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March 27, 2009

Harold C. Sox, M.D., Chair
Committee on Comparative Effectiveness Priorities
Institute of Medicine
500 Fifth Street, N.W.
Washington, D.C. 20001

Re: IOM-HCS-09-01, Recommendations on the National Priorities for Comparative Effectiveness Research in Health Care.

Dear Dr. Sox:

The American Society of Health-System Pharmacists (ASHP) is pleased to submit written comments pertaining to recommendations for comparative effectiveness research (CER) to be supported by funding from the American Recovery and Reinvestment Act of 2009 (ARRA). As the national professional association representing over 35,000 pharmacists who practice in hospitals and health systems, ASHP can offer unique and vital feedback on this important health care issue. Pharmacists in hospitals and health systems are experts in medication use who serve on interdisciplinary patient-care teams to ensure that medicines are used safely, effectively, and in a cost-conscious manner.

ASHP is publisher of the *American Hospital Formulary Service Drug Information (AHFS DI)*, a comprehensive, independent reference on the clinical use of medications marketed in the United States, which is recognized through federal legislation under Medicare Part B, Medicaid, and Medicare Part D as an official compendium for information on medically accepted uses of medications. The Society's expertise in drug information would benefit CER research and we encourage the Agency for Healthcare Research and Quality (AHRQ), the National Institutes of Health (NIH), other federal agencies, and private entities who conduct CER to partner with ASHP in this research and subsequent efforts to translate the results into practice.

ASHP wishes to submit the following CER recommendations that represent critical information needs to improve patient outcomes:

- Optimal practice models for delivery of patient care,
- Strategies for using information technology (IT)-enabled decision support for delivery of CER, and
- Best practices for disseminating and implementing CER.

A detailed description of each research need is provided followed by a summary of guiding principles that should serve as the foundation for all CER.

Optimal Practice Models for Delivery of Patient Care

As described by the Dartmouth Atlas, the quality and cost of care is inconsistent across geographic regions, with much of this inconsistency attributed to variation in the care setting and the health care professional that provides the service.¹ Under Medicare Part D programs, pharmacists provide medication therapy management (MTM) services that include formulating medication treatment plans; monitoring and evaluating patients' response to therapy; performing medication reviews to identify, resolve, and prevent medication-related problems; and coordinating and integrating MTM services within the broader health care services provided to patients. Pharmacists also participate in chronic disease management and prevention activities under collaborative practice agreements with physicians. MTM programs and published research²⁻¹² have demonstrated that pharmacist management of disease and drug therapy significantly improves patient outcomes, while reducing overall health care costs. However, there is limited research that directly compares this practice model to models in which care is provided by other health care professionals (e.g., nurse, nurse practitioner) or multi-disciplinary teams (e.g., pharmacist–nurse or pharmacist–physician collaborative models). ASHP believes such research would demonstrate best practices and strongly encourages IOM to recommend models of care as a research priority for CER.

Strategies for Using IT-enabled Decision Support for Delivery of CER

A critical element of CER is ensuring that research findings reach the point of care where clinicians, together with patients, can use the information to make informed treatment decisions. Electronic health records and other technologies that support health care processes are expected to provide point-of-care information; however use of these technologies is currently limited. On March 25, 2009, the *New England Journal of Medicine* published research finding that only 17% of U.S. hospitals have computerized prescriber order entry (CPOE) systems in all clinical units within the facility.¹³ Moreover, less than 2% of hospitals have fully implemented an electronic health record with clinical documentation, test and imaging results, CPOE, and decision support. Decision support technology—software programs that guide treatment decisions by integrating clinical guidelines, drug information, and patient-specific data—has significant potential as a mechanism to deliver CER findings. However, strategies for creating and integrating these programs within other technologies, as well as barriers to implementation, are not well-studied. In addition, a 2007 survey conducted by ASHP found that only slightly more than half of prescribers enter most (i.e., more than 75%) of orders via CPOE.¹⁴ Almost 17% of those orders require manual re-entry because of a lack of interface or interoperability between order-entry and other systems. ASHP encourages IOM to recommend research that compares approaches for using clinical decision support and other technologies in the translation and implementation of CER.

Best Practices for Disseminating and Implementing CER

Effective dissemination and translation techniques are needed to ensure that CER findings are used to make informed decisions that improve patient outcomes. ASHP has expertise in synthesizing and disseminating complex information about drugs in an actionable format for use by clinicians and patients at the point of care; therefore, the Society appreciates the inherent challenges in these activities. It is estimated that a lag time of 17 years occurs between evidence generation and its widespread implementation in health care practice.¹⁵ Vast improvement in this rate of adoption is needed if the results of CER are to provide significant benefit for patients. Many strategies and tools have been used to enhance adoption of evidence-based best practices, including clinical and practice-related guidelines, continuing education for health care professionals, patient education tools, and most recently, academic detailing. While these approaches are commonly used, they are not well studied and results are variable. ASHP encourages IOM to recommend research that compares the benefits and limitations of these approaches in order to determine the strategy, or combination of strategies, that facilitates use of CER by each audience (e.g., clinicians, payers, and patients.) Specific to patients, CER studies should evaluate different approaches for communicating information about treatment choices, including information on effectiveness, risk versus benefit (e.g., side effects), and costs. This research should determine strategies that account for variations in consumer health literacy and learning styles.

Guiding Principles for CER

ASHP encourages IOM to recommend the development of sound scientific principles to guide CER. CER supported by ARRA should seek to include information from varying types of research (e.g., randomized controlled trials, patient registries, databases), but base inclusion of this information on pre-established criteria that acknowledge the strengths and limitations of each data type. Methodologies for CER should be transparent and free from industry influence. Full disclosure of funding sources and potential conflicts of interest is essential. It should be noted that peer-reviewed publications in journals have later been discovered to have had financial backing from sources that had a direct financial stake in the research that was published. In other instances, unfavorable results and negative findings have been suppressed by manufacturers and publishers, respectively. ASHP urges IOM to ensure CER includes safeguards that prevent against improper influence, financial or otherwise.

Specific CER projects should be initiated only after well-defined research questions have been established. Patient populations that the research is intended to address should be clearly defined before the research begins and fully described within the research results that are disseminated to stakeholders. Entities involved in CER should consider limitations in the existing evidence base, including narrowly defined patient populations and limited evidence about the use of many treatments in women and minority populations. CER should seek to address this evidence gap whenever possible. In instances where disparities can not be addressed, the results of CER should acknowledge this limitation in a manner that is transparent to all stakeholders who use the information. Patients' individual responses to drug therapy, including the impact of pharmacogenetics,

are important considerations that should not be disregarded in efforts to compare treatment options.

While CER should seek to assess costs of alternative therapies, ASHP believes that costs comparisons are only appropriate when outcomes are comparable and the evidence to support such comparisons is scientifically sound. It should be noted that the methodology and quality of existing economic studies are inconsistent. Results of CER should clearly describe the type of cost-effectiveness analysis (e.g., cost minimization, cost utility, incremental cost-effectiveness ratio) that was performed as well as the perspective of the intended audience (e.g., patients, employers, government agencies, and payers). Cost-effectiveness assessments are most useful when they are based on valid outcome measures (e.g., overall survival versus disease-free survival) and appropriate statistical analyses. It is probable that geographic and patient heterogeneity will limit the ability to issue broad recommendations related to cost of therapies. However, CER should raise awareness of factors that should be considered when comparing costs of similar therapies. Recommendations that appear in the chapter “Strategies for Including Resource Allocation and Economic Considerations” in *Antithrombotics and Thrombolytic Therapy: American College of Chest Physicians (ACCP) Evidence-Based Clinical Practice Guidelines, 8th Edition* may serve as a useful starting point for determining best practices for cost analyses in CER.¹⁶

ASHP welcomes the opportunity to collaborate with AHRQ, NIH, and others as the IOM Committee and the Federal Coordinating Council determine areas for CER that compare specific drug therapies within pharmacologic classes, drug therapies from different classes used to treat the same condition, and drug therapy to other treatment modalities. In addition, the Society is prepared to leverage our existing partnerships with the National Library of Medicine, Consumers Union, Veterans Administration, and electronic content and health information systems vendors, as well our extensive network of member pharmacists who determine and implement drug use policies, to ensure that knowledge gained through AARA-funded CER is disseminated to clinicians, payers, and patients and subsequently translated into practice.

ASHP appreciates this opportunity to provide recommendations for CER. If you have questions regarding our comments, please contact Cynthia Reilly, Director, Practice Development Division by phone at (301) 664-8664 or via e-mail at creilly@ashp.org.

Sincerely,



Henri R. Manasse, Jr., Ph.D., Sc.D.
Executive Vice President & Chief Executive Officer
American Society of Health-System Pharmacists

cc: Roger Herdman, Board Director, IOM Study Staff for the Committee on
Comparative Effectiveness Priorities

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