

AcademyHealth Report

Placement, Coordination, and Funding of Health Services Research within the Federal Government

Approved by the AcademyHealth Board of Directors

September 2005



AcademyHealth

Advancing Research, Policy and Practice

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Executive Summary

Health services research examines how a variety of factors—from financing systems to medical technologies to personal behaviors—affect health care costs, quality, and access. When appropriately funded, coordinated, and disseminated, this research can improve health care management, financing, and delivery by informing health policymaking and clinical practice.

As the professional society for those who conduct and apply this research, AcademyHealth has a clear interest in the reauthorization of the lead agency for health services research, currently the Agency for Healthcare Research and Quality (AHRQ). In addition, AcademyHealth recognizes the significance of implementing the comparative effectiveness function specified in Section 1013 of the Medicare Modernization Act (MMA), which authorizes federal evaluations of pharmaceuticals and other medical technologies for their relative safety, effectiveness, and cost.

In the context of these interests, the AcademyHealth Board of Directors established a special committee to explore the placement, coordination, and funding of health services research within the federal government. During the last two years, AcademyHealth's staff interviewed 38 distinguished leaders in health research and policy to inform the committee's deliberations. This report presents the analysis and recommendations that grew from the committee's work and were approved by AcademyHealth's Board of Directors in June 2005.

In 2003, the federal government expended \$34.3 billion for health research, of which \$1.5 billion, or 5 percent, was dedicated to health services research. Many federal agencies within the Department of Health and Human Services (HHS) conduct or support health services research to inform critical components of their missions. However, AHRQ is the only federal agency whose primary mission is to conduct and support a broad portfolio of health services research, ranging from patient safety to health system effects on economic and clinical outcomes. In addition, it plays critical roles in synthesizing and translating the broad-based research into practice and maintaining the intellectual infrastructure of researchers through a variety of professional development activities.

AcademyHealth's Recommendations

AcademyHealth developed the following five recommendations pertaining to the placement, coordination, and funding of health services research in the federal government. If implemented, the recommendations would strengthen the capacity of health services research to provide needed information for improving health and health care in America.

Recommendation 1: Continue having an agency of HHS, currently AHRQ, as the lead agency for health services research.

By maintaining the lead agency for health services research—currently AHRQ—as an agency of the Department on par with the other HHS agencies, the health services research function maintains considerable visibility and enables the lead agency director to interact more effectively with other HHS agency directors and key members of Congress.

Recommendation 2: Establish comparative effectiveness research either within AHRQ or through the creation of a new entity that would, in varying degrees, be linked to the lead agency for health services research.

AcademyHealth gives placement of the comparative effectiveness function special consideration due to the potentially controversial nature of the research findings and its ultimate use by payers in making coverage decisions. To further consideration of options for this critical research function, AcademyHealth identified four options and adopted five principles to assist Congress and the Administration in their deliberations on the appropriate structure for undertaking and supporting comparative effectiveness research. These options are briefly reviewed below and described and compared in more detail in Section IV of this report.

Recommendation 3: Strengthen the coordination of health services research both within HHS and within the federal government.

Coordination within HHS and across federal agencies is especially important given the complexity of the health care system and the issues that health services research addresses. Coordination of findings and some direction regarding research needs will help increase the efficiency by which research improves the clinical and economic outcomes of the health care system.

Recommendation 4: Establish and fund a *Council of Sponsors* to provide a mechanism to conduct a comprehensive needs assessment for the entire field of health services research and to provide an ongoing forum for funders to review their research plans with stakeholders.

The *Council of Sponsors* would consist of the major sponsors of health services research and would establish a mechanism to represent the key stakeholders for this field. The Council would oversee the development of a strategic plan for the field of health services research and would provide an ongoing forum to facilitate coordination across major research funders in the public and private sectors. The Council would enable research funders to showcase their best work and to focus their collective expertise in shaping the nation's health services research agenda and improving research translation.

Recommendation 5: Increase the total federal funding for health services research spending from \$1.5 billion to \$5 billion.

AcademyHealth strongly supports a substantial increase in funding for health services research with an emphasis on translating research into practice and evaluating treatments in real-world settings. Health services research informs all aspects of health care delivery and policy; increasing the federal investment would yield important, long-run returns.

AcademyHealth's Analysis of Placement Options for Comparative Effectiveness Research

Comparative effectiveness research has the potential to improve health care quality and patient outcomes, while ensuring that consumers, both patients and purchasers, receive the best care at the best value. In accordance with Recommendation 2, AcademyHealth identified the following four options for the placement of this critical research function:

Option 1: AHRQ sponsors and conducts comparative effectiveness studies with oversight and guidance from an external board and panel of experts.

Option 2: AHRQ sponsors and conducts comparative effectiveness studies with oversight and guidance from an external board and panel of experts, and establishes a Federally Funded Research and Development Center (FFRDC).¹ The FFRDC would undertake syntheses of research commissioned by AHRQ and others for the purpose of making comparative effectiveness findings.

Option 3: With AHRQ remaining as currently structured, create a new, separate quasi-governmental entity for comparative effectiveness research.

Option 4: Reconstitute AHRQ as a quasi-governmental entity, retaining most of its existing functions and adding comparative effectiveness research.

AcademyHealth assessed these four options against five principles designed to guide decisions about health services research funding and the placement of the comparative effectiveness function. The principles state that:

1. Funding for the field should continue to support a broad range of topics;
2. Assessments of comparative effectiveness should be based on scientific evidence and kept separate from funding and coverage decisions;
3. The entity commissioning or conducting the research should maintain a close linkage to the lead agency for health services research;
4. The entity should be subject to congressional oversight; and
5. The entity should involve key stakeholders to assure transparency of the methods and process, promote public acceptance of research findings, and support for the entity's mission.

AcademyHealth does not endorse a preferred option, given the potential of unknown factors to shape each option. For example, our support for a particular option would be influenced by the overall funding level provided to support comparative effectiveness research and the capacity of the entity to recruit the expertise needed for this function.

The upcoming reauthorization of AHRQ and the implementation of Section 1013 of the MMA have created an important opportunity to reassess the placement, coordination, and funding of both the broad field of health services research and of comparative effectiveness activities within the federal government. AcademyHealth looks forward to working with Congress and the Administration as they consider these recommendations and options.

¹ An FFRDC is a private, nonprofit organization that is sponsored by an executive branch agency. The sponsoring agency monitors, funds, and assumes responsibility for the overall activities of the FFRDC. While FFRDCs are not subject to federal personnel rules, the organizations are prohibited from competing for government contracts to ensure their independence, objectivity, and freedom from organizational conflicts of interest.

I. Introduction and Purpose

Health services research, when appropriately funded, coordinated, and disseminated, plays a critical role in addressing problems related to the nation's health care system. It "connects the dots" between cutting-edge medical and health discoveries and their practical application. It generates knowledge about the most pressing issues in health and health care today, including prevention, patient safety and quality, access and coverage, disparities in health care, and rising health care costs. It provides an evidence base for public and private decision-makers on what works and at what cost. In short, health services research produces evidence aimed at improving health care by generating and translating research findings to inform policymaking and clinical practice.

The mission of AcademyHealth, as the professional society for health services researchers and health policy professionals, is to:

- Expand and improve the scientific basis of health services research;
- Increase the capacities and skills of researchers; and
- Promote the development of the necessary data resources, financial and human infrastructure.

Given this mission, AcademyHealth has a clear interest in the reauthorization of the lead agency for health services research within the Department of Health and Human Services (HHS)—the Agency for Healthcare Research and Quality (AHRQ). In addition, AcademyHealth acknowledges the potential significance of the expansion of the federal government's investment in comparative effectiveness research for the purpose of comparing and evaluating the effectiveness of pharmaceuticals and other medical technologies.

In preparation for the AHRQ reauthorization and in the context of renewed interest in comparative effectiveness research, the AcademyHealth Board of Directors established a special *Committee on the Placement, Coordination, and Funding of Health Services Research within the Federal Government*. To inform the Placement Committee's deliberations on these issues, AcademyHealth staff interviewed 38 distinguished leaders in health services research and health policy who have served as federal agency executives; members of Congress or senior congressional staff; state officials; employers; health plan executives; or foundation executives. Those interviewed were selected for their knowledge of health services research and their understanding of HHS and how its agencies relate to Congress and others who use health services research. AcademyHealth also received guidance from congressional staff, agency officials, an expert on the history of health services research placement, and a firm with administrative law expertise. The interviews and guidance played an important role in shaping the recommendations put forth by AcademyHealth.

These recommendations will be used by AcademyHealth's advocacy affiliate, the Coalition for Health Services Research, to inform its advocacy related to the reauthorization of AHRQ and to advise on the implementation of the comparative effectiveness function specified in Section 1013 of the Medicare Modernization Act of 2003 (MMA). See Appendix A for a listing of the members of the AcademyHealth and Coalition Boards and the Placement Committee.

Following the recommendations, this report provides AcademyHealth's assessment of options regarding the placement of comparative effectiveness research within the federal government. This review of options also includes an analysis of the differences between Federally Funded Research and Development Centers (FFRDCs) and public foundations, given that these mechanisms have been suggested as possible structures for the conduct of comparative effectiveness research.

II. Background

In 2003, the federal government expended \$34.3 billion for health research.² Of this total, \$1.5 billion or 5 percent was spent on health services research, which includes funding for health statistics and surveys.³ Federal agencies' reported FY 2005 expenditures for health services research are presented in Table 1.

Table 1:
Federal Funding for Health Services Research in Fiscal Year 2005

Federal Agency	Funding (in millions)
Agency for Healthcare Research and Quality	\$319
Centers for Disease Control and Prevention	
o National Center for Health Statistics	\$109
o Public Health Research Program	\$30
Centers for Medicare and Medicaid Services	\$78 ^a
Department of Defense	\$15
National Institutes of Health (All Institutes)	\$910
Veterans Health Administration	\$52 ^b

^a Most of the funding in CMS's research budget represents congressional earmarks for activities that are not necessarily related to CMS's research and demonstration interests.

^b This figure represents direct expenditures for health services research and approaches \$100 million if indirect costs are included.

We estimate that approximately \$164 million or 11 percent of the \$1.5 billion spent for health services research went to fund health statistics and surveys. The data systems funded by these agencies are crucial resources for the health services research and health policy fields.

Health services research is conducted or supported by many federal agencies; however, AHRQ is the only federal agency whose primary mission is to conduct and support health services research. In FY 2005, AHRQ received \$319 million or 21 percent of the \$1.5 billion federal expenditure to fund a broad portfolio of health services research ranging from patient safety and health disparities to examining how health system organization influences clinical and economic outcomes. These funds also supported training programs to produce the next generation of researchers. One of AHRQ's key missions is to facilitate research that helps translate the broad-based knowledge gained through basic and clinical research into practice. AHRQ also plays a critical role in building and maintaining the intellectual infrastructure of researchers through a variety of educational and career development grants and centers of excellence.

² Levit, K. et al. "Health Spending Rebound Continues in 2002," *Health Affairs*, Vol. 23, No. 1, January/February 2004, p. 148.

³ AcademyHealth defines health services research as "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."

It is noteworthy that many federal agencies fund health services research to inform critical components of their missions. The various institutes of the National Institutes of Health (NIH) fund health services research in varying degrees to ensure that the investments made in basic and biomedical research lead to improved health services for the disease and population groups they serve. While the overall NIH budget includes a substantial amount of health services research, that research is spread over many institutes and is a small fraction of the total NIH portfolio. The Centers for Disease Control and Prevention (CDC) funds health services research to guide decisions it must make about public health services and systems. The Centers for Medicare and Medicaid Services (CMS) uses health services research for decisions on Medicare and Medicaid coverage and payment policies. The Department of Defense (DoD) and the Veterans Health Administration (VHA) fund health services research to guide decisions about the health services they provide to military personnel, dependents, retirees, and veterans.

III. Recommendations

AcademyHealth and the leaders who participated in the development of these recommendations undertook their deliberations in the context of a broad understanding of how and where health services research is conducted within the federal government. AcademyHealth believes that in their totality, these recommendations if implemented would substantially improve the capacity of health services research to provide the information needed to improve America's health and health care.

The AcademyHealth Board of Directors approved the following five recommendations on June 28, 2005.

Recommendation 1: Continue having an agency of HHS, currently AHRQ, as the lead agency for health services research.

In reviewing placement alternatives, AcademyHealth assessed options that had been considered in the past by the leadership of the field of health services research, including:

- Retain the current structure of having a lead agency for health services research within HHS;
- Place the health services research functions of AHRQ in the Office of the Assistant Secretary for Planning and Evaluation (ASPE);
- Place the health services research functions of AHRQ in the NIH as either an institute or a center within the office of the director; and
- Consolidate all health services research functions found within HHS into a new expanded agency for health services research.

By maintaining the lead agency for health services research—currently AHRQ—as an agency of the Department on par with the other HHS agencies, the health services research function maintains considerable visibility and enables the lead agency director to interact more effectively with other HHS agency directors and key members of Congress.

The importance of having a health services research agency in HHS with a direct reporting relationship to the Secretary is based on AHRQ's responsibilities within HHS. The direct reporting relationship to the Secretary should be determined by function and scope—not by the size of the agency. In addition to developing information to improve overall health care quality and safety, AHRQ serves as a science partner and collaborator to those federal agencies that support and use health services research. For example, AHRQ conducts

research and analysis to inform CMS coverage decisions related to health technology and collaborates with the VHA on its Quality Enhancement Research Initiative (QUERI) program.

Support for retaining an agency of the Department, in addition to the health services research portfolios that currently exist in many other health-related federal agencies, recognizes the important role health services research plays in helping these agencies fulfill their respective missions. Indeed, the health services research funded in other federal agencies helps in its translation from research to policy and practice, and in developing new research approaches, tools, and concepts.

Placing AHRQ within another HHS agency would limit its effectiveness in providing the science-based support for quality and safety across the entire Department. In addition, it is possible that making AHRQ a subsidiary unit could shift its primary research focus to reflect the mission of the HHS agency to which it was transferred, rather than maintain a broader research portfolio. AcademyHealth does not support placing the health services research functions of AHRQ in ASPE, as this change might politicize the research, reducing its long-term import. ASPE needs an effective policy research arm, but this need should not be met at the expense of retaining an independent health services research capacity within HHS.

The Placement Committee also rejected the idea of placing the health services research function within the NIH. Although there is potential security and stability for health services research if located within a large, well-funded, respected institution such as the NIH, AcademyHealth believes that health services research could be jeopardized in several ways if this were to occur:

- Health services research could face internal budget battles within NIH;
- Securing adequate support for health services research focused on financing and organizational issues might be an even greater challenge if health services research activities were located within NIH, with its emphasis on basic and biomedical research;
- The institutes currently supporting health services research would resist transferring their portfolios to a new institute; and
- NIH leaders may not have expertise or interest to advocate for health services research.

AcademyHealth believes consolidation of all health services research into one location would be unwise. Many agencies (e.g., NIH, CMS, and CDC) need a discrete health services research component in order to answer questions that arise in the context of that agency's mission. For example, CMS needs health services research to inform benefit design, coverage, and payment issues; NIH needs its institutes to focus a portion of their research portfolios on translating biomedical and clinical research results into practice; and CDC needs capacity to undertake public health systems research.

Recommendation 2: Establish comparative effectiveness research either within AHRQ or through the creation of a new entity that would, in varying degrees, be linked to the lead agency for health services research

Comparative effectiveness research is defined as a rigorous assessment of the relative safety, effectiveness, and cost of treatment therapies or approaches for managing the same condition. It could be used by health care providers to promote quality and by public and private purchasers and insurers to inform coverage and treatment decisions. Congress, under Section 1013 of MMA, authorized AHRQ to conduct comparative effectiveness research in the following areas:

- The outcomes, comparative clinical effectiveness, and appropriateness of health care items and services (including prescription drugs); and
- Strategies for improving the efficiency and effectiveness of Medicare, Medicaid and SCHIP, including the ways in which such items and services are organized, managed, and delivered under them.

Research on outcomes, organization, and delivery is a fundamental component of health services research, providing a clear rationale for placing this function within, or closely linked with, the lead federal agency for health services research.

Comparative effectiveness research will have its greatest value when widely disseminated. Comparative effective studies conducted by the public sector are usually disseminated broadly, but private sector entities do not always share their results since this research can provide a competitive advantage in the marketplace which in turn enables them to recoup their research investment. Limited dissemination of private research limits the usefulness of this research and potentially results in unnecessary duplication. The public sector needs to take a more significant role in funding comparative effectiveness research to ensure wide dissemination and support the mission of many federal departments and agencies, including:

- CMS, with 80 million Medicare, Medicaid, and State Children's Health Insurance Program (SCHIP) beneficiaries;
- Office of Personnel Management as it manages the Federal Employees Health Benefits Program, with more than 8 million federal enrollees and dependents;
- DoD, which provides health coverage to more than 1.4 million active duty personnel and their dependents; and
- VHA, which provides care to more than 4.8 million veterans.

AcademyHealth gives placement of the comparative effectiveness function special consideration due to the potentially controversial nature of the research findings and its ultimate use by payers in making coverage decisions. The field of health services research is cognizant that powerful groups may oppose funding for, or seek retribution against, a federal agency that produces findings that do not support their special interest.

Given the centrality of this function in the current health policy discussions, and with the backdrop of the reauthorization of the lead agency for health services research, AcademyHealth identified four options for its placement within the federal government. We then adopted five principles to assist Congress and the Administration as they face critical decisions relating to the placement of comparative effectiveness research function and overall funding for the field of health services research. Finally, we assessed the viability of these four options against the five principles. A description of the options and principles, as well as AcademyHealth's analysis of these options, is provided in Section IV beginning on page 10.

Recommendation 3: Strengthen the coordination of health services research both within HHS and within the federal government with an emphasis on improved linkages between the HHS health statistical and survey units, Quality Improvement Organizations (QIOs) administered by CMS, the Food and Drug Administration (FDA), and the lead agency for health services research.

In 2001, the Secretary of HHS established the Research Coordinating Council (RCC). The stated purpose of the RCC is to coordinate all non-investigator-initiated research within HHS, with the focus being primarily on health services research. AcademyHealth recommends that the RCC be strengthened as follows:

- Broaden the RCC to include representation from federal agencies outside of HHS;
- Provide mechanisms for the RCC to obtain the input and feedback on research priorities from public and private stakeholders who depend on this research to inform their decisions; and
- Provide a formal report on the needs identified by the RCC to inform those outside the process about the Council's assessment of future research needs and priorities, including addressing gaps in federal health data collection efforts.

Improved coordination would maximize the federal government's investment in health services research and avoid unnecessary duplication. The following are examples of agencies whose activities would benefit from greater coordination.

- Located within CDC, the National Center for Health Statistics (NCHS) is the nation's principal health statistics agency. Health services researchers and health policy analysts depend on NCHS data and surveys for their research and analysis. Because of the important link between the research and surveys AHRQ conducts, and the surveys and statistical reports NCHS develops, these agencies should be encouraged to develop closer linkages.
- The 53 Quality Improvement Organizations (QIO) administered by CMS are found in all states, the District of Columbia, and two territories. They work to ensure that patients (especially underserved populations) receive appropriate care at the right time. Given the close relationship the national network of QIOs has to AHRQ's mission, these entities should be more closely linked to the research and translation efforts of AHRQ.
- The Food and Drug Administration (FDA) conducts research on the efficacy of proposed drugs to ensure they meet the highest scientific standards and are demonstrated to be safe and effective. In contrast to research on the efficacy of pharmaceuticals, comparative effectiveness research would compare new pharmaceutical treatments to existing drugs and other treatments. For this reason, the entity conducting comparative effectiveness research should coordinate closely with the FDA to ensure it has access to and understands the research the FDA has already conducted on a drug's efficacy as part of any subsequent comparative effectiveness study. Comparative effectiveness studies, on the other hand, often rely on data collected after FDA approval, and may inform the FDA's post-marketing surveillance efforts.

Coordination across federal agencies is especially important given the complexity of the health care system and the issues that health services research addresses. Coordination of findings and some direction regarding research needs will help increase the efficiency with which research improves the clinical and economic outcomes of the health care system.

However, this coordination function would in no way mean control of how research projects are selected or how the research is conducted.

Recommendation 4: Establish and fund a *Council of Sponsors* to provide a mechanism to conduct a comprehensive needs assessment for the entire field of health services research and to provide an ongoing forum for funders to review their research plans with stakeholders. This Council, consisting of the major sponsors of health services research from the federal government and foundations, would establish a mechanism for key stakeholders to inform the development of a strategic plan for the field of health services research. These stakeholders would include, in addition to the principal funders, representatives from state and local governmental agencies, providers, health plans, patient groups, and researchers.

AcademyHealth endorses the establishment of a *Council of Sponsors* that would oversee the development of a strategic plan for the field of health services research, which would help shape the nation's health services research agenda and address the infrastructure needs of the field. As an ongoing forum, the Council would facilitate coordination across major public and private funders of health services research, enabling them to showcase their best work, learn first-hand about the work of others, and focus their collective knowledge and expertise to help shape the nation's health services research agenda, improve research translation into practice, and ultimately improve health and health care in the United States.

As part of the development of a strategic plan for the field of health services research, the *Council of Sponsors* should adopt a uniform definition for health services research and standard categories for collecting and reporting data about the major research areas. This uniform definition and the standard categories would improve stakeholder understanding of how federal agency funds are currently being allocated to address major priority topics. In turn, foundations would be encouraged to use this uniform definition and standard categories in developing their budgets and reports of expenditures so that all stakeholders would see how foundation and other private investments complement the federal investment. The Council should work with the HHS Research Coordinating Council and the Office of Management and Budget to oversee the implementation of the uniform definition and standard categories.

The strategic plan to be developed by the *Council of Sponsors* would also make recommendations on how to best maintain and build the needed infrastructure for health services research. The most critical components of the research infrastructure include:

- 1) **Development of human resources:** Human resource development includes the training of health services researchers through career development awards, especially those aimed at supporting new investigators (e.g., K Awards), to ensure that researchers are recruited and retained in the research enterprise, particularly within academic settings. Equally important is the need to improve funding opportunities for investigator-initiated research. While investigator-initiated research is recognized as a critical element of biomedical research and clinical research, it has not been a high priority for the funding of health services research.
- 2) **Support for research centers:** The support of research centers through center grants and other funding mechanisms is another critical building block for the research enterprise. The VA health system, which is widely recognized for transforming its health system in ways that have resulted in the delivery of high-quality care for the nation's veterans, is an example of a system that is well-supported by its research centers of excellence.

- 3) **Expanded and improved methods and methods training:** Methods development, including new research methods and the appropriate use of existing methods, is another high priority infrastructure need. Since the usual gold standard of research methods—the randomized control trial—often is not appropriate for studying the performance and effectiveness of the health care delivery system, there is an ongoing need for more and better health services research methods and guidance regarding their appropriate use.
- 4) **Improved quality and quantity of data and data resources:** Data is the linchpin of research and an essential resource for evaluating how the health care system is functioning. Consequently, we need to not only maintain the current level of federal support for national health data, but also look to future data needs associated with the increased demand for research that compares therapeutics and treatment options.

Recommendation 5: Increase the total federal funding for health services research spending from \$1.5 billion to \$5 billion. Health services research informs all aspects of health care delivery and policy, so that increasing the federal investment would yield important, long-run returns.

Securing adequate funding for the health services research field, and specifically for the lead agency, has been a persistent challenge. The unrelenting pressure of rising health care costs, worsening access problems, and increasing evidence that a significant proportion of current treatments are ineffective or sometimes even harmful, underscores the pressing need for a well-planned and substantial increase in funding for health services research to improve the nation's health and health care system. In recent years, while the problems in the health care system have become clearer, little has been done to address the inadequate support for investigator-initiated research by the lead agency. Broad-based solicitations for investigator-initiated research to address critical current and future problems are typically more effective in eliciting fundamental new ideas and solutions than narrowly targeted approaches.

AcademyHealth strongly supports a substantial increase in broad-based funding for health services research with an emphasis on translating research into practice and evaluating treatments in real-world settings to inform policymakers and practitioners. AcademyHealth's recommendation for a substantial increase in funding for health services research is based on responses to interviews of key stakeholders provided to AcademyHealth for this report.⁴ According to these responses, the proposed proportion of total federal health research funding devoted to health services research should be significantly increased from the current level of \$1.5 billion to \$5 billion.⁵ This increase in health services research, with an emphasis on translating research into practice, would ensure that purchasers, plans, providers, and policymakers put biomedical and clinical research findings into practice more quickly. AcademyHealth further recommends that the desired increase for health services research be achieved by expanding the funding base for all health research.

⁴ Interviewees included sponsors of health research, current and former federal agency executives, members of Congress or senior congressional staff, state officials, employers, health plan executives, and foundation executives.

⁵ Interviewees recommended on average that health services research should be 17 percent of federal health research. Rounding down to 15 percent equals \$5 billion of the current investment of \$34.3 billion.

From our interviews with key stakeholders and funders of health services research, AcademyHealth has identified the following priority research areas that should receive increased federal funding:

- Health care quality, including identifying ways to reduce medical errors and improve patient safety;
- Comparative effectiveness research, including comparative clinical effectiveness of drugs and other treatments;
- Using evidence-based management to improve health system performance;
- Coverage and access, including how expanded coverage and access contribute to improved health outcomes;
- Using evidence-based treatments to improve care for chronically ill patients who account for much of our health care expenditures;
- Using research to identify the means of increasing patient-centered care;
- Supporting and bolstering national health surveys to assess coverage and access issues and develop registries of patient care and outcomes to determine what works best over time for specific subsets of the population; and
- Disparities research, especially racial and geographic disparities.

In addition to priority issues such as those identified above, there is a continuing need to fund traditional health services research areas such as health care access and financing. These areas should also be addressed when considering priority areas for increased funding. Furthermore, just as in the clinical sciences, some of the most important long-term contributions come from the development of new methods and analytic approaches that change the way one thinks about problems or provide new tools for examining data.

This substantial increase in funding should be well-planned and guided by the input of major stakeholders or users of this research. Any major increase in federal funding should be informed by a comprehensive needs assessment such as one overseen by the *Council of Sponsors* proposed earlier. As with other major national priorities, it is very important to involve the key stakeholders (including purchasers, consumers, providers, and policymakers) and researchers in specifying research needs.⁶

The Placement Committee does not offer specific recommendations to Congress on how to pay for this increase in funding. Rather, it encourages consideration of mechanisms whereby public and private sector payers would contribute to the funding for this research.

IV. Analysis of Options for Placement of the Comparative Effectiveness Research Function

Comparative effectiveness research—where drugs, devices, and therapies used to treat the same conditions are evaluated for their relative safety, effectiveness, and cost—has great potential to improve health care quality and patient outcomes, while ensuring that consumers, both patients and purchasers, receive the best care at the best value. By definition, this type of health services research often clearly differentiates between “winners”

⁶ The process might follow the national needs assessment process used in the *Conference to Develop a Research Agenda for Outcomes and Effectiveness Research*, conducted by the Association for Health Services Research and the Alpha Center for the Agency for Health Care Policy and Research in April 1992.

and “losers.” After all, if research based on post-marketing surveillance finds that device “A” has better outcomes and fewer risks than drug “B,” one would expect the demand for device “A” to increase at the expense of drug “B.” The manufacturer of drug “B” might then attempt to leverage the political process to discredit the research and/or undermine the entity conducting the research.

Given the political ramifications and potentially controversial implications that comparative effectiveness research presents, AcademyHealth has identified four options for the placement of this critical research function. These options range from fully embedding the comparative effectiveness function in an established federal agency to placing it, along with all other health services research, in a new, quasi-governmental organization. In this section, we review the four options together with the five principles adopted by AcademyHealth to guide Congress and the Administration in assessing the appropriate structure for the comparative effectiveness function.

AcademyHealth does not endorse a preferred option, given the continuing potential for unknown factors to shape each option. For example, the entity’s overall funding and ability to recruit the expertise needed would be critical factors that should inform the choice among these options—the best arrangement for a budget of \$2 billion might not be the best if \$5 billion were immediately available. It may also be desirable to have portions of this responsibility undertaken by a combination of entities. Under such a scenario, the lead agency for health services research might commission and undertake the research studies, an affiliated entity might do the assessments based on that research, and an independent quasi-governmental entity might develop consensus studies on the methods and data to be used for these studies and assessments.

Four Options for the Placement of Comparative Effectiveness Research

AcademyHealth has identified four potential options for placing the responsibility of conducting comparative effectiveness research.

<p>Option 1: AHRQ sponsors and conducts comparative effectiveness studies with oversight and guidance from an external board and panel of experts.</p>	<ul style="list-style-type: none"> • AHRQ would remain the lead agency for health services research, supporting a broad health services research agenda, including comparative effectiveness. • AHRQ would establish an external board to oversee the development of the comparative effectiveness research agenda and a panel of experts to validate the science used to conduct comparative effectiveness studies.
<p>Option 2: AHRQ sponsors and conducts comparative effectiveness studies with oversight and guidance from an external board and panel of experts, and establishes a Federally Funded Research and Development Center (FFRDC).</p>	<ul style="list-style-type: none"> • AHRQ would remain the lead agency for health services research, supporting a broad health services research agenda, including comparative effectiveness. • AHRQ would establish an external board to oversee the development of the comparative effectiveness research agenda and a panel of experts to validate the science used to conduct comparative effectiveness studies. • AHRQ would also establish an independent FFRDC with the limited mission of reviewing and synthesizing comparative effectiveness research.
<p>Option 3: AHRQ remains as currently structured and a new separate quasi-government entity is established to fund and conduct comparative effectiveness research.</p>	<ul style="list-style-type: none"> • AHRQ would remain the lead agency for health services research, supporting a broad health services research agenda, but not comparative effectiveness. • A new quasi-governmental agency would be established, with both public and private funding, to conduct both intramural and extramural comparative effectiveness studies.
<p>Option 4: AHRQ is reconstituted as a quasi-governmental agency retaining most existing functions and adding comparative effectiveness research.</p>	<ul style="list-style-type: none"> • AHRQ reconstituted as a new quasi-governmental entity would conduct and fund health services research, including comparative effectiveness. • Those AHRQ functions that must be performed by a governmental entity, such as the Medical Expenditure Panel Survey (MEPS), would be transferred to other existing HHS agencies. • The new quasi-governmental entity could be supported by public and private funds.

Five Principles to Guide Decisions for the Placement of Comparative Effectiveness Research

AcademyHealth adopted the following five principles to guide decisions related to the placement of comparative effectiveness research and overall funding for the field of health services research.

<p>Principle 1: Overall funding for the field of health services research should continue to support a broad and comprehensive range of topics.</p>	<ul style="list-style-type: none"> • Recognizes that while comparative effectiveness research is important, it is a subset of the broader field of health services research. • Regardless of where comparative effectiveness research is placed, this principle stresses the need to fund a broad health services research portfolio.
<p>Principle 2: Assessments should be based on scientific evidence and kept separate from funding and coverage decisions.</p>	<ul style="list-style-type: none"> • Given the controversial nature of comparative effectiveness findings, this principle stresses the need for a structure that ensures the scientific integrity of comparative effectiveness research. • This principle stresses the need to separate the entity that funds and conducts these studies from the entity directly responsible for making coverage decisions.
<p>Principle 3: Entity commissioning or conducting comparative effectiveness research should maintain close linkage to the lead agency for health services research.</p>	<ul style="list-style-type: none"> • Recognizes that comparative effectiveness research is a subset of the broader field of health services research. • As such, comparative effectiveness research must be closely linked to the lead agency in order to ensure that findings are consistent with the best available research, methods, and data.
<p>Principle 4: Entity commissioning or conducting comparative effectiveness research should be subject to congressional oversight.</p>	<ul style="list-style-type: none"> • Since comparative effectiveness research has the potential to affect the delivery and cost of health care for all Americans, this principle recognizes that the federal government is responsible for ensuring that decisions about what health services and products should be provided are based on sound scientific research. • Since this research requires substantial federal funding (and would not be funded adequately by the private sector alone), this principle recognizes the need for appropriate congressional oversight of public funding to ensure accountability.
<p>Principle 5: Entity commissioning or conducting comparative effectiveness research should involve key stakeholders to assure transparency of the methods and process, promote public acceptance of research findings, and support for the entity's mission.</p>	<ul style="list-style-type: none"> • Given the controversial nature of comparative effectiveness research, this principle recognizes the importance of involving key private sector representatives in developing the research agenda and ensuring the validity of the research produced, thereby increasing public support for the research findings and the entity's mission. • As such, comparative effectiveness research must be funded in an open process to ensure that no one group is perceived as dominating the process and/or skewing the results.

Analysis of Placement Options Using the Guiding Principles

Principle 1 recognizes that while comparative effectiveness research is important, it is a subset of the broader field of health services research. The purpose of this principle is to state clearly that regardless of where comparative effectiveness research is placed, it is critical that a broad health services research portfolio be funded. As an overarching requirement, this principle holds regardless of which option is selected for the placement of comparative effectiveness research.

- Option 3 would separate the funding for the lead agency for health services research from the new entity established for comparative effectiveness. This separation could result in less funding for the core areas of health services research, as this new entity might compete for the limited funds Congress is able to devote to the field health services research.

Though to varying degrees, all four options meet the intent of **Principle 2** in that they all provide mechanisms designed to ensure scientific integrity of comparative effectiveness research and gradations of separation from political and budgetary pressures:

- Option 1 calls for an external board to set the agenda for comparative assessment studies and a panel of experts to assess whether the studies were conducted according to established scientific methods. It provides the least separation from political and budgetary pressures. With comparative effectiveness research located within the lead agency, the entire agency might be at risk from those who may object to conclusions reached from comparative effectiveness studies.
- Option 2, which requires the creation of an independent FFRDC to conduct syntheses of existing research and make comparative effectiveness assessments, would provide an additional level of separation and independence for the entity issuing comparative assessments. This separation provides a buffer against efforts by powerful interests to reduce the funding for the lead agency when research findings are opposed. This option requires that additional resources and time be provided to establish a new FFRDC with staff expertise to conduct syntheses and comparative effectiveness assessments. Congress and the Administration may want to further assess how the FFRDC model has worked for other federal research needs and the applicability of this mechanism for conducting comparative assessment studies.
- Option 3 places comparative effectiveness research in a new, separate quasi-governmental entity and may provide the greatest assurance of scientific integrity for research findings and the greatest separation from political and budgetary pressures. If this option were selected, it would be critical for Congress to establish mechanisms to link this new entity with the lead agency for health services research and other federal agencies that rely on this research to inform their coverage decisions. This option would require considerable resources and time to bring the quasi-governmental entity to a fully functioning level of operation.
- Option 4, which would reconstitute AHRQ as a new quasi-governmental entity, would also provide significant separation from political and budgetary pressures. Unlike Option 3, however, this option would provide a close linkage between the entity making comparative effectiveness assessments and the lead agency for health services research. By removing the current lead agency

for health services research from HHS it might well reduce the impact this lead agency and its research has on the other HHS agencies. AcademyHealth believes that this option should only be considered with a substantial increase in the funding base and with mechanisms to ensure that all federal agencies needing health services research are able to shape the research agenda and promptly access its findings. The establishment of this new entity would also require significant resources and time to transfer critical governmental functions to other federal agencies and to bring the quasi-governmental entity to a fully functioning level of operation.

Options 1, 2, and 4 provide linkages between the lead agency for health services research and the entity commissioning or conducting comparative effectiveness research, as outlined in **Principle 3**. Options 1 and 2 allow for continuing scientific partnerships between the lead health services research agency and other HHS agencies. Option 3 requires that procedures be established to link the lead agency for health services research to the independent entity established to conduct comparative effectiveness studies. Option 4 requires that new mechanisms be established to maintain the desired linkage with federal agencies.

All options include congressional oversight mechanisms, as called for in **Principle 4**. Options 1 and 2 further assure the government's influence over the comparative effectiveness research function by: 1) maintaining the government's ability to use its leverage in collecting data; 2) preserving the federal agencies influence in setting the research agenda; and 3) providing Congress with direct oversight over the lead agency for health services research.

To varying degrees, all options include mechanisms to ensure transparency, engage key stakeholders, and build public acceptance of comparative effectiveness research findings, as called for in **Principle 5**. Under Option 1, private sector involvement is achieved through the establishment of a new external board with representation from key private sector stakeholders. Option 2 provides greater private sector involvement through the establishment of an external board and through the management and funding of the new FFRDC. The private sector would have even greater involvement in the management and commissioning of comparative studies in Options 3 and 4, which call for the establishment of a new quasi-governmental entity. However, this involvement could be at the expense of a more direct public sector involvement in the commissioning of this research.

FFRDC and Public Foundations

Three of the four options for the placement of comparative effectiveness research described in this report call for the creation of various types of quasi-governmental entities. AcademyHealth considered many different models of quasi-governmental entities, including structures such as the Export-Import Bank, the Overseas Private Investment Corporation, and the Health Effects Institute (a joint venture of the Environmental Protection Agency and the automotive industry). Through this process, AcademyHealth learned that quasi-governmental entities could take many forms. None of the models reviewed appeared to provide the “perfect” structure to meet the needs of a federal research agency with responsibility for conducting comparative effectiveness studies and synthesizing and disseminating the findings.

To inform its assessment of quasi-governmental entities, AcademyHealth retained a firm with administrative law expertise. Through this process, legal counsel advised AcademyHealth that an FFRDC model may best meet the situation where a federal agency would commission comparative effectiveness research and an independent FFRDC would conduct syntheses of existing research. In this model, the FFRDC would make recommendations based on the existing research and determine how this assessment should be disseminated and used in making resource allocation decisions.

As suggested by congressional staff, AcademyHealth also sought advice from legal counsel on the differences between FFRDCs and the public foundation model utilized by several federal health agencies (e.g., CDC and NIH). The following analysis of FFRDCs and public foundations summarizes the opinion provided by our legal counsel.

FFRDCs

FFRDCs receive their funding primarily from federal government agencies but operate as private, not-for-profit organizations. They are usually located at a university or an autonomous nonprofit organization. FFRDCs are not subject to federal personnel rules, but are prohibited from competing for government contracts to ensure their independence, objectivity, and freedom from organizational conflicts of interest. They do not have a prescribed organizational structure, but must be *sponsored* by an executive branch agency that monitors, funds, and is responsible for the overall use of the FFRDC. FFRDCs fall into categories such as research laboratory or study and analysis center. In some instances, an FFRDC may be a unit of a larger organization, such as the National Defense Research Institute, which is part of the RAND Corporation.

Public Foundations

Federally sponsored, public foundations are generally set up as nonprofit corporations. Public foundations represent a type of public charity with the primary purpose of making grants. Public foundations must seek money from diverse sources in order to retain their public charity and tax-exempt status under the Internal Revenue Services regulations. Medical research foundations are one type of public foundation. A public foundation may receive substantial support from the government or indirect contributions from the general public as long as it receives at least one-third of its contributions from the general public and it is organized to attract new and additional public support.

The key differences between the FFRDCs and public foundations are:

- Foundations have a broader mission than an FFRDC, supporting the entire mission of its affiliated agency.
- An FFRDC is limited to work that cannot be accomplished by existing government and contractor resources.
- An FFRDC is limited to only accepting 30 percent of its funding from the private sector; public foundations may accept more.
- Foundations act independently of their affiliated agencies. FFRDCs maintain a closer relationship with their parent agency.

AcademyHealth prefers the FFRDC model to the public foundation approach for several reasons:

- The FFRDC is provided with strong public sector involvement and oversight.
- A more limited scope means that an FFRDC will remain focused on its core task.
- The FFRDC model would provide a closer linkage between the agency developing the science and the entity synthesizing the results.

V. Conclusion

The upcoming reauthorization of AHRQ and the implementation of Section 1013 of the MMA have created an important opportunity to reassess the placement, coordination, and funding of both the broad field of health services research and of comparative effectiveness activities within the federal government. AcademyHealth looks forward to working with Congress and the Administration as they consider these recommendations and options.

Appendix A

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