

**America's Health
Insurance Plans**

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June 7, 2004

Mark McClellan MD
Administrator
Centers for Medicare and Medicaid Services
7500 Security Boulevard
Baltimore, MD 21244-1850

Dear Dr. McClellan:

In response to the April 23rd Federal Register notice regarding Fiscal Year 2005 priority areas for research, America's Health Insurance Plans (AHIP) is pleased to submit suggested research areas to improve the quality, effectiveness, and efficiency of health care. AHIP represents nearly 1,300 health plans and insurers providing health benefits to over 200 million enrollees. Many of our member companies participate in the Medicare and Medicaid programs as well as other federally funded coverage programs.

Under Section 1013 of the Medicare Modernization Act, the Secretary of Health and Human Services (HHS) has been directed to establish a broad new research program within the Agency for Healthcare Research and Quality (AHRQ) to conduct and support research to advance understanding of the comparative clinical effectiveness and appropriateness of the organization, management and delivery of health care items and services in the Medicare, Medicaid and State Children's Health Insurance (SCHIP) programs. These comments address key areas of this research that private sector health insurance plans believe need immediate attention.

Focusing Research on Priority Areas

A national agenda is needed to focus resources on key priority areas which should yield improvement in a more timely manner than if research were directed across multiple competing projects. To promote a consistent national approach to research and quality improvement, we encourage the Centers for Medicare and Medicaid Services (CMS), AHRQ and the Food and Drug Administration (FDA) to work collaboratively and identify research areas within the twenty areas recommended by the Institute of Medicine in its *Priority Areas for National Action* report.



These twenty areas—care coordination, patient self-management/health literacy, asthma, cancer screening, children with special health care needs, diabetes, end-of-life care, frailty associated with old age, hypertension, immunization, ischemic heart disease, major depression, medication management, nosocomial infection, pain control in advanced cancer, pregnancy and childbirth, severe and persistent mental illness, stroke, tobacco dependence in adults, and obesity – raise important issues that could impact the health and well-being of beneficiaries enrolled in public programs. Systematic reviews would be helpful in determining what types of evaluations are conducted in these areas, what programs or strategies have demonstrated successful outcomes, and what further research would be useful.

Criteria and Methods Used to Rank the Priority Areas for Research

We ask that the priority areas for research be ranked according to the criteria used by the Institute of Medicine in its *Priority Areas for National Action* report – impact, improvability, and inclusiveness.¹ Use of these criteria will help ensure greater consistency across different national quality initiatives, such as projects being implemented by organizations such as the National Quality Forum and CMS.

Ensuring that the Process is Open and Transparent

AHIP supports HHS' strategy of working in consultation with stakeholders to develop this research framework. We ask that the Steering Committee, comprised of representatives from various federal agencies (e.g., CMS, AHRQ, and the FDA), ensure that the priority-setting process remains open and transparent, and that all interested parties – including stakeholders in the private sector – have the opportunity to provide feedback to be considered as part of the final decision-making process. Additionally, we ask that the Steering Committee make public the basis for decisions (e.g., criteria and methods used to rank the priority areas for research).

¹Institute of Medicine, National Academy of Sciences, *Priority Areas for National Action*. **Impact**—the extent of the burden – disability, mortality, and economic costs, imposed by a condition, including effects on patients, families, communities, and societies; **Improvability**—the extent of the gap between current practice and evidence-based best practice and the likelihood that the gap can be closed and conditions improved through change in an area, and the opportunity to achieve dramatic improvements in the six national quality aims identified in *Crossing the Quality Chasm* (safety, effectiveness, patient-centeredness, timeliness, efficiency and equity); and **Inclusiveness**—the relevance of an area to a broad range of individuals with regard to age, gender, socioeconomic status, and ethnicity/race (equity); the generalizability of associated quality improvement strategies to many types of conditions and illnesses across the spectrum of health care (representativeness); and the breadth of change effected through such strategies across a range of health care settings and providers (reach).



Specific Areas to Consider for the Initial Priority List

In Fiscal Year 2005, we recommend that the following areas be considered for priority research in the short term:

?? *Research on the Comparative Effectiveness and Efficacy of Prescription Drugs and "Similar" Medical Treatments*

Providing a clinically sound and affordable prescription drug benefit within public programs is important to all health care stakeholders but, most particularly, to beneficiaries. Additional research focused on the comparative effectiveness of similar prescription drug therapies, clinical outcomes, and relative use of resources would be useful for the entire health care industry. The analysis will help to focus on the most appropriate services for meeting the patient's need and help prevent gaming of the system.

Research focusing on the comparative effectiveness of medical treatments designed to have similar effects is highly complex. There may be many different reasons why specific medications are given to individual patients (e.g., a patient may have a co-morbid condition(s) that may preclude the physician from prescribing specific medications). Developing further understanding of how similar medications and other treatments interact and their impact on individual patients would provide valuable tools for medical professionals to use in determining appropriate patient-centered therapies.

We offer the following suggestions for conducting clinical comparative effectiveness research:

- ~~///~~ Compare the clinical effectiveness of similar medications for prevalent chronic illnesses effectively treated with prescription drugs, such as asthma, cardiovascular disease, and diabetes. A systematic review could be conducted to investigate the appropriate treatments for specific medical conditions, identify medications that can be used to treat these conditions, and reasons for selecting one medication over another for specific types of patients. For example, reviews could be conducted that evaluate prescribing insulin versus newer oral anti-diabetic agents in patients taking other drugs such as metformin and sulfonylurea, or the use of Cox-2 inhibitors and other NSAIDs with respect to safety and outcomes for patients with cardiovascular or renal disease.
- ~~///~~ Conduct research for the top 10-20 therapeutic classes of prescription drugs, and evaluate the associated clinical, economic, and humanistic outcomes.
- ~~///~~ Create an index of contraindications for certain treatments as a useful tool for providers.



?? ***Research on Evaluating New Technologies***

Every year in the United States, thousands of new technologies, devices and other medical products are being developed and approved by the FDA. As these new products are introduced, organizations that finance the provision of health care, including health plans, insurers, and benefit plan sponsors must make decisions on whether such products are valid medical treatments for inclusion in benefit design. While it is often clear that the devices or tests do what they propose to do, organizations that provide health benefits are often unable to determine if these technologies are clinically efficacious in the short or long term; if they are equal to, better than, or less valuable than existing technology; and/or if their use warrants adoption and payment.

The rapid explosion of innovation in drugs, devices, and therapies makes it difficult for all stakeholders to stay abreast of new approaches. It would be useful to address possible adoption of a broader strategy such as a centralized early advisory system to identify new and emerging technologies, prioritize them according to their potential impact on health care and its delivery, monitor them for possible future action, and publish and distribute assessment reports broadly.

Additional guidance in this area would help make the technology assessment process more transparent to all health care stakeholders, including health plans and insurers, providers, plan sponsors and employers, and consumers. AHIP has submitted a proposal to AHRQ to develop this topic into a technology assessment report as part of the work of the Evidence-based Practice Centers; this could inform discussion of this topic in the context of the Agency's additional responsibilities under the MMA legislation.

?? ***Research on Medication Compliance***

Recent studies of the effects of tiered formularies on patient compliance with prescribed medications indicate that patients with chronic conditions *who are not actively seeing a physician* (defined as two visits a year) do not take medications that are necessary to prevent the development of serious health problems (e.g., heart conditions, asthma, diabetes, etc.). With the new benefit for prescription drugs, Medicare beneficiaries with chronic conditions will be frequent or constant consumers of medication, and research is needed to determine the reasons for and costs of patient non-compliance. Understanding the reasons why patients do not follow physician orders for the use of drugs for the treatment of valid medical conditions would be helpful in the effective utilization of the new Medicare Part D coverage. Knowledge of the roles of various factors such as the lack of insurance coverage, lack of economic or social resources, and need for better patient education would also contribute to a more effective implementation of the Medicare prescription drug benefit.

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AHIP and our member health plans and insurers look forward to working with CMS, AHRQ and the FDA as they finalize their research agendas for the Fiscal Years 2005 and 2006. Please contact me (cbocchino@ahip.net or 202.778.3278) if you have any questions about our comments.

Sincerely,

A handwritten signature in cursive script that reads "Carmella Bocchino".

Carmella Bocchino
Senior Vice President, Medical Affairs
AHIP