

May 31, 2012

Patient-Centered Outcomes Research Institute Begins Process to Fund Clinical Effectiveness Research Grants

RESOURCE LINKS

PCORI Website

<http://www.pcori.org/fundingopportunities/pfa>

IMPORTANT DATES

June 1, 2012

PCORI Online Application System Opens

June 15, 2012

Letters of Intent Due

July 31, 2012

First Application Cycle Due Date

November 30, 2012

March 13, 2013

Additional Application Cycle Due Dates

On May 22, 2012, the Patient-Centered Outcomes Research Institute (“PCORI”),¹ a private nonprofit entity established by the Patient Protection and Affordable Care Act of 2010, announced that it will be seeking applications to fund an initial \$96 million in grants for innovative research projects in clinical effectiveness research.² These grants will be awarded in four areas recently identified in PCORI’s National Priorities Research Agenda:³

- **Assessment of Prevention, Diagnosis, and Treatment Options** – This area includes comparisons related to the effectiveness and safety of alternative health care services in order to determine which alternatives work best for people with a particular health problem.⁴
- **Improving Healthcare Systems** – This area involves the comparison of health-system level approaches in access, patient self-care, health information technology, care coordination, and workforce efficiency.⁵
- **Communication and Dissemination** – This area involves the comparison of approaches that improve the use of comparative effectiveness research and approaches that support shared decision-making between patients and providers.⁶
- **Addressing Disparities** – This area involves identifying differences in effectiveness and outcomes among subsets of patients in order to achieve optimal outcomes in each population.⁷

PCORI research grants differ from traditional health services research grants in that they require patients, caregivers, and practicing clinicians all to be actively engaged throughout the research process.⁸ However, PCORI has not dictated the specific areas in which it will be looking to direct research; “studies may focus on specific diseases, conditions and interventions, or they may be

cross-cutting, including broader study populations or examining interventions or issues that apply across multiple diseases and chronic conditions.”⁹

Proposed studies will be evaluated on the following criteria:¹⁰

- Impact on Health of Individuals and Populations
- Probability of Improvability via Research
- Inclusiveness of Different Populations
- Address Current Gaps in Knowledge/Variation in Care
- Impact on Healthcare System Performance
- Potential to Influence Decision-Making
- Patient-Centeredness
- Rigorous Research Methods
- Efficient Use of Research Resources

For these four grant areas, the online application system will open June 1, 2012, with letters of intent due by June 15, 2012. The first cycle of applications have a due date of July 31, 2012. PCORI will review additional cycles of applications with due dates of November 30, 2012, and March 31, 2013, respectively. Applications may be submitted by any private sector research organization.

Given the increased focus on comparative effectiveness (both cost and clinical), clients should consider these appropriations in comparative effectiveness research and development and determine whether this PCORI funding opportunity might advance strategic research goals. The PCORI website (at <http://www.pcori.org/funding-opportunities/pfa>) provides additional information and instructions for those interested in applying for these grants.

For more information about this issue of *IMPLEMENTING HEALTH AND INSURANCE REFORM*, please contact the author below or the member of the firm who normally handles your legal matters.

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¹ PCORI was authorized under Section 6302 of the Patient Protection and Affordable Care Act of 2010 and codified in 42 U.S.C. §1301. PCORI's stated mission is to "help people make informed health care decisions and improve health care delivery and outcomes by producing and promoting high integrity, evidence-based information that comes from research guided by patients, caregivers, and the broader health care community."

² Press Release, PCORI, "Patient-Centered Outcomes Research Institute Seeks Applications to Fund \$120 Million in Comparative Clinical Effectiveness Research in 2012" (May, 22, 2012), *available at* <http://www.pcori.org/2012/pfa/>.

³ National Priorities for Research and Research Agenda, PCORI (May 21, 2012), *available at* <http://www.pcori.org/assets/PCORI-National-Priorities-and-Research-Agenda-2012-05-21-FINAL.pdf>.

⁴ PCORI intends to fund 54 projects totaling up to \$48 million in this area. Projects may not exceed three years in duration, and budgets may not exceed \$500,000 in direct costs per year. See <http://www.pcori.org/assets/PFA-Assessment-of-Options-05222012.pdf>.

⁵ PCORI intends to fund 27 projects totaling up to \$24 million in this area. Projects may not exceed \$500,000 in direct costs per year. See <http://www.pcori.org/assets/PFA-Improving-Healthcare-Systems-05222012.pdf>.

⁶ PCORI intends to fund about 14 contracts totaling up to \$12 million in this area. Projects may not exceed \$500,000 in direct costs per year. See <http://www.pcori.org/assets/PFA-Communication-and-Dissemination-05222012.pdf>.

⁷ PCORI intends to fund about 14 contracts totaling up to \$12 million in this area. Projects may not exceed \$500,000 in direct costs per year. See <http://www.pcori.org/assets/PFA-Addressing-Disparities-05222012.pdf>.

⁸ PCORI will fund comparative studies with a focus on outcomes that are experienced by and important to patients. The application's research question should be stated clearly and compare two (or more) relevant alternatives presented to patients, their caregivers, or clinicians; health care systems; or policymakers. See <http://www.pcori.org/assets/PFAguidelines.pdf>.

⁹ National Priorities for Research and Research Agenda, PCORI, (May 21, 2012), *available at* <http://www.pcori.org/assets/PCORI-National-Priorities-and-Research-Agenda-2012-05-21-FINAL.pdf>.

¹⁰ *Id.* at 13.

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