

EXPLAINING HEALTH CARE REFORM: COMPARATIVE EFFECTIVENESS RESEARCH FEES

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Patient-Centered Outcomes Research Institute

- The ACA, Section 6301, created the Patient-Centered Outcomes Research Institute to advance comparative effectiveness research and help patients, clinicians, purchasers and policy-makers make informed health decisions.

“(b) PATIENT-CENTERED OUTCOMES RESEARCH INSTITUTE.—

“(1) ESTABLISHMENT.—There is authorized to be established a nonprofit corporation, to be known as the ‘Patient-Centered Outcomes Research Institute’ (referred to in this section as the ‘Institute’) which is neither an agency nor establishment of the United States Government.

“(2) APPLICATION OF PROVISIONS.—The Institute shall be subject to the provisions of this section, and, to the extent consistent with this section, to the District of Columbia Non-profit Corporation Act.

“(3) FUNDING OF COMPARATIVE CLINICAL EFFECTIVENESS RESEARCH.—For fiscal year 2010 and each subsequent fiscal year, amounts in the Patient-Centered Outcomes Research Trust Fund (referred to in this section as the ‘PCORTF’) under section 9511 of the Internal Revenue Code of 1986 shall be available, without further appropriation, to the Institute to carry out this section.

“(c) PURPOSE.—The purpose of the Institute is to assist patients, clinicians, purchasers, and policy-makers in making informed health decisions by advancing the quality and relevance of evidence concerning the manner in which diseases, disorders, and other health conditions can effectively and appropriately be prevented, diagnosed, treated, monitored, and managed through research and evidence synthesis that considers variations in patient subpopulations, and the dissemination of research findings with respect to the relative health outcomes, clinical effectiveness, and appropriateness of the medical treatments, services, and items described in subsection (a)(2)(B).

Patient-Centered Outcomes Research Institute

- Independent, non-profit organization.
- Governed by a 21-member Board of Governors.
- Created to conduct research to provide information about the best available evidence to help patients and their health care providers make more informed decisions.
- Patient-centered outcomes research is designed to inform health care decisions by providing evidence on the effectiveness, benefits and harms of different treatment options for different patients. The evidence is generated from studies that compare drugs, medical devices, tests, surgeries or ways to deliver health care.
- PCORI's research will be responsive to the preferences, values and experiences of patients in making health care decisions and the impact diseases and conditions can have on daily life.

Mission Statement

- The Patient-Centered Outcomes Research Institute helps people make informed health care decisions – and improves 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

Patient Centered Outcomes Research helps people make informed health care decisions and allows their voice to be heard in assessing the value of health care options. This research answers patient-focused questions:

- “Given my personal characteristics, conditions and preferences, what should I expect will happen to me?”
- “What are my options and what are the benefits and harms of those options?”
- “What can I do to improve the outcomes that are most important to me?”
- “How can the health care system improve my chances of achieving the outcomes I prefer?”

To answer these questions, PCOR:

- Assesses the benefits and harms of preventive, diagnostic, therapeutic, or health delivery system interventions to inform decision making, highlighting comparisons and outcomes that matter to people;
- Is inclusive of an individual's preferences, autonomy and needs, focusing on outcomes that people notice and care about such as survival, function, symptoms, and health-related quality of life;
 - Incorporates a wide variety of settings and diversity of participants to address individual differences and barriers to implementation and dissemination; and
- Investigates (or may investigate) optimizing outcomes while addressing burden to individuals, resources, and other stakeholder perspectives.



Patient-Centered Outcomes Research Institute

Draft National Priorities for
Research and Research Agenda
Version 1

Presented for Public Comment

January 23, 2012

- **Accelerating Patient-Centered and Methodological Research.** Research should focus on 1) ways to improve the quality and usefulness of clinical data in follow-up studies, 2) methods to combine and analyze clinical data that follow patients over time, 3) use of registries and clinical data networks to support research about patient-centered outcomes, including rare diseases, 4) strategies to train researchers and enable patients and caregivers to participate in patient-centered outcomes research.

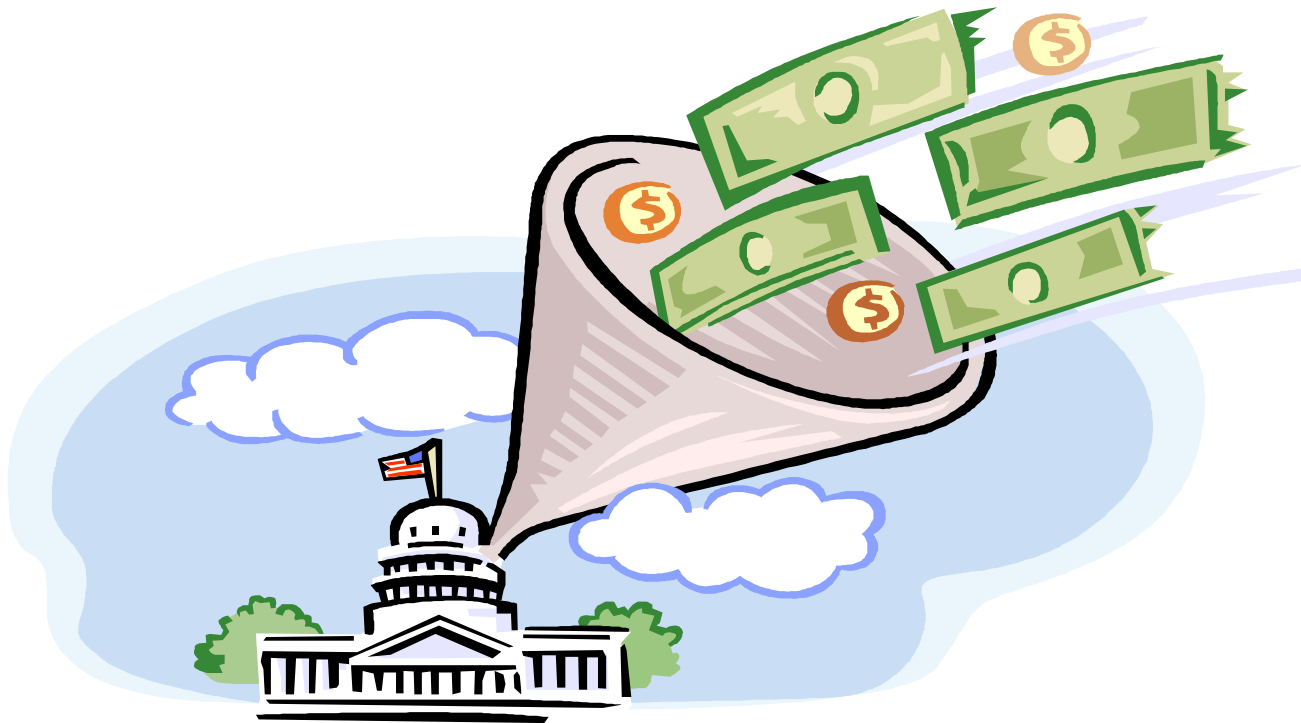
Public Comment: How You Can Help

PCORI encourages bold thinking about research projects. This means that PCORI is looking to you—patients, caregivers, professionals, and the general public—for help in shaping its national priorities and research agenda. Here are ways you can help:

- **Provide comment through the online survey.** You can do so from January 23-March 15, 2012, at the PCORI website, <http://www.pcori.org/provide-input>
- **Attend the National Patient and Stakeholder Dialogue.** This will be held February 27, in Washington, D.C. A webcast and teleconference will be provided, if you cannot attend in person. Learn more and register at the PCORI website, <http://www.pcori.org/meetings-events/event/pcori-national-patient-and-stakeholder-dialogue/>
- **Learn more.** You can find more information at the PCORI website, www.pcori.org

Thank you for your interest in PCORI. Together, we offer patients and caregivers the information they need to make important healthcare decisions. Questions about the Proposed National Priorities for Research and Research Agenda may be directed to PCORI by email at info@pcori.org.

Funding



“SEC. 9511. PATIENT-CENTERED OUTCOMES RESEARCH TRUST FUND.

“(a) CREATION OF TRUST FUND.—There is established in the Treasury of the United States a trust fund to be known as the ‘Patient-Centered Outcomes Research Trust Fund’ (hereafter in this section referred to as the ‘PCORTF’), consisting of such amounts as may be appropriated or credited to such Trust Fund as provided in this section and section 9602(b).

“(b) TRANSFERS TO FUND.—

“(1) APPROPRIATION.—There are hereby appropriated to the Trust Fund the following:

“(A) For fiscal year 2010, \$10,000,000.

“(B) For fiscal year 2011, \$50,000,000.

“(C) For fiscal year 2012, \$150,000,000.

“(D) For fiscal year 2013—

“(i) an amount equivalent to the net revenues received in the Treasury from the fees imposed under subchapter B of chapter 34 (relating to fees on health insurance and self-insured plans) for such fiscal year; and

“(ii) \$150,000,000.

“(E) For each of fiscal years 2014, 2015, 2016, 2017, 2018, and 2019—

“(i) an amount equivalent to the net revenues received in the Treasury from the fees imposed under subchapter B of chapter 34 (relating to fees on health insurance and self-insured plans) for such fiscal year; and

“(ii) \$150,000,000.

The amounts appropriated under subparagraphs (A), (B), (C), (D)(ii), and (E)(ii) shall be transferred from the general fund of the Treasury, from funds not otherwise appropriated.

“SEC. 4376. SELF-INSURED HEALTH PLANS.

“(a) **IMPOSITION OF FEE.**—In the case of any applicable self-insured health plan for each plan year ending after September 30, 2012, there is hereby imposed a fee equal to \$2 (\$1 in the case of plan years ending during fiscal year 2013) multiplied by the average number of lives covered under the plan.

“(b) **LIABILITY FOR FEE.**—

“(1) **IN GENERAL.**—The fee imposed by subsection (a) shall be paid by the plan sponsor.

“(2) **PLAN SPONSOR.**—For purposes of paragraph (1) the term ‘plan sponsor’ means—

Comparative Effectiveness Research Fees

IRS Notice 2011-35

- This notice is how the IRS is implementing Section 630 of the ACA.
- Section 6301 added Section 9511 – a provision creating a Patient-Centered Outcomes Research Trust Fund — to the Internal Revenue Code to provide funding for a new Patient-Centered Outcomes Research Institute.
- This is only the first guidance on implementation of the fees and asks for comment on several issues.

Comparative Effectiveness Research Fees

Entities that Pay the Fees

- Two new sections in the Internal Revenue Code address the comparative effectiveness research fees.
 - One section applies to health insurance policies, with the fees paid by the issuers of the policies.
 - The other section applies to self-insured health plans, including self-insured state and local governmental plans, with the fees paid by the plan sponsor of the plan.

Comparative Effectiveness Research Fees

For self-funded plans, the "plan sponsor" is responsible for paying the fee.

- For a plan established or maintained by a single employer, the employer is responsible.
- For a plan established or maintained by an employee organization, the employee organization is responsible.
- For a plan established or maintained by two-plus employers or jointly by employers/employee organizations (i.e., a multiemployer plan), the association, committee, joint board of trustees or other similar group of representatives of the parties who establish or maintain the plan is responsible.
- For a plan established or maintained by a cooperative or association, the cooperative or association is responsible.

Effect on Medical Loss Ratios

- Premium revenue is adjusted to exclude federal and state taxes and licensing and regulatory fees.
- The comparative effectiveness research fee meets the definition of a federal tax and is therefore deducted from premium revenue to appropriately calculate the MLR.

Comparative Effectiveness Research Fees

Effective Date

- The notice states that for calendar-year plans the fee would apply to calendar-plan years 2012 through 2018.
- For plans that do not operate on a calendar-year basis, the fee would apply to the first plan year that ends on or after October 1, 2012 (e.g., a plan year beginning on November 1, 2011).
- The fees do not apply to plan years ending after September 30, 2019.
- The notice asks for comments on whether guidance is needed on how to define “plan year.”

Comparative Effectiveness Research Fees

The Fees

- The fee is \$1.00 per covered life for plan/policy year for initial year.
- Thereafter, it is \$2.00 per covered life per plan/policy year.
- The \$2.00 fee will be adjusted by the percentage increase in the projected per capita amount of National Health Expenditures, as most recently published by HHS before the beginning of the fiscal year.
- The notice suggests that fees are to be paid annually.

Comparative Effectiveness Research Fees

- The notice asks for comments on reasonable methods to calculate the number of covered lives that would reduce the administrative burden.
- The notice also asks for comments on whether transition rules will be needed for the first plan year the fees are in effect.
- Comments were requested on whether the fees should be reported and paid annually rather than quarterly and whether they should be due on a fixed date regardless of the plan year.

Comparative Effectiveness Research Fees

Exempt plans

- Dental and vision benefits that are separately insured are exempt.
 - Self-insured dental and vision benefits would be exempt only if they are “limited-scope” benefits (i.e., participants elect this coverage separately from the medical benefit and pay an additional premium if they elect the coverage).
- Notice 2011-35 asks for comments on whether HRAs should be subject to or exempt from the fees.
- Retiree-only plans are not addressed.

QUESTIONS