>
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<tr>
<td>• Identify priorities for research related to health care items and services, including prescription drugs.</td>
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<tr>
<td>• Evaluate and synthesize evidence about comparative clinical effectiveness related to these priorities.</td>
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<tr>
<td>• Identify key information gaps for future research</td>
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<tr>
<td>• Disseminate the results of comparative effectiveness reviews to the public, Medicare Advantage plans, and other health plans.</td>
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**AHRQ Research Priorities for Comparative Effectiveness under MMA**

<table>
<thead>
<tr>
<th>Ischemic heart disease</th>
<th>Cancer</th>
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<tbody>
<tr>
<td>Chronic obstructive pulmonary disease/asthma</td>
<td>Stroke, including control of hypertension</td>
</tr>
<tr>
<td>Arthritis and non-traumatic joint disorders</td>
<td>Diabetes mellitus</td>
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<tr>
<td>Dementia, including Alzheimer's disease</td>
<td>Pneumonia</td>
</tr>
<tr>
<td>Peptic ulcer/dyspepsia</td>
<td>Depression and other mood disorders</td>
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64 Health Care Research and Quality Act of 1999 § 2(a) (codified as amended Public Health Service Act § 901(b), 42 U.S.C. §299(b) (2010)).


advance private and public efforts to improve health care quality.\textsuperscript{67} As a matter of mission, the statute imposed requirements on for research with respect to rural and inner-city areas and priority populations.\textsuperscript{68}

In executing its mission, the agency director has specified statutory duties. These duties include: (1) conducting and supporting research, evaluations, and training, (2) supporting demonstration projects, research networks, and multidisciplinary centers, (3) providing technical assistance, and (4) disseminating information on health care and systems for the delivery of such care.\textsuperscript{69} The research and other activities must address the issues listed in Figure 3. The statute requires that the agency’s activities must be “appropriately coordinated” with experiments, demonstration projects, and other related activities conducted with respect to the Medicare, Medicaid and SCHIP programs.\textsuperscript{70}

Finally, the statute definitely states that the agency “shall not mandate national standards of clinical practice or quality health care standards” and that “[r]ecommendations resulting from projects funded and published by the Agency shall include a corresponding disclaimer.”\textsuperscript{71} The statute closes with the admonition that “[n]othing in this section shall be construed to imply that the Agency’s role is to mandate a national standard or specific approach to quality measurement and reporting.”\textsuperscript{72} Congress undoubtedly included this admonition to prevent the political fallout AHCPR experienced when it engaged in developing specific medical practice guidelines.

In Section 1013 of the MMA, enacted in 2003, Congress expanded AHRQ’s duties, requiring it to conduct activities pertinent to evaluating, generating, and disseminating evidence about the comparative effectiveness of medications, devices, and other interventions.\textsuperscript{73} These activities are as well as research priorities are listed in Figure 4.

\textsuperscript{67} Health Care Research and Quality Act of 1999 § 2(a) (codified as amended Public Health Service Act § 901(b)(1)(B & C), 42 U.S.C. §299(b)(3) (2010)).

\textsuperscript{68} Health Care Research and Quality Act of 1999 § 2(a) (codified as amended Public Health Service Act § 901(c), 42 U.S.C. §299(c) (2010)).

\textsuperscript{69} Health Care Research and Quality Act of 1999 § 2(a) (codified as amended Public Health Service Act § 902(a), 42 U.S.C. §299a(a) (2010)).

\textsuperscript{70} Health Care Research and Quality Act of 1999 § 2(a) (codified as amended Public Health Service Act § 902(d), 42 U.S.C. §299a(d) (2010)).

\textsuperscript{71} Health Care Research and Quality Act of 1999 § 2(a) (codified as amended Public Health Service Act § 902(e), 42 U.S.C. §299a(e) (2010)).

\textsuperscript{72} Health Care Research and Quality Act of 1999 § 2(a) (codified as amended Public Health Service Act § 902(f), 42 U.S.C. §299(f) (2010)).

C. The Saga of Medicare Coverage Policy

As health care costs continued to rise, the stewards of the Medicare program in HCFA became increasingly interested in Medicare coverage policy. Health policy experts have long been concerned that Medicare’s coverage of health care ineffective services and products, particularly new technology, contribute to increased Medicare expenditures.74

Beginning in the early 1980s, HCFA began examining whether specific medical technologies and procedures constituted “reasonable and necessary” as well as “non-experimental” health care services that would be covered and paid for by the Medicare program.75 One impetus for this examination was the realization that Medicare was paying for heart transplants in some areas of the country and not others and that the decision to cover heart transplants had been made, as was the practice in the Medicare program since its inception, by local Medicare contractors. In 1980, HCFA issued a national coverage determination (NCD) that denied coverage for heart transplants in the future because of potential inequities and other issues.76 A year later, HCFA reversed its decision and issued a ruling covering them under certain circumstances.77

In the early 1980s, HCFA developed an internal process for making national coverage decisions.78 Specifically, HCFA convened an informal committee of physicians who worked for HCFA.79 The committee was not established by statute or regulation and met privately with no published agenda or opportunity for participation by

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75 Kinney, supra note 22, at 869.


78 Kinney, supra note 22, at 879–83.

79 See id. at 880.
interested parties or members of the public. For more complex or controversial coverage issues, the HCFA coverage policy-making office would request a technology assessment from the National Center for Health Care Technology and its successor agencies.

In 1987, as part of the settlement of *Jameson v. Bowen*, a lawsuit challenging a coverage policy, HCFA published a notice explaining its procedures for making coverage decisions. In 1989, HCFA published a proposed rule to make a more public, accountable process for making national and local coverage policy for the Medicare program. This proposed rule proved controversial chiefly because of its articulation of cost effectiveness as a criterion for making coverage decisions. There was a resounding outcry from the medical device industry and other stakeholders who argued that Medicare did not have the statutory authority to use cost-effectiveness as a coverage criterion. Since the 1980s, HCFA and its successor agency CMS have had difficulty promulgating criteria for making NCDs. Following publication of the 1989 proposed rule, HCFA established an internal review process with its Technical Advisory Committee (TAC), which was comprised of medical directors from Medicare contractors and representatives of other interested federal agencies, among others.

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80 See id.

81 Id. at 881.


Through the 1990s, HCFA continued to struggle with designing a coverage decision-making process that responded to the concerns of beneficiaries, providers, and device manufacturers, and other critics. In 1995, HCFA did promulgate a final rule on criteria and procedures for extending coverage to certain devices and related services. In 1998, the U.S. General Accounting Office (GAO) reported that the TAC violated the Federal Advisory Committee Act. Following this report, HCFA appointed a Medicare Coverage Advisory Committee (MedCAC), comprised of outside experts, which conducted public meetings on coverage issues and permitted manufacturers and other interested parties to present their views.

In the late 1990s, the Republican-dominated House Ways and Means Committee pressured HCFA to reform its coverage decision-making and appeals processes. The Health Subcommittee held multiple hearings on the coverage decision-making and appeals processes. In April 1999, in response to pressure from the subcommittee and (statement of Hon. Bruce C. Vladeck, Administrator, Health Care Financing Administration); see Grinstead, supra note 85 at 14.


the medical device industry, HCFA published a notice that outlined the administrative process for making national coverage policy.  

The Medicare, Medicaid, and SCHIP Benefits Improvement and Protection Act of 2000 (BIPA) established statutory requirements for the national and local coverage decision-making processes. In making a NCD, HCFA (now CMS) was required to afford the public notice and opportunity to comment prior to implementation of the determination as well as meetings of relevant advisory committees. HCFA (and now CMS) must consider applicable information (including clinical experience and medical, technical, and scientific evidence) and provide a clear statement of the basis for the determination (including responses to comments received from the public) as well as the assumptions underlying that basis. CMS must also make the data used in making the decision available to the public. While HCFA had already adopted many of the BIPA reforms in its April 1999 notice, BIPA mandated an open process. BIPA also required that HCFA file a report with Congress on its progress in implementing these requirements.

Further, BIPA contained improvements to the MedCAC process that HCFA had established. Specifically, any advisory committee appointed to advise HCFA (now CMS) was required to ensure the full participation of the nonvoting members in the

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96 BIPA § 522(a) (2000) (codified in Social Security Act § 1862(a), 42 U.S.C. § 1395y(a)).

97 BIPA § 522(a) (2000) (codified in Social Security Act § 1862(a), 42 U.S.C. § 1395y(a)).

98 BIPA § 522(a) (2000) (codified in Social Security Act § 1862(a), 42 U.S.C. § 1395y(a)).


100 BIPA § 552(c) (codified as amended at Social Security Act § 1114(i)(1), 42 U.S.C. 1314(i)(1)).
deliberations of the advisory committee, and shall provide such non-voting member access to all information and data made available to voting members of the advisory committee. In addition, BIPA reformed the process for beneficiary appeals of coverage decisions, and provided a process for beneficiaries to appeal a NDC directly without raising it in the context of a claim.

In 2003, Congress again made major changes to the national coverage policymaking process in Section 731 of the Medicare Modernization Act. MMA also provided changes in the appeals process for beneficiaries appealing adverse Medicare coverage decisions.

The first improvement required CMS to develop “factors” to consider in making NCDs. The “factors” were not specified in the statute. Rather, CMS was required to develop “guidance documents” like those issued under section 701(h) of the Federal Food, Drug, and Cosmetic Act. MMA Section 731 also imposed time limits on CMS in making NCDs. Deadlines for NCDs vary from six to nine months depending on whether an external technology assessment or an advisory committee deliberation is needed or a clinical trial is involved. MMA Section 731 also established a process for public comment on NCDs. Within six months of a request for an NDC, CMS must make a “draft of the proposed decision on the request” and make this draft available to

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101 BIPA § 552(c) (codified as amended at Social Security Act § 1114(i)(1), 42 U.S.C. 1314(i)(1)). Non-voting members include six industry representatives, six consumer representatives and six patient advocates appointed to the committee.

102 BIPA § 521 (codified as amended at Social Security Act §1869(f), 42 U.S.C. §1395ff(f)).

103 BIPA § 522(a) (codified as amended at Social Security Act §1869(f), 42 U.S.C. §1395ff(f)).

104 MMA § 731(a)(1) (codified at Social Security Act § 1862(l)(1), 42 U.S.C. §1395y(l)).

105 MMA § 731(a)(1)(B) (codified at Social Security Act § 1862(l)(1), 42 U.S.C. §1395y(l)(1)).

106 Id., citing 21 U.S.C. 301(h).


the public on CMS’ website. The comment period is thirty days. CMS must make a decision within sixty days after the close of the comment period. What must be included in the final decision are presented at Figure 5.

MMA 731 also reformed the process for making local coverage decisions. CMS is charged with making a plan to evaluate new local coverage determinations to determine which determinations should be adopted nationally and to what extent greater consistency can be achieved among local coverage determinations. CMS should serve as a center to disseminate information on local coverage determinations among fiscal intermediaries and carriers to reduce duplication of effort.

While the concerns have focused on national coverage policy, there have also been concerns raised about local coverage policy-making. In 2003, the US Governmental Accountability Office raised concerns over inconsistent local coverage policy around the country. GAO noted that Medicare covered about 99 percent of the

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<td>• Summaries of the public comments received and responses to such comments;</td>
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<tr>
<td>• Availability to the public of the evidence and other data used in making such a decision when the decision differs from the recommendations of the Advisory Committee.</td>
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<tr>
<td>• For approved NCDs, assignment of a temporary or permanent code (whether existing or unclassified) and implement the coding change.</td>
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114 MMA § 731(a)(1) (B) (codified at Social Security Act § 1862(l)(5), 42 U.S.C. § 1395y(l)(5)).  

115 MMA § 731(a)(1) (B) (codified at Social Security Act § 1862(l)(5)(A), 42 U.S.C. § 1395y(l)(5)(A)).  

116 MMA § 731(a)(1) (B) (codified at Social Security Act § 1862(l)(5)(C), 42 U.S.C. § 1395y(l)(5)(C)).  


118 U.S. GOV’T ACCOUNTABILITY OFFICE, 03-175, MEDICARE: DIVIDED AUTHORITY FOR POLICIES ON COVERAGE OF PROCEDURES AND DEVICES RESULT IN INEQUITIES (2003),
procedures and devices for which the American Medical Association or other authoritative body has assigned codes in 2001. The great majority of procedures and devices were assigned without coverage policies that describe the circumstances for Medicare coverage or through local coverage determinations. This situation has led to inequities in coverage across states.

In 2000, CMS issued a notice of intent to engage in a rulemaking to establish criteria for coverage decision-making. In a September 2003 notice, CMS announced that it would not pursue this rulemaking due to the fact that "there are substantial competing interests about the coverage criteria." In 2006, CMS published a guidance document outlining the criteria for referring a proposed NCD to the advisory committee.

HCFA and then CMS have struggled to develop criteria for making Medicare coverage policy and have been unable to promulgate a final rule on such criteria. Much of the debate is whether CMS should use cost-effectiveness analysis in making


119 Id.

120 Id.

121 Id.


Medicare coverage policy. Some scholars specifically suggested that Medicare use cost-effectiveness analysis in coverage policy and identified ways CMS could do so.

In recent years, CMS is placing great emphasis on assuring that coverage decisions are based on sound evidence. In April 2005, CMS posted a draft guidance document describing a new approach to coverage policy called "coverage with evidence development" (CED) on its website. CMS has also promoted the use of comparative effectiveness research in making Medicare coverage policy.

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130 See e.g., Mathew J. Lindsay et al., The National Oncologic PET Registry: Expanded Medicare Coverage for PET under Coverage with Evidence Development, 188 AM. J. ROENTGENOLOGY 1109 (2007); Tanisha Carino et al., Medicare’s Coverage of Colorectal Cancer Drugs: A Case Study in Evidence Development and Policy, 25 HEALTH AFF. 1231 (2006); Sean Tunis, A Clinical Research Strategy to Support Shared
D. The AHRQ, the NIH and Comparative Effectiveness Research

Ostensibly, the concept of comparative effectiveness emerged from the evidence-based medicine movement.\textsuperscript{131} Policy makers and researchers have recognized that a more concerted effort to facilitate comparative effectiveness research with a strong federal role in terms of funding the research is needed. Several influential health policy experts have called for such a federal role.\textsuperscript{132}

Also, important work has examined methods for conducting comparative effectiveness research.\textsuperscript{133} One important issue is whether cost-effectiveness analysis should be a part of comparative effectiveness research.\textsuperscript{134}

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With respect to comparative effectiveness research, the NIH has played an important role. Specifically, the NIH has funded important studies on the comparative effectiveness of different treatment modalities. Funding from the American Recovery and Reinvestment Act of 2009 (ARRA), described below, has enabled the NIH to fund a substantial amount of comparative effectiveness research.

Since 1995, AHRQ has been the lead federal agency on comparative effectiveness research and technology assessment. Its Centers for Education and Research on Therapeutics (CERTs) demonstration program is a national initiative to conduct research and provide education that advances the optimal use of therapeutics (i.e., drugs, medical devices, and biological products). The program consists of 14 research centers and a coordinating center and is funded and run jointly by AHRQ and the FDA. Another initiative, Developing Evidence to Inform Decisions about Effectiveness, conducts and supports research specifically on “treatment appropriateness, health outcomes, and

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136 See, e.g., Gerald L. Andriole et al., Mortality Results from a Randomized Prostate-Cancer Screening Trial, 360 NEW ENGLAND J. MED 1310 (2009); Jeffrey A. Lieberman et al., Effectiveness of Antipsychotic Drugs in Patients with Chronic Schizophrenia, 353 NEW ENGLAND J. MED. 1209 (2005); Gust H. Bardy et al., Amiodarone or an Implantable Cardioverter–Defibrillator for Congestive Heart Failure, 352 NEW ENGLAND J. MED 225 (2005); Diabetes Prevention Program Research Group, Reduction in the Incidence of Type 2 Diabetes with Lifestyle Intervention or Metformin, 346 NEW ENGLAND J. MED. 393 (2002); The Antihypertensive and Lipid-Lowering Treatment to Prevent Heart Attack Trial (ALLHAT) Officers and Coordinators for the ALLHAT Collaborative Research Group, Major Outcomes in High-Risk Hypertensive Patients Randomized to Angiotensin-Converting Enzyme Inhibitor or Calcium Channel Blocker Vs Diuretic, 288 JAMA 2981 (2002). See Hodes, supra note 141.


138 See note 161-163 infra and accompanying text.

comparative effectiveness.” Also, the newer Evidence-based Practice Centers Program is intended to “improve the quality and effectiveness of healthcare through technology assessments.”

Congress has also shown interest in comparative effectiveness research with several bills establishing comparative effectiveness research initiatives. The most important bill, in terms of its influence on PPACA, was S. 3408 introduced by Senators Max Baucus (D-MT) and Kent Conrad (D-SD) in 2008. This bill proposed establishment of an independent institute along the lines of the Patient-Center Outcomes Research Institute established in PPACA.

In August 2007, the House passed H.R. 3162, Children's Health and Medicare Protection Act of 2007 (CHAMP Act), which included a provision proposing a Center for


144 See note 161-163 infra and accompanying text.
Comparative Effectiveness Research within AHRQ. In addition, the bill would establish an independent Comparative Effectiveness Research Commission to oversee and evaluate the Center's activities as well as a Coordinating Council for Health Services Research and amend the Internal Revenue Code to establish in a Health Care Comparative Effectiveness Research Trust Fund financed in part by fees on health insurer and employer health plans. This bill borrows extensively from H.R. 2184, Enhanced Health Care Value for All Act. This model also served as the model for the Patient-Centered Outcomes Research Institute established in PPACA.


In the wake of the economic crash of 2008, then newly-elected President Barak Obama pressed the United States Congress to enact the American Recovery and Reinvestment Act of 2009 (ARRA).

Section 804 of ARRA established a Federal Coordinating Council for Comparative Effectiveness Research (the Council) essentially to coordinate comparative effectiveness research across the federal government. The purpose of the Council was as follows:

The Council shall foster optimum coordination of comparative effectiveness and related health services research conducted or supported by relevant agencies.

ARRA § 804(d) (2).


146 Id.


148 See Section III.D. infra.


150 ARRA § 804(a) (codified at 42 U.S.C. § 299b–8(a).
Federal departments and agencies, with the goal of reducing duplicative efforts and encouraging coordinated and complementary use of resources. 151

The duties of the Council were to assist federal agencies in conducting or supporting comparative effectiveness research. 152 The other duty was to advise the President and Congress on “strategies with respect to the infrastructure needs of comparative effectiveness research within the Federal Government” and “organizational expenditures for comparative effectiveness research by relevant Federal departments and agencies.” 153 The Council was comprised of fifteen senior officers or employees of the federal agencies listed in Figure 6. 154 At least half of the members were to be physicians or “other experts with clinical expertise.” 155 The Secretary of DHHS served as its chair. 156

The Council was also required to prepare reports to Congress. 157 Rules of construction governed these reports. Specifically, the Council was prohibited from mandating coverage, reimbursement, or other policies for any public or private payer nor shall any of the Council’s recommendations be “construed as mandates or clinical guidelines for payment, coverage, or treatment.” 158 Upon enactment of PPACA, Federal Coordinating Council created in the American Recovery and Reinvestment Act of 2010 sunseted. 159 In June 2009, the Federal Coordinating Council for Comparative Effectiveness Research issued its report with recommendations on approaches and priorities. 160

151 ARRA § 804(b) (codified at 42 U.S.C. § 299b–8(b).


158 ARRA § 804(g) (codified at 42 U.S.C. § 299b–8(g).

159 PPACA § 6303.

160 Federal Coordinating Council for Comparative Effectiveness Research, Report to the President and Congress. U.S. Department of Health and Human Services (2009),
ARRA also awarded included an extraordinary amount of money, $1.1 billion, to fund comparative effectiveness research.\textsuperscript{161} The funds were designated for agencies and the Office of the Secretary within DHHS: $300 million for the AHRQ, $400 million for the NIH, and $400 million for the Office of the Secretary.\textsuperscript{162} The allocation to AHRQ alone was more than its total budget of $370 million for fiscal year 2009.\textsuperscript{163}

ARRA directed and funded the Institute of Medicine (IoM) to develop a definition of comparative effectiveness research as well as research priorities.\textsuperscript{164} The IoM’s report, \textit{Initial National Priorities for Comparative Effectiveness Research},\textsuperscript{165} defined comparative effectiveness research as follows:

CER is the generation and synthesis of evidence that compares the benefits and harms of alternative methods to prevent, diagnose, treat, and monitor a clinical condition or to improve the delivery of care. The purpose of CER is to assist consumers, clinicians, purchasers, and policy makers to make informed decisions that will improve health care at both the individual and population levels.\textsuperscript{166}

The IoM also selected 100 topics for comparative effectiveness research after obtaining extensive input from professional organizations and the public.\textsuperscript{167} For example,

\begin{itemize}
  \item Available at http://www.hhs.gov/recovery/programs/cer/annualrpt.pdf;
  \item \textit{Id.}
  \item \textit{COMMITTEE ON COMPARATIVE EFFECTIVENESS RESEARCH PRIORITIZATION, INSTITUTE OF MEDICINE, INITIAL NATIONAL PRIORITIES FOR COMPARATIVE EFFECTIVENESS RESEARCH} (National Academies Press, 2009).
  \item \textit{Id.} at 13.
  \item \textit{100 Initial Priority Topics for Comparative Effectiveness Research}, \textbf{INSTITUTE OF MEDICINE},
\end{itemize}
the first priority is: “Compare the effectiveness of treatment strategies for atrial fibrillation including surgery, catheter ablation, and pharmacologic treatment.”\textsuperscript{168}

The NIH has important responsibilities under ARRA to conduct and support comparative effectiveness research. The NIH has established and published research priorities.\textsuperscript{169} It has also established several initiatives, a major one of which is the Research and Research Infrastructure "Grand Opportunities," or "GO" grants.\textsuperscript{170} Comparative effectiveness research supported by the "GO" grants program should provide a “high short-term return” and offer a high likelihood of enabling growth and investment in biomedical research and development, public health, and health care delivery.\textsuperscript{171} The NIH has recently published a report on comparative effectiveness research at the NIH.\textsuperscript{172}

In addition, ARRA provided funding for the FDA to engage in a program to improve methodologies for comparative effectiveness research.\textsuperscript{173} FDA’s basic responsibility under ARRA is to build the clinical data and standards infrastructure, tools, skills, and capacity for comparative effectiveness research. A major priority for the

\textsuperscript{168}Id.


\textsuperscript{171}Id.

\textsuperscript{172}See Michael S. Lauer & Francis S. Collins, Using Science to Improve the Nation's Health System: NIH's Commitment to Comparative Effectiveness Research, 303 JAMA. 2182 (2010).

\textsuperscript{173}US Food and Drug Administration, Comparative Effectiveness Research Plan, Science Board Meeting (Nov. 15, 2010) (PowerPoint Presentation). This presentation is available through the agenda materials for the meeting; see US Food and Drug Administration, Slides for the November 15, 2010 Meeting of the Science Board to the FDA, available at http://www.fda.gov/AdvisoryCommittees/CommitteesMeetingMaterials/ScienceBoardtotheFoodandDrugAdministration/ucm233252.htm.

\textsuperscript{174}Id.
FDA’s work is “to harness the capacity of large study data repositories to answer questions about care for priority interventions through infrastructure development.”

Under ARRA, AHRQ had the major role in promoting comparative effectiveness research as well as educating stakeholders, medical professionals and the public about it. AHRQ’s Effective Health Care program has already funded an ambitious agenda of research projects. AHRQ has issued a report summarizing its implementation of comparative effectiveness research.

2. The Brouhaha over Comparative Effectiveness Research in 2009

In the debate over health reform, Governor Sarah Palin made a connection between federally-sponsored comparative effectiveness research and rationing of health care that precipitated a national debate about government-mandated health care rationing under health reform. Former Alaska Governor Sarah Palin injected a jolt into the debate with a comment on Facebook with the following assertions:

As more Americans delve into the disturbing details of the nationalized health care plan that the current administration is rushing through Congress, our collective jaw is dropping, and we’re saying not just no, but hell no!

* * *

And who will suffer the most when they ration care? The sick, the elderly, and the disabled, of course. The America I know and love is not one in which my parents or my baby with Down Syndrome will have to stand in front of Obama’s ‘death panel’ so his bureaucrats can decide, based on a

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175 Id.


subjective judgment of their 'level of productivity in society,' whether they are worthy of health care. Such a system is downright evil.  

A key inspiration for the attack of conservative commentators and politicians about comparative effectiveness and rationing was the Federal Coordinating Council for Comparative Effectiveness Research under ARRA. Dr. Ezekiel Emanuel, brother of the President’s Chief of Staff, Rahm Emanuel and a member of the council, made statements in several academic articles years before that implied the appropriateness of rationing health care services taking into account social circumstances as a criterion for rationing. The New York Post reported the story, and created uproar among many on the right end of the political spectrum.

III. PATIENT-CENTERED OUTCOMES RESEARCH INSTITUTE

To establish the Patient-Centered Outcomes Research Institute, PPACA enacts a new part to Title XI of the Social Security Act entitled “Comparative Effectiveness Research.” PPACA also amends Title IX of the Public Health Service Act to provide for the dissemination of research and building research capacity in collaboration (and


183 PPACA § 6301(a) (codified at Social Security Act §§1181-1183, 42 U.S.C. §§ 1320e.)
pursuant to contract) with AHRQ and the NIH.\textsuperscript{184} Finally, PPACA establishes the Patient-Center Outcomes Research Trust Fund (PCORTF),\textsuperscript{185} and amends the Internal Revenue Code to provide for the supervision and funding of the trust fund.\textsuperscript{186}

A. Key Definitions

PPACA defines “comparative clinical effectiveness research” and “research” follows:

The terms ‘comparative clinical effectiveness research’ and ‘research’ mean research evaluating and comparing health outcomes and the clinical effectiveness, risks, and benefits of 2 or more medical treatments, services, and items described in subparagraph (B).\textsuperscript{187}

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

The medical treatments, services, and items described in this subparagraph are health care interventions, protocols for treatment, care management, and delivery, procedures, medical devices, diagnostic tools, pharmaceuticals (including drugs and biologicals), integrative health practices, and any other strategies or items being used in the treatment, management, and diagnosis of, or prevention of illness or injury in, individuals.\textsuperscript{188}

PPACA also defines “conflicts of interest” including “real conflicts of interest” that, as described below, are of operational interest in the affairs of the Institute. \textsuperscript{189} A

\textsuperscript{184} PPACA § 6301(b) (codified at Public Health Service Act §937, 42 U.S.C. §1320e(b))

\textsuperscript{185} PPACA § 6301(b)(3) & (d) (codified at Social Security Act §1181(b)(3) & §1183(a), 42 U.S.C. §1301((b)(3) & §1303).

\textsuperscript{186} PPACA § 6301(e) (codified at Internal Revenue Code §9511 (creation and federal funding of trust fund) & §§ 4375-4377 (taxation of private health plans to support the trust fund).

\textsuperscript{187} PPACA § 6301(a) (codified at Social Security Act §1181(a)(2)(A), 42 U.S.C. §1301((a)(2)(A)).

\textsuperscript{188} PPACA § 6301(a) (codified at Social Security Act §§118-18(a)(2)(B), 42 U.S.C. §§ 1301((a)(2)(B)).

\textsuperscript{189} PPACA § 6301(a) (codified at Social Security Act §1181(a)(3) & (4), 42 U.S.C. §1301((a)(3) & (4)).
“conflict of interest” is an “association, including a financial or personal association, that have the potential to bias or have the appearance of biasing an individual’s decisions in matters related to the Institute or the conduct of activities under the statute.” Avoiding real conflicts of interest is a paramount objective of the design of the Institute’s structure and procedures.

**B. Purpose of the Institute**

PPACA states the purpose of the Institute as follows:

The purpose of the Institute is to assist patients, clinicians, purchasers, and policy-makers in making informed health decisions by advancing the quality and relevance of evidence concerning the manner in which diseases, disorders, and other 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 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).

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<td><strong>Considerations for Research Priorities</strong></td>
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<td>• Factors of diseases incidence, prevalence and burden in the United States (with an emphasis on chronic diseases),</td>
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<td>• Gaps in evidence in terms of clinical outcomes, practice variations and health disparities in terms of delivery and outcomes of care,</td>
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<tr>
<td>• The potential for new evidence to improve patient health, well-being, and the quality of care,</td>
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<tr>
<td>• The effect on national expenditures associated with a health care treatment, strategy, or health conditions, as well as patient needs, outcomes, and preferences,</td>
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<tr>
<td>• The relevance to patients and clinicians in making informed health decisions,</td>
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<tr>
<td>• Priorities in the National Strategy for quality care established under section 399H of the Public Health Service Act,</td>
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<tr>
<td><strong>Considerations for a Research Project Agenda</strong></td>
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<tr>
<td>• The types of research that might address each priority,</td>
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<tr>
<td>• The relative value (determined based on the cost of conducting research compared to the potential usefulness of the information produced by research) associated with the different types of research,</td>
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<tr>
<td>• Such other factors as the Institute determines appropriate.</td>
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190 PPACA § 6301(a) (codified at Social Security Act §1181(a)(3), 42 U.S.C. § 1301(a)(3)).  
191 PPACA § 6301(a) (codified at Social Security Act § 1181(c), 42 U.S.C. § 1301(c)).
C. Duties

The duties of the Institute are straightforward and are described in the statute in great detail. The duties are all concerned with developing and executing a research project agenda. Several “duties” pertain to establishing processes to ensure the quality of the research, the proper dissemination of research results, and the transparency and integrity of the research and reporting processes. The statute is unusually detailed in specifying methodologies and processes to guide the work of the Institute.

1. Identifying Research Priorities and Establishing a Research Project Agenda

The first duty is to identify and establish research priorities and a research agenda. In identifying research priorities as well as a research project agenda, the Institute must take into account the considerations specified in Figure 7. The second duty of the Institute is to carry out the research project agenda.

Research projects must conform to standards established by Methodology Committee established within the Institute. PPACA also specifies the methodologies to be used in the Institute’s research projects. These include systematic reviews and assessments of existing and future research and evidence including original research conducted subsequent to the date of the enactment as well as primary research, such as randomized clinical trials, molecularly informed trials, and observational studies.

PPACA also authorizes the Institute to contract for the management of funding and conduct of research, with appropriate agencies and instrumentalities of the Federal Government as well as appropriate academic research, private sector research, or study-conducting entities. PPACA states a preference for awarding contracts to the NIH.

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192 PPACA § 6301(a) (codified at Social Security Act § 1181(d), 42 U.S.C. § 1301(d)).

193 PPACA § 6301(a) (codified at Social Security Act § 1181(d)(1), 42 U.S.C. § 1301(d)(1)).

194 PPACA § 6301(a) (codified at Social Security Act § 1181(d)(2), 42 U.S.C. § 1301(d)(2)).

195 PPACA § 6301(a) (codified at Social Security Act § 1181(d)(6), 42 U.S.C. § 1301(d)(6)).


and AHRQ, “but only if the research to be conducted or managed under such contract is authorized by the governing statutes of such Agency or Institutes.”

PPACA also establishes detailed conditions for the contracts for research projects, which conditions are presented in Figure 8. PPACA also expressly permits a researcher who conducts original research pursuant to contract with the Institute or an agency to publish such research in a peer-reviewed journal or other publication, as long as the researcher enters into a data use agreement with the Institute regarding the use of data from the original research.

Some additional requirements for the Institute’s research agenda include authorization to cover insurance copayments or coinsurance to the extent necessary “to preserve the validity of a research project, such as in the case where the research project must be blinded.” Also the Institute is not to allow “the subsequent use of data from original research in work-for-hire contracts with individuals, entities, or instrumentalities that have a financial interest in the results, unless approved under a data use agreement with the Institute.” The Institute must also “review and update evidence on a periodic basis as appropriate.”

Finally, in the design of its research projects, the Institute must “take into account the potential for differences in the effectiveness of health care treatments, services, and items . . . with various subpopulations, such as racial and ethnic minorities, women, age, and groups of individuals with different comorbidities, genetic and molecular sub-types.

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198 PPACA § 6301(a) (codified at Social Security Act § 1181(d)(2)(B)(i), 42 U.S.C. § 301(d)(2)(B)(i)).


201 PPACA § 6301(a) (codified at Social Security Act § 1181(d)(2)(B)(iii), 42 U.S.C. § 1301(d)(2)(B)(iii)).


203 PPACA § 6301(a) (codified at Social Security Act § 1181(d)(2)(C)), 42 U.S.C. § 1301(d)(2)(C)).
or quality of life preferences.” These groups should be included in the research projects “as feasible and appropriate.” The research must also be designed to “take into account different characteristics of treatment modalities that may affect research outcomes, such as the phase of the treatment modality in the innovation cycle and the impact of the skill of the operator of the treatment modality.”

2. Collecting Data

The Institute’s third duty is data collection. The Secretary of DHHS is to make data collected by CMS for the Medicare, Medicaid and S-CHIP programs available to the Institute as well as provide access to data networks developed under section 937(f) of the Public Health Services Act. Complying with current state and federal law, the Institute is also authorized to obtain data from federal, state, or private entities, including data from clinical databases and registries.

3. Appointing Expert Advisory Panels

The Institute may appoint “permanent or ad hoc expert advisory panels as determined appropriate to assist in identifying research priorities and establishing the research project agenda” as well as for other purposes. The Institute is required to appoint expert advisory panels for randomized clinical trials. In addition to serving

204 PPACA § 6301(a) (codified at Social Security Act § 1181(d)(2)(D), 42 U.S.C. § 1301(d)(2)(D)).

205 PPACA § 6301(a) (codified at Social Security Act § 1181(d)(2)(D), 42 U.S.C. § 1301(d)(2)(D)).

206 PPACA § 6301(a) (codified at Social Security Act § 1181(d)(2)(E), 42 U.S.C. § 1301(d)(2)(E)).

207 PPACA § 6301(a) (codified at Social Security Act § 1181(d)(3), 42 U.S.C. § 1301(d)(3)).


as resource for technical questions, the panels must address “the research question involved and the research design or protocol, including important patient subgroups and other parameters of the research.” 212 For research studies of rare diseases, the Institute must appoint an expert advisory panel to assist in the study’s design and in determining the relative value and feasibility of the study.” 213

Any expert advisory panel must include “representatives of practicing and research clinicians, patients, and experts in scientific and health services research, health services delivery, and evidence-based medicine who have experience in the relevant topic, and as appropriate, experts in integrative health and primary prevention strategies.” 214 The Institute may include a “technical expert of each manufacturer or each medical technology that is included under the relevant topic, project, or category for which the panel is established.” 215

4. Supporting Patient and Consumer Representatives

The Institute is required to “provide support and resources to help patient and consumer representatives effectively participate” on the Board and expert advisory panels appointed by the Institute. 216

5. Establishing a Methodology Committee

The Institute must establish a “standing methodology committee,” 217 composed of not more than fifteen members appointed by the Comptroller General. 218 Committee members must be experts in their scientific fields, such as health services research, clinical research, comparative clinical effectiveness research, biostatistics, genomics, and


213 PPACA § 6301(a) (codified at Social Security Act § 1181(d)(4)(A)(iii), 42 U.S.C. § 1301(d)(4)(A)(iii)).

214 PPACA § 6301(a) (codified at Social Security Act § 1181(d)(4)(B), 42 U.S.C. § 1301(d)(B)).

215 PPACA § 6301(a) (codified at Social Security Act § 1181(d)(4)(B), 42 U.S.C. § 1301(d)(B)).

216 PPACA § 6301(a) (codified at Social Security Act § 1181(d)(5), 42 U.S.C. § 1301(d)(5)).

217 PPACA § 6301(a) (codified at Social Security Act § 1181(d)(6)(A), 42 U.S.C. § 1301(d)(6)(A)).

218 PPACA § 6301(a) (codified at Social Security Act § 1181(d)(6)(B), 42 U.S.C. § 1301(d)(6)(B)).
research methodologies. Expert stakeholders may also be appointed to the committee.

In addition, the Directors of NIH and AHRQ (or their designees) are to be members of the committee.

The Methodology Committee must develop and improve the science and the methods of comparative clinical effectiveness research. The committee must also periodically update the methodological standards for research. PPACA provides a detailed description of methodological standards for research:

Such methodological standards shall provide specific criteria for internal validity, generalizability, feasibility, and timeliness of research and for health outcomes measures, risk adjustment, and other relevant aspects of research and assessment with respect to the design of research. Any methodological standards developed and updated shall be scientifically based and include methods by which new information, data, or advances in technology are considered and incorporated into ongoing research projects by the Institute, as appropriate.

The statute also specifies the process for developing and updating such standards which must include input “from relevant experts, stakeholders, and decisionmakers” and “provide opportunities for public comment.” The statute also specifies that the standards include “methods by which patient subpopulations can be accounted for and evaluated in different types of research.” The standards should also “build on existing

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219 PPACA § 6301(a) (codified at Social Security Act § 1181(d)(6)(B), 42 U.S.C. § 1301(d)(6)(B)).

220 PPACA § 6301(a) (codified at Social Security Act § 1181(d)(6)(B), 42 U.S.C. § 1301(d)(6)(B)).

221 PPACA § 6301(a) (codified at Social Security Act § 1181(d)(6)(B), 42 U.S.C. § 1301(d)(6)(B)).

222 PPACA § 6301(a) (codified at Social Security Act § 1181(d)(6)(C), 42 U.S.C. § 1301(d)(6)(C)).

223 PPACA § 6301(a) (codified at Social Security Act § 1181(d)(6)(C), 42 U.S.C. § 1301(d)(6)(C)).

224 PPACA § 6301(a) (codified at Social Security Act § 1181(d)(6)(C)(i), 42 U.S.C. § 1301(d)(6)(C)(i)).

225 PPACA § 6301(a) (codified at Social Security Act § 1181(d)(6)(C)(i), 42 U.S.C. § 1301(d)(6)(C)(i)).

226 PPACA § 6301(a) (codified at Social Security Act § 1181(d)(6)(C)(i), 42 U.S.C. § 1301(d)(6)(C)(i)).
work on methodological standards for defined categories of health interventions and for each of the major categories of comparative clinical effectiveness research methods.”

Further, the Institute is charged with developing “a translation table” that is “designed to provide guidance and act as a reference for the Board to determine research methods that are most likely to address each specific research question.”

The Methodology Committee may consult and contract with the IoM as well as expert academic, nonprofit, or other private and governmental entities as well as stakeholders. The Methodology Committee must submit reports to the Institute’s board of directors with recommendations to adopt methodological standards developed and updated by the methodology committee as well as other actions deemed necessary to comply with such methodological standards for adoption by the Institute.

6. Providing a Peer Review Process for Primary Research

The Institute must ensure a process for peer review of primary research conducted under its authority. The peer review process must consider evidence to assess scientific integrity and adherence to methodological standards. The Institute must make public a list of the names of individuals contributing to any peer review process during the preceding year or years, and this list should also be included in annual reports. The peer-review process must be so designed as to avoid bias and real conflicts of interest on the part of the reviewers.

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227 PPACA § 6301(a) (codified at Social Security Act § 1181(d)(6)(C)(i), 42 U.S.C. § 1301(d)(6)(C)(i)).

228 PPACA § 6301(a) (codified at Social Security Act § 1181(d)(6)(C)(ii), 42 U.S.C. § 1301(d)(6)(C)(ii)).

229 PPACA § 6301(a) (codified at Social Security Act § 1181(d)(6)(D)), 42 U.S.C. § 1301(d)(6)(D)).

230 PPACA § 6301(a) (codified at Social Security Act § 181(d)(6)(E)), 42 U.S.C. § 1301(d)(6)(E)).

231 PPACA § 6301(a) (codified at Social Security Act § 1181(d)(7)(A), 42 U.S.C. § 1301(d)(7)(A)).


234 PPACA § 6301(a) (codified at Social Security Act § 1181(d)(7)(B), 42 U.S.C. § 1301(d)(7)(B)).
Where the Institute enters into a contract or agreement with another entity for the conduct or management of research, it may utilize the peer-review process of such entity so long as such process otherwise meets statutory standards for peer review. The Institute may also utilize the peer-review of process of appropriate medical journals if such process meets statutory standards.

7. Releasing Research Findings

PPACA has very specific provisions for the release of research findings. Specifically, the Institute must make research findings available to clinicians, patients, and the general public, not later than ninety days after the conduct or receipt of research findings. The Institute must ensure that the research findings meet certain criteria, which are presented in Figure 9. Research findings are defined as “the results of a study or assessment.”

8. Adopting Policy

PPACA requires that the Institute formally adopt by majority vote the following items as policy: (1) the national priorities identified, (2) the research agenda established, (3) the methodological standards developed and updated by the methodology committee, and (4) any peer review process. In the case where the Institute does not adopt these

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236 PPACA § 6301(a) (codified at Social Security Act § 1181(d)(7)(C)(i), 42 U.S.C. § 1301(d)(7)(C)(i)).

237 PPACA § 6301(a) (codified at Social Security Act § 1181(d)(8), 42 U.S.C. § 1301(d)(8)).

238 PPACA § 6301(a) (codified at Social Security Act § 1181(d)(8)(B), 42 U.S.C. § 1301(d)(8)(B)).

239 PPACA § 6301(a) (codified at Social Security Act § 1181(d)(9), 42 U.S.C. § 1301(d)(9)).
items, it must refer them to staff within the Institute or to the methodology committee, if appropriate, for further review.”

9. Submitting Annual Reports

PPACA requires that the Institute submit an annual report to Congress and the President and make the annual report available to the public. The items that must be included in the report are presented at Figure 10.

D. Institutional Design, Governance, and Administration

The structure of the Institute is unique. The Institute is basically a private, nonprofit entity governed by a public-private sector board of directors appointed by the Comptroller General. The statute specifically provides that the Institute is “neither an agency nor establishment of the United States Government” and is organized under the District of Columbia Nonprofit Corporation Act. For fiscal year 2010 and following, funding for the Institute will come from the Patient-Centered Outcomes Research Trust Fund (PCORTF) established under PPACA.

Figure 10

<table>
<thead>
<tr>
<th>Items Included in the Institute’s Annual Report</th>
</tr>
</thead>
<tbody>
<tr>
<td>• A description of the activities conducted under Section 1181(d) as well as identified research priorities and methodological standards developed and updated by the methodology committee.</td>
</tr>
<tr>
<td>• The research project agenda and budget of the Institute for the following year.</td>
</tr>
<tr>
<td>• Any administrative activities conducted by the Institute during the preceding year.</td>
</tr>
<tr>
<td>• The names of individuals contributing to any peer review process without identifying them with a particular research project.</td>
</tr>
<tr>
<td>• Any other relevant information including information on the membership of the Board, expert advisory panels, methodology committee, and the executive staff of the Institute, any conflicts of interest with respect to these individuals, and any bylaws adopted by the Board during the preceding year.</td>
</tr>
</tbody>
</table>


240 PPACA § 6301(a) (codified at Social Security Act § 1181(d)(9), 42 U.S.C. § 1301(d)(9)).

241 PPACA § 6301(a) (codified at Social Security Act § 1181(d)(10), 42 U.S.C. § 1301(d)(10)).

242 PPACA § 6303(b)(1 & 2) (codified at Social Security Act § 1181, 42 U.S.C. § 1301(1 & 2)).

243 PPACA § 6303(b)(3) (codified at Social Security Act § 1181, 42 U.S.C. § 1301(3)).
1. Administration

PPACA has specific provisions pertaining to the administration of the Institute. Specifically, its Board of Governors is charged with carrying out the duties of the Institute and may not delegate its statutory duties.

2. Board of Governors

PPACA directs the Comptroller General to appoint 19 of 21 members of the Institute’s Board of Governors. In addition, the Director of the Agency for Healthcare Research and Quality and the Director of the National Institutes of Health, or their designees, serve on the Institute’s Board. The Act specifies different qualifications for individual board members. At Figure 11 is a list of these qualifications.

In addition, PPACA spells out some characteristics of board members. Specifically, the board must “represent a broad range of perspectives and experiences."

<table>
<thead>
<tr>
<th>Figure 11 Institute Board of Governors</th>
</tr>
</thead>
<tbody>
<tr>
<td>The Director of Agency for Healthcare Research and Quality (or the Director’s designee).</td>
</tr>
<tr>
<td>The Director of the National Institutes of Health (or the Director’s designee).</td>
</tr>
<tr>
<td>3 members representing patients and health care consumers.</td>
</tr>
<tr>
<td>7 members representing physicians and providers, including 4 members representing physicians (at least 1 of whom is a surgeon), 1 nurse, 1 State licensed integrative health care practitioner, and 1 representative of a hospital.</td>
</tr>
<tr>
<td>3 members representing private payers, of whom at least 1 member shall represent health insurance issuers and at least 1 member shall represent employers who self-insure employee benefits.</td>
</tr>
<tr>
<td>3 members representing pharmaceutical, device, and diagnostic manufacturers or developers.</td>
</tr>
<tr>
<td>1 member representing quality improvement or independent health service researchers.</td>
</tr>
<tr>
<td>2 members representing the Federal Government or the States, including at least 1 member representing a Federal health program or agency.</td>
</tr>
</tbody>
</table>


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244 PPACA § 6301(a) (codified at Social Security Act § 1181(e); 42 U.S.C. § 1301(e)).
245 PPACA § 6301(a) (codified at Social Security Act § 1181(e); 42 U.S.C. § 1301(e)).
248 PPACA § 6303 (codified at Social Security Act § 1181(f)(1)(C), 42 U.S.C. § 1301(f)(1)(C)).
collectively have scientific expertise in clinical health sciences research, including epidemiology, decisions sciences, health economics, and statistics. In appointing the Board, the Comptroller General must consider and disclose any conflicts of interest. Also, members of the board are required to recuse themselves from relevant Institute activities when the member (or an immediate family member) has a real conflict of interest directly related to the research project.

The terms of board members is six years staggered evenly over a two-year period with a two term limit. The Comptroller General designates the chair and vice chair of the board from among board members for a three year term. The board may employ staff, including an executive director, and contract with experts and consultants as needed for the performance of the Institute’s duties. Finally, the board must hold hearings at the call of the chair or a majority of its members with meetings not solely concerning matters of personnel must be advertised in advance and open to the public.

<table>
<thead>
<tr>
<th>Figure 12</th>
<th>Mandated Reviews of Institute Activities</th>
</tr>
</thead>
<tbody>
<tr>
<td>• The dissemination and training activities and data networks established under section 937 of the Public Health Service Act (every 5 years).</td>
<td></td>
</tr>
<tr>
<td>• The overall effectiveness of activities conducted its activities, “the dissemination, training, and capacity building activities conducted under section 937 of the Public Health Service Act (every 5 years).”</td>
<td></td>
</tr>
<tr>
<td>• The “adequacy and use of the funding for the Institute and the activities conducted under section 937 of the Public Health Service Act,” including a determination as to whether, based on the utilization of research findings by public and private payers, funding sources for the Patient-Centered Outcomes Research Trust Fund are appropriate and whether such sources of funding should be continued or adjusted (every 8 years).</td>
<td></td>
</tr>
</tbody>
</table>

249 PPACA § 6303 (codified at Social Security Act § 1181(f)(2), 42 U.S.C. § 1301(f)(2)).
250 PPACA § 6303 (codified at Social Security Act § 1181(f)(2), 42 U.S.C. § 1301(f)(2)).
251 PPACA § 6303 (codified at Social Security Act § 1181(f)(2), 42 U.S.C. § 1301(f)(2)).
252 PPACA § 6303 (codified at Social Security Act § 1181(f)(3), 42 U.S.C. § 1301(f)(3)). Vacancies are filled in the same manner as the original appointment was made.
253 PPACA § 6303 (codified at Social Security Act § 1181(f)(4), 42 U.S.C. § 1301(f)(4)).
254 PPACA § 6303 (codified at Social Security Act § 1181(f)(6), 42 U.S.C. § 1301(f)(6)).
255 PPACA § 6303 (codified at Social Security Act § 1181(f)(7), 42 U.S.C. § 1301(f)(7)).
3. Financial and Governmental Oversight

The Institute must arrange for financial audits of the Institute on an annual basis with an expert private entity.\textsuperscript{256} The Comptroller General must review these financial audits at least annually.\textsuperscript{257} The Institute must also review the research priorities and the conduct of research projects at least every five years to determine whether information produced is “objective and credible,” meets statutory requirements, and is developed in a transparent process.\textsuperscript{258} Other matters subject to review are presented at Figure 12. By the first day of April each year, the Comptroller General must report to Congress on the reviews described above as well as recommendations for such legislation and administrative action as the Comptroller General determines appropriate.\textsuperscript{259}

4. Financial Credibility and Access

The Institute must establish procedures to ensure that its work is transparent, credible and accessible.\textsuperscript{260} The Institute must provide for a public comment period with a specified period of time for the identified national research priorities, the research project agenda, the methodological standards developed by the Methodology Committee, the peer review process, and the draft findings with respect to systematic reviews of existing research and evidence.\textsuperscript{261}

\textsuperscript{256} PPACA § 6303 (codified at Social Security Act § 1181(g)(1), 42 U.S.C. § 1301(g)(1)).

\textsuperscript{257} PPACA § 6303 (codified at Social Security Act § 1181(g)(2)(A)(i), 42 U.S.C. § 1301(g)(1)(A)(i)).

\textsuperscript{258} PPACA § 6303 (codified at Social Security Act § 1181(g)(2)(A)(ii), 42 U.S.C. § 1301(g)(1)(A)(ii)).

\textsuperscript{259} PPACA § 6303 (codified at Social Security Act § 1181(g)(2)(B), 42 U.S.C. § 1301(g)(1)(B)).

\textsuperscript{260} PPACA § 6303 (codified at Social Security Act § 1181(h), 42 U.S.C. § 1301(h)).

\textsuperscript{261} PPACA § 6303 (codified at Social Security Act § 1181(h)(1), 42 U.S.C. § 1301(h)(1)).

<table>
<thead>
<tr>
<th>Figure 13</th>
<th>Items to be Disclosed on the Institute’s Website</th>
</tr>
</thead>
<tbody>
<tr>
<td>•</td>
<td>Information contained in research findings.</td>
</tr>
<tr>
<td>•</td>
<td>The process and methods for the conduct of research, including the identity of the entity and the investigators conducting such research and any conflicts of interests of such parties, any direct or indirect links the entity has to industry, and research protocols, including measures taken, methods of research and analysis, research results, and such other information the Institute determines appropriate) concurrent with the release of research findings.</td>
</tr>
<tr>
<td>•</td>
<td>Notice of public comment periods. Comments received during each of the public comment periods.</td>
</tr>
<tr>
<td>•</td>
<td>As appropriate, proceedings of the Institute.</td>
</tr>
</tbody>
</table>

PPACA § 6303 (codified at Social Security Act § 1181(h)(3), 42 U.S.C. § 1301(h)(3)).
The Institute must also support forums to increase public awareness and obtain and incorporate public input and feedback through media (such as an Internet website) on research priorities, research findings, and other matters as appropriate.\textsuperscript{262} At Figure 13 is a list of the items that the Institute must make available to the public through its official website. PPACA also requires disclosure of conflicts of interest in a specific manner.\textsuperscript{263} Finally, the Institute, its board or staff, are prohibited from accepting gifts, bequests, or donations of services or property or from establishing a corporation or generating revenues from activities other than as provided under PPACA.\textsuperscript{264}

E. Dissemination and Building Capacity for Research

A key mission of the Institute is to disseminate research findings and build research capacity. PPACA amends Title IX of the Public Health Service Act to provide for such efforts.\textsuperscript{265} Regarding dissemination, PPACA provides that the Office of Communication and Knowledge Transfer (the “Office”) of AHRQ in conjunction with the NIH, will broadly disseminate the research findings that are published by the Institute and other government-funded research relevant to comparative clinical effectiveness research.\textsuperscript{266}

1. General Functions

An important function of the Office is dissemination of research findings. To that end, the Office must create informational tools that organize and disseminate research findings for physicians, health care providers, patients, payers, and policy makers, among others.\textsuperscript{267} The Office must also develop a publicly available resource database that collects and maintains government-funded evidence and research from public, private, not-for-profit, and academic sources.\textsuperscript{268}

\textsuperscript{262} PPACA § 6303 (codified at Social Security Act § 1181(h), 42 U.S.C. § 1301(h)).

\textsuperscript{263} PPACA § 6303 (codified at Social Security Act § 1181(h)(4), 42 U.S.C. § 1301(h)(4)).

\textsuperscript{264} PPACA § 6303 (codified at Social Security Act § 1181(i), 42 U.S.C. § 1301(i)).

\textsuperscript{265} PPACA § 6303 (codified at Social Security Act § 1181(g), 42 U.S.C. § 1301(g)), amending Public Health Service Act § 937 (codified at 42 U.S.C. 299).

\textsuperscript{266} PPACA § 937 (codified at Public Health Services Act § 937(a)(1); 42 U.S.C. § 299b-37(a)(1)).

\textsuperscript{267} PPACA § 937 (codified at Public Health Services Act § 937(a); 42 U.S.C. 299b-37(a)).

\textsuperscript{268} PPACA § 937 (codified at Public Health Services Act § 937(a)(1); 42 U.S.C. 299b-37(a)(1)).
Materials, forums, and media used to disseminate the findings, informational tools, and resource databases must meet specific requirements. First, these materials must describe considerations for specific subpopulations, the research methodology, the limitations of the research, and the names of the entities, agencies, instrumentalities, and individuals who conducted any research. Second, such research findings must “not be construed as mandates, guidelines, or recommendations for payment, coverage, or treatment.”

2. **Other Requirements and Obligations**

Section 937 is quite explicit about other aspects of research dissemination. The Office, in consultation with relevant medical and clinical associations, must assist users of health information technology to promote timely incorporation of research findings into clinical practices. The Office must also establish a process to receive feedback from physicians, health care providers, patients, and vendors of health information technology focused on clinical decision support, appropriate professional associations, and federal and private health plans about the value of the information disseminated and the assistance provided under this section. Finally, agencies and instrumentalities of the federal government may contract with the Institute, and accept and retain funds, for the conduct and support of Institute-sponsored research.

3. **Researcher Training**

AHRQ, in consultation with the NIH, must build capacity for comparative clinical effectiveness research by establishing a grant program that provides for the training of researchers in the methods used to conduct such research, including systematic reviews.

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271 PPACA § 937 (codified at Public Health Services Act § 937(b), 42 U.S.C. 299b-37(b)).

272 PPACA § 937 (codified at Public Health Services Act § 937(c), 42 U.S.C. 299b-37 (c)).

273 PPACA § 937 (codified at Public Health Services Act § 937(g), 42 U.S.C. 299b-37(g)).
of existing research and primary research such as clinical trials.  At a minimum, such training is to be in methods that meet specified methodological standards.

4. Data for Research

The Secretary of DHHS must coordinate relevant federal health programs to build data capacity for comparative clinical effectiveness research. This data capacity includes the development and use of clinical registries and health outcomes research data networks. The purpose of these activities is to develop and maintain a comprehensive, interoperable data network to collect, link, and analyze data on outcomes and effectiveness from multiple sources, including electronic health records.

F. Limitations on Use of Comparative Effectiveness Research

PPACA is very emphatic that the research conducted or sponsored by the Institute not be used to make coverage policy. In its “rules of construction,” the statute states:

Nothing in this section shall be construed—(A) to permit the Institute to mandate coverage, reimbursement, or other policies for any public or private payer; or (B) as preventing CMS from covering the routine costs of clinical care received by an individual entitled to, or enrolled for, benefits under title XVIII, XIX, or XXI in the case where such individual is participating in a clinical trial and such costs would otherwise be covered under such title with respect to the beneficiary.

Then PPACA adds a new part to title XI of the Social Security Act entitled: “Limitations on Certain Uses of Comparative Clinical Effectiveness Research.” The first limitation concerns use of research findings in making Medicare coverage

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274 PPACA § 937 (codified at Public Health Services Act § 937(e), 42 U.S.C. 299b-37 (e)).

275 PPACA § 937 (codified at Public Health Services Act § 937(e), 42 U.S.C. 299b-37 (e)).

276 PPACA § 937 (codified at Public Health Services Act § 937(f), 42 U.S.C. 299b-37(f)).

277 Id.

278 Id.

279 PPACA § 6301 (codified at Social Security Act § 1181, 42 U.S.C. 1320e(j)(1)).

280 PPACA § 6301(c) (codified at Social Security Act § 1182, 42 U.S.C. 1302).
determinations. The research can only be used “if such use is through an iterative and transparent process which includes public comment and considers the effect on subpopulations.” The statute continues that nothing in the Institute’s enabling statute can be construed as “superseding or modifying” Medicare coverage policy or authorizing CMS to deny coverage of items or services “solely on the basis of comparative clinical effectiveness research.”

Additionally, CMS may not use research findings and evidence 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. Nor can the CMS do so based upon a comparison of the difference in the effectiveness of alternative treatments in extending an individual’s life due to the individual’s age, disability, or terminal illness.

Also research findings and evidence cannot be used in ways that preclude or intentionally 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. However, this provision cannot be construed to limit the application of differential copayments based on factors such as cost or type of service or prevent CMS from using evidence or findings from such comparative clinical effectiveness research. Further, no PPACA provision can be construed to limit comparative clinical effectiveness research or any other research, evaluation, or dissemination of information concerning the likelihood that a health care treatment will result in disability.

Finally, the Institute cannot develop or employ 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 establish what type of health care is cost effective or

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281 PPACA § 6301(c) (codified at Social Security Act § 1182(a), 42 U.S.C. 1302(a)).

282 PPACA § 6301(c) (codified at Social Security Act § 1182(b), 42 U.S.C. 1302(b)).

283 PPACA § 6301(c) (codified at Social Security Act § 1182(c)(1), 42 U.S.C. 1302(c)(1)).

284 PPACA § 6301(c) (codified at Social Security Act § 1182(c)(2), 42 U.S.C. 1302(c)(2)).

285 PPACA § 6301(c) (codified at Social Security Act § 1182(d)(1), 42 U.S.C. 1302(d)(1)).

286 PPACA § 6301(c) (codified at Social Security Act § 1182(d)(2), 42 U.S.C. 1302(d)(2)).

287 PPACA § 6301(c) (codified at Social Security Act § 1182(d)(3), 42 U.S.C. 1302(d)(3)).
recommended. CMS may not utilize such an adjusted life year (or such a similar measure) as a threshold to determine Medicare coverage, reimbursement, or incentive programs.

G. Establishment and Funding of the Patient-Centered Outcomes Research trust Fund (PCORTF)

To fund the Institute, PPACA establishes the Patient-Centered Outcomes Research Trust Fund (PCORTF) to support the work of the Institute. The trust fund will obtain funds contributions from the Medicare trust funds, commercial health insurance plans, and employer-sponsored health plans.

1. Establishment of the Patient-Centered Outcomes Research Trust Fund

PPACA amends the Internal Revenue Code of 1986 to establish the Patient-Centered Outcomes Research Trust Fund (PCORTF) within the Department of the Treasury. The Secretary of the Treasury is a trustee of the PCORTF. The PCORTF is terminated on September 30, 2019, with remaining funds reverting to the Treasury.

2. Uses of Trust Funds

Funds in the PCORTF are available, without further appropriation, to the Institute to carry out its work. The Trustee of the PCORTF must transfer 20 percent of the amounts appropriated or credited to the PCORTF for each of fiscal years 2011 through 2019 to the Secretary of DHHS to carry out Section 937 of the Public Health Service Act, which provides for the dissemination and building capacity for research. Of these funds, 80 percent will go to the Office of Communication and Knowledge Transfer in

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288 PPACA § 6301(c) (codified at Social Security Act § 1182(e), 42 U.S.C. 1302(e)).

289 Id.

290 PPACA § 6301(e)(1)(A) (codified at Internal Revenue Code of 1986 § 9511(a)).

291 PPACA § 6301(e)(1)(A) (codified at Internal Revenue Code of 1986 § 9511(c)).

292 PPACA § 6301(e)(1)(A) (codified at Internal Revenue Code of 1986 § 9511(d)(1)).

293 PPACA § 6301(e)(1)(A) (codified at Internal Revenue Code of 1986 § 9511(d)(2)(A)).
AHRQ and the other 20 percent will go to the Secretary to carry out responsibilities for disseminating research findings and building research capacity.

3. Financing the Patient-Centered Outcomes Research Trust Fund

The funding of the PCORTF is complex. PPACA first amends the Social Security Act to authorize payment from the trust funds for Medicare Part A and Part B according to a specified formula based on the number of beneficiaries for each part of the Medicare program, and with adjustments for increases in health care spending. The statute calls for the appropriation and subsequent transfer of funds to the PCORTF in specified amounts (presented in Figure 14) from fiscal year 2010 to 2019.

There are also limits on transfers to PCORTF. Specifically, no amount may be appropriated or transferred to the PCORTF on and after the date of any expenditure from the PCORTF that is not permitted under the statute. However, the determination of whether an expenditure is so permitted must be made without regard to any provision of law that is not contained in PPACA or is subsequently enacted to or directly or indirectly seeks to waive the application of this paragraph. The purpose of this provision is to prevent political retribution from subsequent congressional actions – a situation that haunted AHCPR.

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**Figure 14 Schedule of Appropriations to PCORTF**

<table>
<thead>
<tr>
<th>Fiscal Year</th>
<th>Amount of Transfer</th>
</tr>
</thead>
<tbody>
<tr>
<td>2010</td>
<td>$10,000,000</td>
</tr>
<tr>
<td>2011</td>
<td>$50,000,000</td>
</tr>
<tr>
<td>2012</td>
<td>$150,000,000</td>
</tr>
<tr>
<td>2013</td>
<td>$150,000,000</td>
</tr>
<tr>
<td>2019</td>
<td>Net Revenue from fees imposed on health insurance and self-insured health plans</td>
</tr>
</tbody>
</table>

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295 PPACA § 6301(e)(1)(A) (codified at Internal Revenue Code of 1986 § 9511(d)(2)(b)).

296 PPACA § 6301(d) (codified at Social Security Act § 1183(a), 42 U.S.C. § 1303(a)) & PPACA § 6301(e)(1)(A) (codified at Internal Revenue Code of 1986 § 9511(b)(2)).

297 PPACA § 6301(d) (codified at Social Security Act § 1183(b), 42 U.S.C. § 1303(b)).

298 PPACA § 6301(e)(1)(A) (codified at Internal Revenue Code of 1986 § 9511(d)(b)).

299 PPACA § 6301(e)(1)(A) (codified at Internal Revenue Code of 1986 § 9511(b)(3)).

300 PPACA § 6301(e)(1)(A) (codified at Internal Revenue Code of 1986 § 9511(b)(3)(A-B)).

301 See notes 57-61 *supra* and accompanying text.
The third source of funds for the PCORTF is fees imposed on commercial health insurance plans and employer self-funded health plans. For so-called specified health insurance policies of commercial health insurance companies, the fee is one dollar times the number of covered lives under the policy in fiscal year 2013 and two dollars times the number of covered lives for fiscal years thereafter. The issuer of the policy is statutorily liable for these fees. A specified health insurance policy is an accident or health insurance policy that covers conventional health insurance benefits and includes HMOs. If health care expenditures increase, the fees on specified health insurance policies may be increased. These fees are terminated after fiscal year 2019.

For self-insured health plans, there are similar fees. The fee is one dollar times the number of covered lives under the policy in fiscal year 2013 and two dollars times the number of covered lives for fiscal years thereafter. The health plan sponsor is statutorily liable for these fees. An applicable self-insured health plan is defined as one providing coverage through means other than a commercial health insurance policy and is intended for employees. If health care expenditures increase, the fees may be increased. These fees are also terminated after fiscal year 2019.

IV. CAN THE COMPARATIVE EFFECTIVENESS INITIATIVE SUCCEED?

The big question regarding the Institute is whether it can succeed at promoting and implementing a successful comparative effectiveness research agenda. Clearly other similar federal efforts to develop and use health services research and technology

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303 PPACA § 6301(e)(2)(A) (codified at Internal Revenue Code of 1986 §4375(a)).
304 PPACA § 6301(e)(2)(A) (codified at Internal Revenue Code of 1986 §4375(b)).
305 PPACA § 6301(e)(2)(A) (codified at Internal Revenue Code of 1986 §4375(c)).
306 PPACA § 6301(e)(2)(A) (codified at Internal Revenue Code of 1986 §4375(d)).
307 PPACA § 6301(e)(2)(A) (codified at Internal Revenue Code of 1986 §4375(e)).
308 PPACA § 6301(e)(2)(A) (codified at Internal Revenue Code of 1986 §4376(a)).
309 PPACA § 6301(e)(2)(A) (codified at Internal Revenue Code of 1986 §4376(b)).
310 PPACA § 6301(e)(2)(A) (codified at Internal Revenue Code of 1986 §4376(c)).
311 PPACA § 6301(e)(2)(A) (codified at Internal Revenue Code of 1986 §4376(d)).
312 PPACA § 6301(e)(2)(A) (codified at Internal Revenue Code of 1986 §4375(e)).
assessment have faltered. The following discussion highlights the major problems and challenges encountered by past efforts as well as how the current comparative effectiveness research initiative can overcome these challenges and be successful. And success can be defined only as the use of the findings of comparative effectiveness to make medical practice less costly, more efficient and more effective.

A. Political Fall-Out from Federal Standard Setting

The most important challenge faced by past efforts to use findings of health services research to influence policy has been political opposition from the medical profession and the provider community. With respect to early efforts of technology assessment and later with medical practice guideline setting, considerable opposition came from organized medicine on grounds that these prescriptive norms invaded the professional judgment of individual physician. By the 1980s, the organized medical community became more comfortable with the movement to develop medical practice guidelines and quality performance measures. Indeed, the American Medical Association and medical specialty societies participated directly in the development of medical practice guidelines and standards of care.

However, it proved politically difficult for a federal agency to developed medical practice guidelines as the experience of the AHCPR demonstrated. Indeed, the furor over the medical practice guideline for lower back pain nearly cost AHCPR its funding when the Republican-controlled Congress. Clearly the medical profession viewed the entire federal guideline making exercise as an attack on the power of the medical


314 See generally Kinney, The Brave New World of Medical Standards of Care, supra note 310; Kinney & Wilder, Medical Standard Setting in the Current Malpractice Environment: Problems and Possibilities, supra note 310.

315 See John Kelly & Joanna Swartwout, Development of Practice Parameters by Physician Organizations, 16(2) QUAL. REV. BULL. 54 (1990); Mark R. Chassin, Standards of Care in Medicine, 25 INQUIRY 437 (1988); Linda Johnson White & John Ball, Clinical Efficacy Assessment Project of the American College of Physicians, 1(1) INT’L J. TECH. ASSESSMENT IN HEALTH CARE 67 (1985); J Sanford Schwartz, The Role of Professional Medical Societies in Reducing Practice Variations, 3(2) HEALTH AFF. 90 (1984); see also Council of Medical Specialties, Standards of Quality in Patient Care: The Importance and Risks of Standard Setting (published proceedings from Invitational Conference of the Council of Medical Specialty Societies, Washington, D.C., September 25-26, 1987).

316 See notes 57-61 supra and accompanying text.
profession to determine the content of medical care. And the power to determine the content of medical care is also the power to determine payment levels from public and private health insurers.

Interestingly, organized medicine has not been as vociferous a critic of the Medicare coverage policymaking process. Perhaps this is due to the fact that CMS, and its predecessor HCFA, have been fairly deferential to the medical profession in setting Medicare coverage policy. It is noteworthy that the American Medical Association develops the codes that are used to classify medical procedures and technologies for payment purposes.

B. The Conundrum of Cost Effectiveness

Contention over cost effectiveness has been problematic. Historically, the pushback on cost effectiveness as a criterion in Medicare coverage policy-making has come primarily from the medical device manufacturers and suppliers. Because many medical devices are prescribed on an outpatient basis as well as not within a bundle of services, the cost and effectiveness of medical devices is more visible to CMS regulators. Medical device manufacturers and suppliers are thus especially affected by Medicare coverage decision-making.

The concept of cost effectiveness has been particularly troubling in setting criteria for Medicare coverage of new technologies and procedures. As noted above, since the 1980s, neither CMS nor HCFA has adopted cost effectiveness as a criterion for Medicare coverage decision-making. The medical device industry has argued that the Medicare statute does not authorize the consideration of the cost effectiveness as a criterion for Medicare coverage as the concept is not implicit in the “reasonable and necessary” language in the Medicare statute. However, ultimately, the device


320 See Thompson & Dahl, supra note 89 at 41.

321 See notes 122-127 supra and accompanying text.


323 See Thompson & Dahl, supra note 89 at 41.
manufacturers and suppliers must realize that public and private payers must take into account the cost effectiveness of their products. Public payers have an obligation to taxpayers. Private payers have an obligation to shareholders – an obligation that for-profit manufacturers can surely appreciate.

In 2003, Congress added a prescription drug benefit to the Medicare program, which extended Medicare’s regulatory influence over pharmaceutical manufacturers and suppliers.\textsuperscript{324} To date, Medicare’s coverage of prescription drugs has not been a particularly controversial issue. Perhaps the fact that drug coverage is provided through private plans that have responsibility for selecting the drugs in their formularies.\textsuperscript{325}

The FDA within DHHS regulates the safety and efficacy of pharmaceutical and medical device products under the Food, Drug and Cosmetics Act.\textsuperscript{326} The regulatory scheme for these products focuses on ensuring that products are not adulterated and labeled appropriately. If the product is safe and effective as claimed and demonstrated to be so in a regulatory review process, the FDA approves the product. There are no other requirements that the product must meet to go to market.

Heretofore, pharmaceutical products manufacturers have not faced other regulatory hurdles. They have much to fear from comparative effectiveness research, especially if cost-effectiveness is part of the equation as the cost of new pharmaceutical products are usually high to recoup research and development costs.\textsuperscript{327} They are likely to always be more expensive than existing and off-patent drugs.\textsuperscript{328} Further, in markets in which there are multiple drugs for the same condition, the differences between the effectiveness of drugs are not great.\textsuperscript{329} Thus, drugs that are more costly are a great disadvantaged when compared. Some observers are concerned that comparative effectiveness research will compromise the availability of multiple drugs to treat


\textsuperscript{328} Ernst R. Berndt, Pharmaceuticals in U.S. Health Care: Determinants of Quantity and Price, 16(4) JOURNAL OF ECONOMIC PERSPECTIVES 45 (2002).

individuals with particular personal characteristics. Specifically, the Partnership to Improve Patient Care, a coalition of industry, patient-advocacy, and clinician organizations, raised concerns that comparative effectiveness would “stymie progress in personalized medicine.”

CMS must be especially careful in how it uses the findings of comparative effectiveness research. PPACA does not preclude CMS and the Medicare program from using comparative effectiveness research in its coverage decision-making. Rather it precludes the Institute from making coverage policy and decisions. CMS may use the results of comparative effectiveness research in its coverage decision-making but must do so in a transparent and inclusive process. If the experience of coverage decision-making for new technology is any example, CMS can expect a vigilant pharmaceutical industry at every turn.

C. The Private Sector Does the Hard Lifting

<p>| Figure 15 |</p>
<table>
<thead>
<tr>
<th>Benefit Categories for the “Essential Health Benefits” for Private Health Plans under PPACA</th>
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<tbody>
<tr>
<td>• Ambulatory patient services.</td>
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<tr>
<td>• Emergency services.</td>
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<tr>
<td>• Hospitalization.</td>
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<tr>
<td>• Maternity and newborn care.</td>
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<tr>
<td>• Mental health and substance use disorder services, including behavioral health treatment.</td>
</tr>
<tr>
<td>• Prescription drugs.</td>
</tr>
<tr>
<td>• Rehabilitative and habilitative services and devices.</td>
</tr>
<tr>
<td>• Laboratory services.</td>
</tr>
<tr>
<td>• Preventive and wellness services and chronic disease management.</td>
</tr>
<tr>
<td>• Pediatric services, including oral and vision care.</td>
</tr>
</tbody>
</table>


331 Partnership to Improve Patient Care. Individualized Patients, Personalized Care (2009), quoted by Garber and Tunis, supra note 330.

332 See Section III.F supra.

333 See notes 281-282 supra and accompanying text.
Unlike public health insurance plans, PPACA contains no restrictions on how private health plans use comparative effectiveness research. PPACA specifies categories of “essential health benefits” (see Figure 15) as well as cost-sharing limits are required for health plans that are offered through the state Health Exchanges under PPACA. The statute leaves the specific definition of “essential health benefits” to be included in category of benefits up to the Secretary of DHHS to establish through rulemaking.

One substantive limitation on the essential health benefits is that they be “equal to the scope of benefits provided under a typical employer plan.” PPACA specifies requirements for cost-sharing with respect to the essential health benefits. Under PPACA, there are three levels of coverage based on the percentage of the cost of the essential health benefits paid for by the plan.

PPACA also specifies so-called “required elements for consideration” in “defining” the essential health benefits. These elements are presented in Figure 16. These elements do not include any mention of the use of comparative effectiveness research.

**Figure 16**

**Key Elements to be considered in Defining the Essential Health Benefits**

- Ensure that essential health benefits reflect an appropriate balance among the categories so that benefits are not unduly weighted toward any category;
- Not make coverage decisions, determine reimbursement rates, establish incentive programs, or design benefits in ways that discriminate against individuals because of their age, disability, or expected length of life;
- Take into account the health care needs of diverse segments of the population, including women, children, persons with disabilities, and other groups;
- Ensure that health benefits established as essential not be subject to denial to individuals against their wishes on the

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334 PPACA § 1302(a).
335 PPACA § 1302(a).
336 PPACA § 1302(b)(1).
337 PPACA § 1302(c).
338 PPACA § 1302(d).
339 PPACA § 1302(b)(4).
PPACA imposes no prohibitions or even requirements on health plans in their use of comparative effectiveness research as there are for public health insurance plans under the Social Security Act. Likewise, PPACA does not contain any prohibitions on DHHS in defining the essential health benefits in required regulations. Of note, the Secretary of DHHS has asked the IoM to develop recommendations on the essential benefits package.

This omission of the concept of comparative effectiveness research in defining essential health benefits to be offered by private health plans is noteworthy. Either the omission is unintentional, which could be quite possible in such a massive statute. Or, the omission is deliberate and indicates that Congress contemplates that private health plans and their sponsors will use comparative effectiveness research to delineate coverage policy and devise approaches to reduce unnecessary and costly care. Obviously, Congress would not create an Institute devoted to the promotion and conduct of comparative effectiveness research if it did not have a use for the research in mind. The fact that private health plan sponsors, be they employers or insurance companies, are required to contribute financially to the Institute suggests that they are free to use generated comparative effectiveness research to bend the cost curve.

Clearly it is beneficial for private as well as public sponsors of health plans to use comparative effectiveness research results in crafting coverage and payment policy. However, such use must be done in a transparent manner, which PPACA requires for the Medicare program. Historically, private health plans and their sponsors have not been very transparent in the processes for making coverage and other policy. Transparency will help private health plans avoid the pitfalls encountered by managed care organizations in the 1990s when they sought to impose rigid cost-saving strategies of plan enrollees.

* * *


See Section III.F. supra.


See Section III.G.3. supra and accompanying text.

See notes 281-282 supra and accompanying text.


basis of the individuals’ age or expected length of life or of the individuals’ present or predicted disability, degree of medical dependency, or quality of life;

- Provide that a qualified health plan shall not be treated as providing coverage for the essential health benefits unless it meets certain requirements regarding emergency services.
Nevertheless, comparative effectiveness research provides health plans and their sponsors effective tools to craft coverage and payment policy that can garner the support of patients and their providers. Private health plans and their sponsors would do well to develop processes for the transparent use of comparative effectiveness research results in making coverage, payment and other health plan policy to avoid the kind of backlash against managed care plans observed in the 1990s. Also, with comparative effectiveness research, health plans can make a better case to patients and providers that they, in fact, are covering the most effective health care items and services and that their decisions are based on evidence and not other more nefarious bases.

D. The Ideal Structure and Governance of Federal Efforts

The design of the Institute reflects the considerable controversy over federal sponsorship and involvement in comparative effectiveness research with the Federal Coordinating Council for Comparative Effectiveness Research. Until the Institute, comparative effectiveness research efforts have been conducted and supported by offices within the U.S. Department of Health and Human Services – namely CMS, the NIH, and AHRQ.

The most recent effort under ARRA was supervised by a coordinating council comprised of federal officials. As noted above, one federal official, Dr. Ezekiel Emanuel, was targeted by the political right as an advocate for death panels based on his prior research and conclusions that decisions about allocation of health care resources on the basis of social attributes might be necessary. Clearly this controversy is


347 Jerry Avorn, Debate about Funding Comparative-Effectiveness Research, 360 NEW ENG. J. MED. 1927 (2009).

348 See Section II.D.1. supra.

349 See notes 180-182 supra and accompanying text.
reminiscent of the experience of AHCPR and medical practice guideline development. Direct federal involvements in efforts to prescribe normative policy that will limit the promotion and utilization of any services or product generates opposition from those who would otherwise profit from the promotion and utilization. Such federal efforts subject the agency to charges that it is rationing care.

PPACA endeavors to reduce these concerns about the structure and governance of federal involvement by making the Institute a not-for-profit corporation under District of Columbia law, and arranging for its funding to be independent, after a set period, from the congressional appropriations process.

To assure success where other federal efforts have failed, PPACA has insulated the Institute both politically and financially. The Institute is a private, not-for-profit corporation with a board appointed by the congressional watchdog agency, the Comptroller of the Currency. The Institute’s funding comes chiefly from set contributions from the Medicare trust funds and Private Health Plan sponsors. And all the appropriations the institute will ever get are awarded in PPACA. Congress thus will have a difficult time defunding the Institute and limiting its work with a change of political winds. The Executive Branch also has authority limited of the institute. The heads of the NIH and AHRQ get on the Institute’s board and some of the Institute Committees. They are also recipients of comparative effectiveness research funds for both internal use and external distribution. These agencies also have responsibilities in the dissemination of research funding and findings.

The question is whether these institutional arrangements are adequate to refute charges that the federal government is rationing health care. Nevertheless, no federally funded effort thus far has been able to withstand this kind of allegation from either the medical profession or the conservative right. The organized medical profession seeks to retain clinical and thereby financial control over the content of medical care. Some members of the conservative right attribute inappropriate motives on the federal government in an effort to discredit the federal government and ensure that private payers, providers, and investors can maximize revenues and profits without federal interference.

V. CONCLUSIONS

The Institute is now in the initial stages of its launch. The Comptroller of the Currency has selected the Institute’s board and its leadership. The Institute is just now

350 See notes 57-61 supra and accompanying text.

351 See note 242 supra and accompanying text.

352 See note 298 supra and accompanying text.

beginning its work. The big question is whether the Institute can avoid the pitfalls of the past efforts of federally directed health services research to improve efficiency and efficacy of medical care as well as navigate all of the pushback that is inevitable in the venomous political atmosphere of today. Below are outlined some thoughts for the Institute and policymakers to consider in making the PPACA comparative effectiveness research initiative a success.

Comparative effectiveness research, like other health services research, fundamentally challenges physician control over the content of medical care. It also challenges the claims of pharmaceutical and medical device manufacturers and suppliers that their products are effective, particularly when compare to other available products. This control over the content of medical care has huge financial implications for physicians and other providers as well as pharmaceutical and medical device manufacturers and suppliers. The stakes are high. There will be surely be political fallout when the results of comparative effectiveness are applied in ways that affect the income of providers and/or the profits of manufacturers and suppliers.

Comparative effectiveness will only be influential and only overcome mounted political opposition of vested interests if it is scientifically persuasive. Specifically, comparative effectiveness research must influence and convinced the thought leaders in the relevant medical specialties. Preferably, as the statutory processes allow and, indeed, encourage, relevant medical specialty societies should be in the research and disseminations processes. Where medical services and procedures generate income and profits, the findings of comparative effectiveness research have to especially persuasive and developed in a transparent and inclusive process as the political challenges will be greater. The case of the back surgery guidelines and AHCPR, discussed above, is exemplary of a health services research exercise that backfired because the underlying science was not sufficiently persuasive to overcome the political pressure.

Further, the medical profession should be accorded the lead in determining the content of medical care. Only the medical profession has the requisite expertise to determine the appropriateness of various procedures and services are necessary for the care and treatment of a particular patient with a particular condition. Comparative effectiveness research will only be useful in bending the so-called cost curve if it is persuasive enough scientifically to convince the medical profession to mount political opposition. The politics are complicated by the fact that opinion within the medical profession is not unanimous. Practitioners, for example, who stand to gain much economically from particular products and procedures are likely to have different views about the science than researchers in academic medical centers. Health reform and bending the cost curve will only be implemented successfully if the majority of physicians understand the need for health reform and concur with the scientific basis of decision-making on coverage and payment policy in public and private health insurance programs.

However, even with the best science completed use of comparative effectiveness research cannot be assured. If there is an enduring lesson of past federal efforts to use

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355 See notes 57-61 *supra* and accompanying text.
health services research results to shape federal payment and coverage policy, it is that, in the end, politics prevails. There are strong professional and financial interests at stake which are not necessarily aligned with federal health policy goals. Those goals are currently to expand access to health coverage for the uninsured while getting better value for health expenditures and bending the cost curb. Furthermore, stakeholders are able to clothe their interests in an ideological vocabulary that assures government involvement with healthcare decision-making and such rhetoric often resonates with many in the American Public.

Finally, PPACA is silent on what happens to the Institute after 2019. At that time, congress will revisit the Institute and appropriate more funds for its support. It may be that the Institute is able to prove its value, raise funds and continue it work after 2019. The Institute’s financial survival will inevitably depend on the success of the Institute in bringing value to payers. The Institute’s design does promote sound and persuasive science and addresses the influence of politics on its work. But what is done the science will always be a political matter. As such, it will enter the cacophony of chatter, fact and fiction that animates the political discourse of the day. The science will ultimately have influence only if it is genuinely authoritative and palatable politically.