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**Patient, Clinician Perspectives Critical to Successful Design of
Comparative Effectiveness Research**

***Working Group on Evidence-Based Healthcare Recommends
Steps to Federal Coordinating Council to Improve Involvement***

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ALEXANDRIA, Va. (May 12, 2009)—Patient and clinician perspectives must be involved in Comparative Effectiveness Research (CER) to ensure findings are balanced and offer a sound direction and design, The National Working Group on Evidence-Based Healthcare (Working Group) said today.

The American Recovery and Reinvestment Act enacted in February includes a major expansion of comparative effectiveness research, investing \$1.1 billion for studies that will evaluate the effectiveness of different drugs, devices and procedures on the same medical condition.

A 15-member Federal Coordinating Council (FCC), authorized under the legislation, will assist federal agencies in coordinating and comparing the effectiveness of health services research. The Council will hold the second of three public hearings tomorrow in Chicago to gather suggestions on where to focus its efforts.

In public comments presented to the FCC at its first meeting, the Working Group urged deeper patient involvement in comparative effectiveness research. Mental Health America, which convenes the Working Group, emphasized that point today.

“The creation of new evidence and new decision support techniques to inform patient's treatment decisions offer great potential to improve care,” said David L. Shern, Ph.D., president and CEO of Mental Health America. “If we are to generate the balanced and practical clinical evidence that the legislation envisions, it will be critical for the Council to ensure that all those conducting federal CER incorporate the patient and clinician perspective into the direction and design of that research.”

The Working Group is recommending that the FCC implement specific steps to enable patients to advise on topic selection, help determine what data should be captured, and assist in CER dissemination and implementation. Specifically, it recommends that the FCC:

- Create a national citizens’ advisory board to help the Department of Health and Human Services (HHS) better understand the perspectives and values of the general public when designing and disseminating CER. The Working Group pointed to a Citizens Council that the United Kingdom convenes for its comparative effectiveness program.
- Establish an Office of Patient Values and Inclusion at HHS to advise on CER. The Working Group said the Food and Drug Administration’s Patient Representative Program is an excellent model for this kind of participation. The program educates patients to be effective advisors, and then includes them on advisory boards that correspond to their particular medical experience.
- Sponsor research that is designed to improve clinical decision making by both clinicians and patients. Research that considers the individuality of health conditions and factors such as family history, individual experience in treatment and patient values and preferences is needed, the Working Group said.

The Working Group recently held a regional forum in Boston to inform advocates and stakeholders and broaden their participation in evidence-based healthcare policy decisions.

In its comments to the FCC, the Working Group said greater roles for patient advocates are essential to advance medicine. Patients must work in collaboration with scientists and physicians to interpret the effectiveness of therapies.

"Understanding the experiences of patients and the public is important to helping organizations work more effectively to evaluate and improve services," it states. "People should have the opportunity to be actively involved in shaping the organization and the delivery of health and social care services for their communities. Changes that are made to the delivery of services should be based on their experiences and views."

About the Working Group

The National Working Group on Evidence-Based Healthcare is a coalition of more than 40 patient and disease advocacy groups representing consumers, caregivers, practitioners, and researchers and seeks to ensure that patients and consumers are a part of policymaking about the future of health care. The National Working Group on Evidence-Based Health Care is committed to promoting accurate and appropriate evidence-based policies and practices that improve the quality of health care services in the United States.

Since 2005, the Working Group has worked to broaden participation of patient groups in all aspects of evidence-based care to improve the usefulness of this information for consumers and clinicians as well as to assure that the locus of decision making remain with the patient and his/her clinician. Through information exchange and engagement in public dialogue, the Working Group has emphasized the importance of balancing an understanding of scientific research with real-world clinician expertise, each individual patient's needs and history as well as their perspectives and preferences. For more information about the Working Group, please visit www.evidencebasedhealthcare.org.

*Celebrating 100 years of mental health education and advocacy, **Mental Health America** is the country's leading nonprofit dedicated to helping all people live mentally healthier lives. With our more than 300 affiliates nationwide, we represent a growing movement of Americans who promote mental wellness for the health and well-being of the nation—every day and in times of crisis. In 2009, we are marking a century of achievement with a year-long Centennial Observance: "Celebrating the Legacy. Forging the Future."*

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