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MessageFrom: wheeler, Deborah [Dwheeler@ahip.org]  
Sent: Wednesday, July 14, 2004 6:43 PM  
To: fdadockets@oc.fda.gov  
Cc: Bocchino, Carmella  
Subject: America's Health Insurance Plans' Comments Regarding Fiscal Year 2006  
Research Areas in Response to the FDA Docket ID 2004S-0170

Attached are recommendations from the America's Health Insurance Plans in response to the Federal Register notice regarding Fiscal Year 2006 priority areas for research as defined in Section 1013 of the Medicare Modernization Act.

Please contact Carmella Bocchino, Senior Vice President, Medical Affairs with any additional questions at cbocchino@ahip.org or at (202) 778-3278.

Thank you for the opportunity to submit these comments.

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July 21, 2004

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

Dear Dr. McClellan:

In response to the April Federal Register notice regarding Fiscal Year 2006 priority areas for research, America's Health Insurance Plans (AHIP), on behalf of our members, 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 Americans. Many of our member companies participate in the Medicare and Medicaid programs as well as other federally funded coverage programs.

**Focusing Research on Priority Areas**

Consistent with our previous comments on Fiscal Year 2005 research areas, we believe there is a need for the Centers for Medicare and Medicaid Services (CMS), the Agency for Healthcare Research and Quality (AHRQ) and the Food and Drug Administration (FDA) to work collaboratively to identify research areas within the twenty areas recommended by the Institute of Medicine in its 2003 *Priority Areas for National Action* report.

These twenty areas focus on key conditions that could impact the health and well-being of beneficiaries enrolled in public programs. Systematic reviews would be helpful in determining what evaluations are currently conducted in these areas, what programs or strategies have demonstrated successful outcomes which have had little to no effect, and what further research would be beneficial.

**Specific Areas to Consider for Fiscal Year 2006**

In Fiscal Year 2006, we recommend that the following areas be considered, in the short term, for priority research:

- ***Research on the Impact of Pharmaceuticals on Non-pharmaceutical Health Care Services and Overall Health Care Costs***

A comprehensive evaluation of the real cost of prescription drugs to society should include an assessment of the impact of medication use on other health services (e.g., decline in recurrent heart attacks and subsequent health care services for patients receiving appropriate beta blocker treatment or the effect of drug-to-drug interactions that may lead to increased hospitalizations or emergency care).



- ***Research to Evaluate the Effectiveness of the State Children's Health Insurance Program (SCHIP) and Medicaid***

While we recognize that CMS conducts on-going assessments of SCHIP and Medicaid, a systematic evaluation of the investment and health outcomes of these programs is necessary to fully understand their value. We recommend that HHS oversee research that evaluates the effectiveness of these programs – especially those programs that have been granted waivers from certain requirements of Medicaid law – to gain a better understanding of the programs' impact on access, quality, consumer satisfaction, and affordability.

- ***Research to Determine the Optimal Benefit of Consumer Incentives to Use Centers of Excellence***

The Institute of Medicine (IOM) urged health care stakeholders to re-align payment incentives with the delivery of safe and effective, high-quality care. In turn, the IOM's work has helped to give momentum to an emerging trend in health care, the development of alternative financing systems that reward providers for the delivery of high quality of care and consumers for selecting high quality providers.

One current strategy is to support the Centers of Excellence concept in which consumers are encouraged to use preferred facilities that have met or exceeded specific quality and volume criteria. To fully understand the impact of these approaches, we recommend that HHS conduct a systematic evaluation to determine consumer behavior, satisfaction, potential savings and unintended consequences. Among questions that this research should raise are:

- 1) Do consumers understand the benefits of a "preferred center" rather than facilities that are routinely utilized?
- 2) If not selected as a "preferred" hospital, what impact does this have on hospital behavior to prompt further excellence in quality improvement or market stability?
- 3) What incentives —financial or non-financial —have the greatest impact on consumer choice?

- ***Research on the Methods Used to Assess Physician Performance***

Rewarding providers for high quality care is becoming an increasingly common trend within the health care industry. Much of the current focus is on the development of performance measures that assess health plan or hospital performance. Less attention has been paid to the appropriate methods to assess physician performance. We recommend that HHS conduct research to determine the most effective methods for assessing physician performance to ensure a statistically valid and reliable approach (e.g., adequate sample size per physician practice to achieve an acceptable confidence level).

- ***Comparative Research about the Value of Non-physician Practitioners***

Health care today is being delivered by a variety of auxiliary practitioners including nurse practitioners and physician assistants. As these services become more highly integrated, research is needed to fully understand the impact of non-physician practitioners on clinical resource consumption, health care outcomes, and patient satisfaction.



- ***Additional Research about Chronic Conditions and Disease Management***

More than 125 million Americans are affected by chronic conditions such as diabetes, congestive heart failure, and asthma. This number is projected to grow to 157 million by 2020. The prevalence of chronic conditions increases with age. The baby boom generation, which is starting to age in to Medicare, will account for 13 percent of the population by 2011, and 20 percent of the population by 2030.<sup>1</sup> The impact of this age group on the future of the Medicare program will be significant, and we recommend that HHS focus additional research on the following related topics:

- Evaluate the impact of cost sharing for people with chronic illnesses to inform the future design and implementation of cost sharing strategies.
- Conduct evaluative research to standardize an approach to determine the business case for disease management programs with a goal of strengthening current and future disease management programs being implemented within the public sector.
- Develop a better understanding of the risk factors for chronic conditions such as cardiovascular disease, diabetes, and asthma, and current barriers to reduce these risks and are essential for the success of targeted disease management interventions.

- ***Research Addressing Provider-Patient Communication***

Effective provider-patient communication is essential to the delivery of high quality health care. Key components include the clear communication of expectations for health outcomes by providers and patients and the availability of appropriate medical information to all providers who deliver clinical care to patients. We suggest research in the following areas:

- A systematic evaluation of how providers communicate with patients the preferred treatments for certain conditions and the potential adverse effects associated with these therapies.
- Effective patient care depends upon ensuring that critical medical information from a variety of sources is available and used at the point of care. Additional research is needed into the most effective methods for broad dissemination and appropriate utilization of this information by physicians and other health care professionals at the time care is delivered.

- ***Using Technology to Deliver Evidence-Based Health Care***

Implementing information technology systems in provider practices may improve health care quality and help achieve better compliance with evidence-based guidelines. These linkages between information technology adoption and improved quality, however, are not fully understood and the results of a systematic evaluation into the following areas would be useful:

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<sup>1</sup> Statistics taken from *Partnership for Solutions*

July 21, 2004  
Page 4



- Research should focus on how technology can improve compliance with evidence-based guidelines and how the adoption of information technology influences positive changes in provider behavior. In addition, this evaluation should focus on the financial implications of introducing new systems, including implementation costs, opportunity costs, possible savings from efficiency and the potential societal benefits.
- Additional research should focus on the implementation of electronic medical records systems, addressing appropriate standards for systems adoption, the inherent value in implementing electronic medical records, any barriers or limitations (e.g., implementation issues, impact on privacy), and the general implications for introducing such technology.
- ***Research into the Use of Evidence-based Medicine in Medicare or Medicaid Coverage Decisions***  
We also ask that HHS conduct further research to ensure that current scientific evidence is linked with the coverage decisions made within the Medicare and Medicaid programs.

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.org 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