



National Health Council

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United States Senate Committee on Appropriations
The Capitol, S-131
Washington, D.C. 20510

Dear Senators:

On behalf of the more than 100 million Americans living with chronic diseases and disabilities, the National Health Council¹ (NHC) takes this opportunity to thank you for your commitment to improving health care in this country. NHC is encouraged and excited about the opportunities to foster a more effective, safe, efficient and affordable health care system. These efforts *must* be focused on the needs of individual patients.

NHC is concerned about the potential impact of comparative effectiveness research on patients as currently described in the American Recovery and Reinvestment Act of 2009. Proposed spending in both the U.S. House and Senate stimulus packages includes \$1.1 billion for comparative effectiveness research with broad and largely undefined authority. The current proposed legislation offers few safeguards to ensure a patient-focus or stakeholder inclusion. We urge members of Congress to consider 1) the true definition of evidence-based medicine and 2) previous comparative effectiveness research policy proposals outlined by the health care community.

The principles of evidence-based medicine can help guide comparative effectiveness research policy to be more patient-focused. Evidence-based medicine means integrating individual clinical expertise, the best evidence, and individual patients' predicaments, rights, and preferences to make health care decisions.² As currently written, the comparative effectiveness research provisions in the stimulus package fail to take into account the individual circumstances of patients undergoing treatment or include patients as meaningful stakeholders in the governance of this new, significant federal investment.

Since Gail Wilensky's seminal *Health Affairs* article in 2006, which called for the creation of a comparative effectiveness research entity, Congress has introduced legislation and several health care stakeholders have drafted proposals to significantly increase the nation's investment in comparative effectiveness research. Health care stakeholders have spent significant time and effort to ensure that comparative effectiveness research proposals consider general principles like transparency, scientific credibility, political independence, and stakeholder engagement. NHC has evaluated many of these proposals and recognized a need to move beyond general principles.

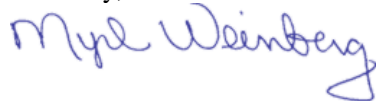
- **Mission/Objective: NHC believes that the mission and objective of the comparative effectiveness research investment needs to be clearly articulated in a manner that is patient-focused.** Legislation must improve health care delivery to benefit both individual patients and society by recognizing and incorporating unique patients' preferences and balancing them with the needs of society. As currently formulated, the comparative effectiveness research provisions in the stimulus package do not create a mandate for developing information to improve individual patient decision making.
- **Structure/Governance: Ensure that patients have a meaningful voice equivalent to other stakeholders on the new Federal Coordinating Council for Comparative Effectiveness Research.** Unlike previous comparative effectiveness research policy proposals, including the Comparative Effectiveness Research Act of 2008 (S. 3408), the current legislation does not allow patients to explicitly contribute to the governance body, the Federal Coordinating Council. NHC believes that patients need to be an explicit part of the governance body. In addition, to foster transparency, the Federal Coordinating Council must create a process that includes all stakeholders, including patients, to define methodological

standards for conducting comparative effectiveness research and evaluating evidence. The creation of standards will help to create buy-in and foster transparency among the public.

- **Scope/Type of Research: Focus the research agenda on a range of treatments and health care delivery issues.** By relying on existing programs at the Agency for Healthcare Research and Quality (AHRQ) and the National Institutes of Health (NIH), and by leaving the determination of research priorities to the Federal Coordinating Council, there are not assurances that the research agenda will address individual patients' preferences in all research. The provisions in the act must be modified to state that the comparative effectiveness research agenda includes health care delivery issues, such as the organization, design, and management of patient care. This research agenda also should utilize a variety of methodologies to conduct "real world" research, including clinical trials, observational studies, and systematic reviews. If economic analyses are conducted, they must be designed in a way to include individual patients' predicaments, rights, and preferences.
- **Use of Research: Comparative effectiveness research results must not drive de facto coverage or reimbursement recommendations until they are evaluated in "real world" settings to determine their impact on individuals and various subpopulations.** Additionally, all stakeholders, including patients, must be involved in disseminating comparative effectiveness research findings. The current research provisions provide little detail on this point. We believe that patients and other stakeholders have vital experiences that should be considered and that a process and committee to oversee the dissemination of evidence must be defined.

We appreciate the efforts of Congress to improve the efficiency and quality of health care through comparative effectiveness research. We are anxious to work with you and your colleagues to finalize this legislation. Please do not hesitate to contact Kevin Cain, our assistant vice president of government affairs, if you or your staff would like to discuss these issues in greater detail. He may be reached by phone at 202-973-0542 or via e-mail at kcain@nhcouncil.org. You may also reach me on my direct, private line at 202-973-0546 or via e-mail at mweinberg@nhcouncil.org.

Sincerely,



Myrl Weinberg, CAE
President

CC: Senate Committee on Finance
Senate Committee on Health, Education, Labor, and Pensions
House of Representatives Committee on Appropriations

¹ The Council and its approximately 110 member organizations share a common objective: improving the health of all people, particularly those with chronic diseases or disabilities. Through communication, collaboration, and consensus, the Council's member organizations – representing all segments of the health care community – work to achieve this important objective.

² Sackett, D.L. et al. (1996) Evidence based medicine: what it is and what it isn't. *BMJ* 312 (7023), 13 January, 71-72). Available at: <http://cebmr.jr2.ox.ac.uk/ebmisisnt.html>.