## PATIENT SAFETY BLOG

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## **Setting Standards for Research and Treatment**

## February 1, 2012 by Patrick A. Malone

Created by the health reform legislation of 2010, the Patient-Centered Outcomes Research Institute (PCORI) is charged with helping to determine the most effective treatments using objective, science-based standards. We introduced this agency to our readers last year.

Last week, as reported by Kaiser Health News, the PCORI issued its draft priorities and research agenda. What it didn't do was enumerate specific diseases, treatments or procedures warranting further study.

The agency, which is composed of health care professionals and is not a governmental body, will oversee billions of dollars in research funding. In declining to cite in the draft specific areas of inquiry, it defines "a set of questions and topics" under five broad categories. They are: **1.** comparing medical options; **2.** improving the health-care system; **3.** improving communication of research findings to patients and clinicians; **4.** addressing health disparities; and **5.** improving research methods.

We've written before about "comparative effectiveness research," a concept that is the currency of PCORI. It's about comparing different treatments for a given illness and compiling a body of knowledge from which doctors and patients can choose the best option for a given case.

Patrick A. Malone Patrick Malone & Associates, P.C. 1331 H Street N.W. Suite 902 Washington, DC 20005 pmalone@patrickmalonelaw.com www.patrickmalonelaw.com 202-742-1500 202-742-1515 (fax) Unfortunately, comparative effectiveness research is wearing a "kick me" sign for Republican lawmakers, who say it will be used to ration care. By failing to be disease-specific, as Kaiser Health News points out, the PCORI draft "sidesteps controversy that might arise from selecting certain diseases or treatments, but not others." So instead of setting priorities for which diseases to study, researchers will submit questions they want answered in funding applications.

"If they get 1,000 grants submitted on 400 different topics, who is going to make the decision on, say, whether they should fund a project on low back pain, but not one on multiple sclerosis?" Robert Dubois, chief science officer for the National Pharmaceutical Council, told Kaiser Health News. His organization is a policy research group funded by the drug industry. Dubois said the PCORI approach lends itself to one of the institute's goals of creating a self-sustaining and robust research community, but he's not alone in wanting funding to be directed as well toward "actual, unanswered clinical questions."

Arnold Epstein, chairman of the Department of Health Policy and Management at Harvard University School of Public Health is a board member of PCORI. He said that the agency's priorities are to get patients involved from the beginning and to fund research that incorporates solid scientific methods to illuminate the gaps in knowledge. The point is to enable patients and doctors to make informed decisions.

PCORI has \$3 billion over the next decade to dole out for comparative effectiveness research. If you want to weigh in on how those funds should be spend, review the draft agenda here. Public comment is open through March 15, then a final version will be adopted. PCORI is staging a series of focus groups and sponsoring a national forum on Feb. 27 in Washington, D.C.

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