

July 1, 2004

Department of Health and Human Services

Re: Medicare Prescription Drug, Improvement, and Modernization Act of 2003, Section 1013: Suggested Priority Topics for Research, FY 2006. Docket No. 2004S-0170: 69 Fed. Reg. 22045 (April 23, 2004).

The Pharmaceutical Research and Manufacturers of America appreciates this opportunity to recommend research priorities for fiscal year 2006 research under Section 1013 of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (MMA).

PhRMA is a voluntary, nonprofit association representing the country's leading research-based pharmaceutical and biotechnology companies, which are devoted to inventing and manufacturing medicines that allow patients to lead longer, healthier, and more productive lives. In 2003, PhRMA member companies invested an estimated \$33 billion in discovering and developing new medicines. These research dollars fund the search for new cures and better treatments for many of the most serious diseases and conditions patients face, such as diabetes, heart disease, Alzheimer's, as well as many rare diseases and conditions. As leaders in the search for innovative new treatments that contribute to improved health care quality, effectiveness and efficiency, PhRMA is pleased to offer input on AHRQ research priorities in pursuit of this common goal.

Background:

PhRMA previously submitted recommendations to HHS in its comments for initial (FY 2005) research priorities under Section 1013. In those comments, we recommended a research program based on priority diseases and conditions such as heart disease, diabetes, and the emerging epidemic of obesity. PhRMA recommended a research program that provides information needed by patients and physicians on the range of items and health care services available to address these diseases, and information needed by decision-makers to improve health care quality and efficiency.ⁱ

Section 1013 of the MMA creates a new program within the Agency for Healthcare Research and Quality (AHRQ) for health outcomes research to improve the quality, effectiveness and efficiency of health care delivered under the Medicare, Medicaid, and State Children's Health Insurance (SCHIP) programs. The research program described by the statute includes activities to identify improvements in "ways in which such items and services are organized, managed, and delivered under such

programs.” The provision mandates a broad scope of research on health items and services, and directs HHS to follow an open public process for setting research priorities.

Section 1013 also describes the scope of HHS’ longer-term research program. The statute instructs HHS to identify options that may be undertaken in voluntary collaboration with private and public entities (as appropriate) for the: provision of more timely information on outcomes and quality of patient care; acceleration of the adoption of innovation and quality improvement; and development of management tools, potentially through use of administrative or claims data.

Innovative medical technologies, services and delivery systems represent important solutions to Medicare, Medicaid and private payers seeking to improve health care quality and efficiency. AHRQ’s authorizing legislation recognizes this by calling for research activities to “increase awareness of new uses” of medical technologies and to “improve the quality of health care while reducing the cost of health care” through “an increase in the appropriate use of” medical technologies.

Improving access to innovation and improving health care quality are closely related issues that AHRQ should seek to address simultaneously. Section 1013 provides HHS an opportunity to initiate new research to identify ways to improve adoption of innovative technologies and services to improve health care quality. In conducting this research, HHS should maximize the effectiveness of its research by focusing on priority diseases and conditions.

Recommendations:

Consistent with the language of Section 1013, HHS research priorities in FY 2006 should include research to identify improvements in the organization, management and delivery of high-quality care under Medicare, Medicaid and SCHIP programs. It also should identify steps to accelerate the adoption of innovation and quality improvement. Research under Section 1013 to achieve these goals should address two basic problems: 1) systemic barriers to diffusion of innovation in health care, and; 2) the health system’s widespread failure to make use of interventions known to be effective.

Slow Diffusion of Innovation

Patients, physicians and other health care professionals currently face substantial barriers to adoption of innovative medical technologies. Studies have found that some medical technologies can take as long as 15 to 20 years to fully reach widespread adoption in medical practice.ⁱⁱ

Coye et al. state that “the ‘natural’ rate of diffusion today of many *proven* new health technologies and treatments is not optimal.” They said that “our major challenge today is to better understand the drivers and barriers of diffusion.”ⁱⁱⁱ

Inadequate Access to Effective Interventions

The U.S. health system's failure to provide recommended care to a large percentage of patients is increasingly well-documented. Several recent articles addressing this issue were discussed in PhRMA's May 7, 2004 recommendations to HHS on initial research priorities under Section 1013,^{iv} including research by McGlynn et al. showing that a large percentage of patients with diseases like diabetes, heart disease and colorectal cancer do not receive recommended care.

Research to Support Diffusion of Innovation and Access to Quality Care

The findings described above suggest that what is needed primarily is not more research on health technologies and services known to work, but more research to determine which approaches are most effective at improving the rate of diffusion of innovative technologies and services and improving health care quality. HHS research priorities under Section 1013 should seek to address these challenges, focusing on previously identified priority diseases and conditions.

Factors that can affect diffusion of innovation include:

- Knowledge barriers – provider and patient awareness of the technology and how to use it;
- Financial barriers – patient co-payments and cost-sharing, socioeconomic status and insurance status all can affect access to innovation;
- Organizational barriers – such as prior authorization requirements can discourage adoption of innovation

All of these factors should be assessed by AHRQ in developing recommendations on accelerating innovation and improving health care quality.

Research related to knowledge barriers:

Lack of awareness of innovative medical technologies likely contributes to the extensive underuse documented in the literature. AHRQ should support additional research to identify situations in which patients with priority diseases or conditions are not receiving recommended tests, treatments or other items and services, and seek to determine the extent to which this is due to lack of awareness of these interventions. In addition, AHRQ should assess strategies to determine the most effective methods of information dissemination regarding innovative technologies.

Research related to financing and organizational barriers:

A number of articles identify payment policy as a significant barrier both to diffusion of innovation and access to recommended care. More research is needed on specific aspects of payment policy that impede diffusion of innovation and access to quality care.

Coye et al. point to suboptimal use of information technology and “a reimbursement system that fails to provide coverage for innovative technology in a timely manner” as impediments to health care quality improvement.^v

At a 2001 conference sponsored by the National Academy of Sciences, reimbursement policies were identified as a key public policy barrier to innovation in health care. For example, Dr. Mark McClellan, then a nominee to the president’s Council of Economic Advisors, suggested at the conference that current reimbursement incentives created a barrier to adoption of computer technology by hospitals and other institutions.^{vi}

In addition, in its report *Crossing the Quality Chasm: A New Health System for the 21st Century*, the Institute of Medicine’s (IOM) Committee on Quality of Health Care in America concluded that “current payment methods do not adequately encourage or support the provision of high quality care.”^{vii}

The IOM report recommends research to identify the scope of services and interventions across the continuum of care needed by patients with priority diseases and conditions. HHS’ FY 2006 research priorities under Section 1013 of the MMA should adopt this recommendation. Identifying these services and interventions can help improve coordination of patient care and better align health care payment and organization with the needs of patients with priority diseases and conditions.

As highlighted in *Crossing the Quality Chasm*, current payment methods often discourage adoption of innovative, quality-improving delivery systems as well and innovative technologies.

“It is critical that payment policies be aligned to encourage and support quality improvement,” the report states. “Most payment methods have an objective of cost containment or reflect consideration of issues of access” but “do not have the explicit goal of ensuring quality care or facilitating quality improvement.”

The report recommended that private and public purchasers “examine their current payment methods to remove barriers that currently impede quality improvement, and to build in stronger incentives for quality enhancement.” Research under Section 1013 should identify steps that have been taken to implement this recommendation, as well as additional steps that still need to be taken.

Research also should identify specific payment policy barriers in Medicare and Medicaid programs that impede adoption of innovation and improvement in health care quality. These could include delays in coverage, coding and payment decisions for new medical technologies: payment policies that fail to reflect the cost of advances in care; and policies that discourage establishment of innovative health care services like coordinated care and disease management.

A recent study supported by AHRQ found that one managed care tool – increased patient cost-sharing through drug co-pays – can have an adverse effect on use of needed medicines and patient outcomes. The researchers estimated that a doubling of co-pays in a typical two-tier drug plan “resulted in an approximately 45 percent reduction in the use of anti-inflammatory drugs and antihistamines, a drop of approximately 35 percent in the use of cholesterol-lowering medications and drugs to treat ulcers and asthma, and a decrease of about 25 percent in the use of medicines used to treat high blood pressure, depression, and diabetes,” according to AHRQ.^{viii}

According to AHRQ, the study also “found preliminary evidence that patient health suffers as individuals with some chronic illnesses cut back on their medicines. For example, as the use of prescription drugs declined, visits to hospital emergency rooms increased 17 percent and hospital stays rose by 10 percent among patients with diabetes, asthma, and gastric acid diseases.” These findings underscore why AHRQ research on improving diffusion of innovation and improving health care quality should take a holistic view of the health care system.

In many cases, the estimated reductions in medicine use in the AHRQ-sponsored study occurred in conditions for which significant under-use of medicines already has been documented, such as high cholesterol, hypertension, diabetes, asthma. A recent study by Pharmetrics, for example, found that 17 to 34 percent of insured people with type II diabetes are not receiving needed medicines for the disease, and that these patients had higher hospitalization rates and ancillary health care costs.^{ix}

Recent research suggests that new health care delivery approaches are needed to improve the quality of pharmaceutical care received by seniors. A 2004 study by Higashi et al. of 372 “vulnerable” older patients in two managed care plans suggested that avoiding use of inappropriate medicines is a far smaller problem than ensuring use of needed medicines. “Efforts to improve the quality of pharmacologic care for older patients should focus on prescribing indicated medications and avoiding adverse events by monitoring, documentation, education, and continuity,” the authors conclude.^x

This type of research underscores the importance of research to address policy questions arising from the new Medicare prescription drug benefit. Key research questions under the new Medicare drug benefit include the clinical and/or economic consequences associated with implementation of the drug benefit and what impact the drug benefit has on patient adherence with medication.

HHS should support additional research to examine a range of delivery systems and payment policies that have been successful at accelerating adoption of innovation and improving access to recommended care, such as disease management and coordinated care for chronic conditions. Research also should identify barriers to broader adoption of these approaches and recommend ways to overcome them. Such research could help identify key issues for CMS to consider as it supports innovative approaches to managing chronic diseases and coordinating care for Medicare beneficiaries.

Conclusion:

Innovative medical technologies and delivery systems represent important solutions to the challenge of rising health care costs. Yet our health system often creates significant barriers to adoption and use of the innovations, and too often fails to make use of tests, treatments and delivery system known to be effective for improving quality and efficiency of care.

HHS research under Section 1013 can help overcome these barriers and improve the quality and efficiency of care received by patients under Medicare, Medicaid and SCHIP programs.

Sincerely,



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ⁱ “Medicare Prescription Drug, Improvement, and Modernization Act of 2003, Section 1013: Suggested Priority Topics for Research,” PhRMA, May 7, 2004.

ⁱⁱ “Medical Innovation in a Changing Healthcare Marketplace: Conference Summary” 2002, National Academy of Sciences

ⁱⁱⁱ “The Tipping Point and Health Care Innovations: Advancing the Adoption of Beneficial Technologies,” Molly Coye, MD, MDP, et al., The Health Technology Center, Commissioner Paper Synopsis, Accelerating Quality Improvement in Health Care conference proceedings, National Institute for Health Care Management and National Committee for Quality Health Care, Jan. 27-28, 2003, Washington D.C., ,

^{iv} PhRMA, *op. cit.*

^v Coye et al., *op. cit.*

^{vi} National Academy of Sciences, *op. cit.*, Appendix C, p. 64

^{vii} *Crossing the Quality Chasm: A New Health System for the 21st Century*, Institute of Medicine, Washington, D.C., National Academy Press, 2001

^{viii} *Significant Increases in Drug Co-Payments May Reduce Patients' Use of Needed Medications*. Press Release, May 18, 2004. Agency for Healthcare Research and Quality, Rockville, MD.

<http://www.ahrq.gov/news/press/pr2004/drugcopapr.htm>

^{ix} PharMetrics, Patterns of Treatment, Resource Utilization, and Costs Among People with High Low-Density Lipoprotein Levels, (Watertown, MA: PharMetrics, May 2004)

^x T. Higashi, MD, University of California, Los Angeles, et al., The Quality of Pharmacologic Care for Vulnerable Older Patients, *Ann Intern Med.*, 2004;140:714-720