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Health Reform: What It Means for Health Services Research

Comprehensive health system change begins, not ends with the historic health reform legislation signed into law by President Obama on March 23, 2010. The Patient Protection and Affordable Care Act authorizes many new programs and changes many existing programs in ways that will undoubtedly change the face of health and health care in the United States and will transform the field of health services research, both what we study and how we study it.

Over the next few months, and in some cases years, the administration will undertake the Herculean task of implementation, issuing hundreds of regulations, reorganizing the existing infrastructure, and appointing members to nearly 150 commissions and advisory groups. In many instances the law is not explicit on where programs shall be housed, how they will be organized, or how much funding should be appropriated. The health community will be instrumental in informing these decisions and making this law a reality.

The following analysis describes some key provisions from The Patient Protection and Affordable Care Act that directly impact the field of health services research, and discusses potential challenges with the programs and their implementation. The Coalition for Health Services Research will track these programs and work to influence their implementation, both the construction of the programs and the appropriation of funding.

Sec. 6301 Patient-Centered Outcomes Research (and corrections in Sec. 10602)

Representing the most fundamental change to the existing health services research infrastructure, Sec. 6301 of the Patient Protection and Affordable Care Act will make an indelible impact on our field and the future of comparative effectiveness research.

Governing Structure

The Patient Protection and Affordable Care Act establishes a nonprofit corporation to conduct comparative clinical effectiveness research. This new Patient-Centered Outcomes Research Institute, which is neither an agency nor establishment of the federal government, would “assist patients, clinicians, purchasers, and policymakers 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 relative health outcomes, clinical effectiveness, and appropriateness of medical treatments.”

The new Institute would be governed by a Board of Governors of public and private stakeholders, appointed by the Comptroller General not later than six months after the enactment of the Act. The Board’s composition includes:

- The Director of the Agency for Healthcare Research and Quality (AHRQ) or designee;
- The Director of the National Institutes of Health (NIH) or designee;
- Three patient representatives;
- Seven provider representatives, including at least four physicians (with one a surgeon), one nurse, one integrative health care practitioner, and one hospital representative (as amended in Sec. 10602 of the Act);
- Three representatives of private payers—both health insurance issuers and employers who self-insure employee benefits;
- Three members representing pharmaceutical, device, and diagnostic developers or manufacturers;
- One member representing quality improvement or independent health services researchers; and
- Two members representing the federal government or the states, including at least one representing a federal health program or agency.

The Board must represent a “broad range of perspectives and collectively have scientific expertise in clinical health sciences research, including epidemiology, decisions sciences, health economics, and statistics.”

The Act dissolves the Federal Coordinating Council for Comparative Effectiveness Research established under the American Recovery and Reinvestment Act on the date of health reform’s enactment.

While the creation of the new Institute is immediately authorized, the Act does not specify when the Institute would be fully functioning and who would be responsible for building it from the ground up. We can assume that the Board of Governors and its Chair and Vice Chair once appointed by the Comptroller General will be responsible for hiring the Institute’s Executive Director as its first order of business. The Executive Director would then likely be responsible for hiring staff, securing office space, and arranging for the first meeting of the Board. The Government Accountability Office will be responsible for issuing a call for nominations through the *Federal Register*, reviewing nominations, and interviewing candidates, with the appointments made by the Comptroller General. The Act requires the Comptroller General appoint the Board members, the Chair, Vice Chair within six months of the enactment of the Act, but one could reasonably expect it to take 12 – 18 months after the appointments before the Institute is fully operational.

Mandatory Trust Fund for Research

Research funding is typically discretionary—that is, congressional appropriators on an annual basis use their discretion in determining what funding will be available for research. In this sense, funding can wax and wane depending on the federal priorities, the budget deficit, or political pressures. The Act provides an unprecedented mandatory funding stream for comparative clinical effectiveness research by establishing a Patient Centered Outcomes Research Trust Fund. The Act provides for a transfer from the Treasury to the Trust Fund, including \$10 million in FY 2010, \$50 million in FY 2011 and up to \$150 million thereafter. In addition, the Secretary shall provide for transfer of \$2 per Medicare beneficiary from the Federal Hospital Insurance Trust Fund and the Federal Supplementary Medical Insurance Trust Fund. Beginning September 30, 2012, the Act also requires that health insurers contribute a fee equal to \$2 per covered beneficiary. In total, by FY 2013 the Trust Fund will provide an estimated \$500 million a year for this research, depending on the number of Medicare enrollees and insured individuals.

It is unclear how this new mandatory funding stream will impact discretionary funding for comparative effectiveness research currently conducted by the federal government, and especially AHRQ. AHRQ's Effective Health Care Program—authorized by Sec. 1013 of the Medicare Modernization Act—is currently funded on an annual basis through the appropriations process. Last year, this program received \$300 million in one-time funding through the American Recovery and Reinvestment Act on top of its base funding of \$21 million in FY 2010 (a decrease from \$50 million in FY 2009).

With a new mandatory funding stream for comparative clinical effectiveness supported by the Institute, appropriators looking for budget savings may wish to reallocate discretionary funding from AHRQ's existing comparative effectiveness research portfolio to support other research or non-research priorities within the Department. While we believe the intent of the Act was to supplement funding for AHRQ's current portfolio, there is a considerable risk in the current fiscal environment that funding for the new Institute will ultimately supplant AHRQ's Effective Health Care Program.

Research Priorities

The Institute is responsible for identifying national priorities for research, “taking into account factors of disease incidence, prevalence, and burden in the United States (with emphasis on chronic conditions), gaps in evidence in terms of clinical outcomes, practice variations and health disparities in terms of delivery and outcomes of care, the potential for new evidence to improve patient health, well-being, and the quality of care, the effect on national expenditures associated with a health care treatment, strategy or health condition, as well as the patient needs, outcomes and preferences...”

In setting research priorities, there is no requirement that the Institute incorporate the recommendations of the Federal Coordinating Council for Comparative Effectiveness Research and the Institute of Medicine as directed by the Recovery Act.

Research Methods

The Act requires that the Institute's research be carried out in accordance with "methodological standards" for systematic reviews and assessments of existing and future research, primary research such as randomized clinical trials, molecularly informed trials and observational studies, and "any other methodologies recommended by the Methodology Committee."

The Methodology Committee would be appointed by the Comptroller General within 18 months of the establishment of the Institute to "develop and improve the science and methods of comparative clinical effectiveness research." Specifically, the Committee will develop methodological standards for research. Such standards shall provide specific criteria for internal validity, generalizability, feasibility, and timeliness of research and for health outcomes measures, risk adjustment and other aspects of research relevant to research design. The process for developing and updating such standards shall include input from experts, stakeholders, and decision makers and provide opportunity for public comment. The Committee must also create a "translation table" to act as a user friendly reference for the governing board to determine research methods that are most likely to address each specific research question.

Not more than 15 members of the Methodology Committee shall be "experts in their scientific field, such as health services research, clinical research, comparative clinical effectiveness research, biostatistics, genomics, and research methodologies." The directors of AHRQ and NIH (of their designees) will also serve on the Methodology Committee.

The Committee will issue reports to the Board of Governors that contain recommendations for the Institute to adopt the methodological standards it develops and updates, as well as other actions deemed necessary to comply with these methodological standards.

The Methodology Committee would have the authority to "consult or contract" with entities including the IOM, AHRQ, NIH, and "academic, nonprofit, or other private entities with relevant expertise." The Committee could also consult with stakeholders and other entities knowledgeable in relevant fields, as appropriate.

It is unclear whether the Institute has the direct authority to fund research that would advance scientific exploration and innovation in new methods. Since the research is conducted under contract in response to particular research priorities, and the research must comply with the methodological standards developed by the Methodology Committee and approved by the Board, it seems that investigator initiated research in methods development would not be funded by the Institute.

Capacity Building and Research Dissemination

The Act directs AHRQ in consultation with NIH to build capacity for comparative clinical effectiveness research by establishing a grant program that provides for the training of

researchers in methods “that meet the methodological standards” established by the Methodology Committee and adopted by the Board.

The Act directs the Office of Communication and Knowledge Transfer at AHRQ, in consultation with NIH, to disseminate research findings published by the Institute and other government funded research relevant to comparative clinical effectiveness research to physicians, health care providers, patients, payers, and policymakers. The Office is also required to develop a publicly available resource database that collects and contains government-funded evidence and research from public, private, nonprofit, and academic sources.

Up to 20 percent of the amount in the Patient Centered Outcomes Research Trust Fund shall be used to support research capacity building and dissemination activities. Of this amount, 80 percent may be used by AHRQ for training and dissemination, and 20 percent may be used by the Secretary to coordinate relevant federal health program to build data capacity for comparative clinical effectiveness research, including the development and use of clinical registries and health outcomes research data networks, “in order 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.”

Financing Mechanism

Federal entities use various funding mechanisms to support research, which affects the types of research conducted and the degree of autonomy researchers are afforded in conducting their studies. For example, when a grant is awarded, no substantial federal involvement with recipients is anticipated during the performance of a research activity. Conversely, contracts are awarded when a funder’s purpose is to acquire goods or services for the direct benefit or use of the funder. In these circumstances, the funder has substantial and direct involvement with the contractor throughout the life of the project.

As established by the Act, the Institute will fund research through contracts with “appropriate agencies and instrumentalities of the federal government,” with preference to AHRQ and the NIH, and “appropriate academic research, private sector research, or study-conducting entities.” The Act grants authority for AHRQ and NIH to enter into contracts with the new Institute, though there remains a constitutional question as to whether or not a federal entity can act as a contractor for a nongovernmental entity.

Contracts entered into must abide by transparency and conflicts of interest requirements, comply with methodological standards developed by the Methodology Committee, have appropriate processes in place to manage data privacy, and meet ethical standards for research.

The Institute does not have authority to award grants. In instances where the Institute contracts with AHRQ or NIH, it is unclear whether these federal entities could then award grants, or if work would have to be conducted under a contractual arrangement.

Publication of Research Performed Under Contract

The Act permits “a researcher who conducts original research under the contract for the agency, instrumentality, or other entity to have such research published in a peer-reviewed journal or other publication” as long as the researcher enters into a data use agreement with the Institute (as amended by Sec. 10602). Contained in the legislation is a provision that would have allowed the Institute to impose punitive financial and exclusionary sanctions on institutions whose researchers published results that were deemed by the Institute to be not “within the bounds of and entirely consistent with the evidence.” Thus, the Institute would have had essentially non-reviewable powers to both control the content of the research (whether findings are “within the bounds of and entirely consistent with the evidence” is an issue of substantive interpretation) and sanction researchers whose interpretations were inconsistent with Institute views.

Collaborating with the broader academic research community, the Coalition for Health Services Research led efforts to educate congressional staff about the detrimental effects of this language on the research enterprise, as well as its potential to undermine the legislation's goal of better transparency of research results. The Senate replaced the original language with a new Sec. 10602, “Corrections to Patient-Centered Outcomes Research” of the Patient Protection and Affordable Care Act, which passed the Senate on December 24. This amendment replaces the existing language on “Requirements for Publication of Research” and replaces with:

“Subsequent Use of the Data.—The Institute shall not 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.”

Scope of Work

The Act authorizes the conduct of “comparative clinical effectiveness research,” defined as “research evaluating and comparing the clinical effectiveness, risks, and benefits of two or more medical treatments, services and items,” including “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 in individuals.”

The comparative effectiveness provisions do not explicitly prohibit comparative cost effectiveness research. However, cost or value of health services is conspicuously absent from the statutory definition of comparative clinical effectiveness research described above. In addition, the Act states that the Institute “shall not develop or employ a dollars-per-quality adjusted life year (or similar measure that discounts the value of live because of an individual’s disability) as a threshold to establish what type of health care is cost effective or recommended. The Secretary shall not utilize such an adjusted life year (or such similar measure) as a threshold to determine coverage, reimbursement, or incentive programs...” While this provision pertains to the use of the research, it could be interpreted to extend to the conduct of the research as well.

Transparency

The bill requires that the new Institute establish procedures to ensure “transparency, credibility, and access.” Among these provisions is the requirement for a public comment period of not less than 45 days and not more than 60 days on the following:

- The national research priorities identified by the Institute and its Board and advisory panel(s);
- The methodological standards developed and updated by the Methodology Committee;
- The peer-review process;
- Draft research findings with respect to systematic reviews of existing research and evidence.

Since the Institute is a nongovernmental entity, it is not clear whether or not these notices of public comment will be posted in the *Federal Register* or simply on the Institute’s Web site.

The Institute is also required to hold public forums to increase awareness and obtain and incorporate public input and feedback on research priorities, findings, and other activities of the Institute, as the Institute deems appropriate.

The Institute will make available to the public through its Web site:

- The process and methods for the conduct of the research;

- The identity of the entity and the investigators conducting research , including any links the entity or the researchers have to industry;
- Research protocols, including measures taken, methods of research and analysis, research results, and such other information the Institute determines appropriate; and
- Comments received during each of the public comment periods.

In evaluating the funding, placement, and organization of health services research in the federal government, AcademyHealth adopted five principles to guide decisions related to the placement of comparative effectiveness research. Among these principles, AcademyHealth recommended that the entity 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 entities mission. Specifically, AcademyHealth recommended that stakeholders be involved in developing the research agenda and ensuring the validity of the research produced.

As written, the Act provides for unprecedented levels of stakeholder involvement in the formal governance structure of the Institute, and in the opportunities for formal and informal public comments on nearly all aspects of the research continuum. However, it will be important that these multiple opportunities for stakeholder input—and the associated time required to solicit, review, and incorporate feedback—do not adversely impact the timeliness and thereby the relevance of the comparative clinical effectiveness research ultimately produced.

Research Use

The Act places limitations on certain uses of comparative clinical effectiveness research. For example:

- The Secretary may only use evidence and findings from comparative clinical effectiveness research if such use is “through an iterative and transparent process which includes public comment and considers the effect on subpopulations.”
- The Secretary may not deny coverage of services based solely on comparative clinical effectiveness research.
- The Secretary may not use evidence or findings from this research in determining coverage, reimbursement, or incentive programs in a manner that devalues extending the lives of the elderly.

Nevertheless, there are no blanket prohibitions on the use of this research by public or private payers.

Sec. 3501 Health Care Delivery System Research; Quality Improvement Technical Assistance

Delivery System Research

The Patient Protection and Affordable Care Act authorizes AHRQ to “identify, develop, evaluate, disseminate, and provide training in innovative methodologies and strategies for quality improvement practices in the delivery of health care services that represent the best practices in health care quality, safety, and value.” In so doing, AHRQ is required to pursue such research “in a collaborative manner with other related Federal agencies.”

AHRQ’s Center for Quality Improvement and Patient Safety shall carry out these functions relying on epidemiology, health services research, sociology, psychology, human factors engineering, biostatistics, health economics, clinical research, and health informatics. The Center shall support, “through a contract or other mechanism, research on health care delivery system improvement and the development of tools to facilitate adoption of best practices that improve the quality, safety, and efficacy of health care delivery services. Such support may include establishing a Quality Improvement Network Research Program for the purpose of testing, scaling, and disseminating of interventions to improve quality and efficiency in health care.” Recipients of funding under this program may include nation, state, multi-state, or multi-site quality improvement networks.

The Act authorizes \$20 million per year for FY 2010 – 2014 for this program; however the actual funding level will be left to the congressional appropriators.

Quality Improvement Technical Assistance and Implementation

AHRQ’s Center for Quality Improvement and Patient Safety is authorized to award technical assistance grants or contracts to support technical assistance to institutions that deliver health care so they may implement the models and practices identified in the research conducted by the Center, including the Quality Improvement Networks Research Program. AHRQ may also award implementation grants or contracts to support the implementation of these models. Eligible entities include health care providers, health care provider associations, professional societies, academic health centers, universities, physician-based research networks, and others who have demonstrated expertise in providing information and technical support and assistance to health care providers regarding quality improvement.

Entities must provide support activities conducted under grant or contract in an amount equal to \$1 for each \$5 of federal fund provided. The Act does not authorize a specific funding level for this program.

Sec. 4301. Research on Optimizing the Delivery of Public Health Services

The Act authorizes the Secretary, acting through the CDC Director to provide funding for public health services and systems. Research supported under this section shall:

- Examine evidence-based practices relating to prevention, with a particular focus on high priority areas identified by the Secretary in the National Prevention Strategy or Healthy People 2020, and including comparing community-based public health interventions in terms of effectiveness and cost;
- Analyzing the translation of interventions from academic settings to real-world settings; and
- Identifying effective strategies for organizing, financing, or delivering public health services in real-world community settings, including comparing state and local health department structures and systems in terms of effectiveness and costs.

The research must be coordinated with the Community Preventive Services Task Force and must build on existing partnerships within the federal government, while also considering state, local, and private sector initiatives. On an annual basis, the Secretary would be required to submit a report to Congress summarizing the activities of the program and its research findings.

It is not clear from the statute how much funding would be provided to support these activities, since no funds are authorized to be appropriated. While immediately authorized, the Act does not specify where within CDC this program would be housed or when it would be operational.

Sec. 4302. Understanding Health Disparities: Data Collection and Analysis

The Act requires the Secretary, no later than two years after the enactment of the Act, to ensure that any federally conducted or supported health care or public health program, activity, or survey collects and reports specified demographic data on health disparities, specifically:

- Data on race, ethnicity, sex, primary language, and disability status;
- Data at the smallest geographic level such as state, local, or institutional levels if such data can be aggregated;
- Sufficient data to generate statistically reliable estimate by facial, ethnic, sex, primary language, and disability status subgroups; and
- Any other data deemed appropriate by the Secretary to help understand health disparities.

The Secretary shall make these data available for additional research, analyses, and dissemination to other federal agencies, nongovernmental entities, and the public, in accordance with any federal agency's data user agreements.

The Act does not authorize a specific funding level for this program.

Sec. 5101. National Health Care Workforce Commission

The Act establishes a National Health Care Workforce Commission to serve as a national resource on workforce and to coordinate federal efforts to monitor and address the nation's health workforce challenges. The Commission is made up of 15 members, appointed by the Comptroller General, who are nationally recognized experts in health care labor market analysis, health care finance and economics, health care facility management, health care plans and integrated delivery systems, health care workforce education and training, health care philanthropy, and providers of health care services. Specifically, the membership includes no less than one representative of:

- The health care workforce and health professionals;
- Employers;
- Third-party payers;
- Individuals skilled in the conduct and interpretation of health care services and health economics research;
- Consumer representatives;
- Labor unions;
- State or local workforce investment boards; and
- Education institutions.

The Act does not specify a date for the appointment of the Commission, nor does it authorize a specific funding level for the Commission's activities.

Sec. 5103. Health Care Workforce Assessment

The Act establishes a National Center for Health Workforce Analysis that, in collaboration with the Commission and relevant state and regional agencies shall provide for the development of information describing and analyzing the health care workforce and related issues, develop and publish performance measures and benchmarks, and establish, maintain, and publicize a national registry of grants awarded and a database to collect data from longitudinal evaluations on workforce trends.

The Secretary is authorized to award grants to, or enter into contracts with, entities to collect, analyze, and report data regarding workforce programs and to provide technical assistance to local and regional entities on the collection, analysis, and reporting of data. Eligible entities include states, state workforce investment boards, public health or health professions schools, academic health centers, or appropriate public or private nonprofit entities.

The Act authorizes \$7.5 million per year for the National Center from FY 2010 – FY 2014. State and regional centers are authorized \$4.5 million per year for FY 2010 – FY 2014. In each instance, actual funding levels will be left to the congressional appropriators. The Act does not authorize a specific funding level for the grants program.