May 10, 2012

Congressional Committees

Subject: Patient-Centered Outcomes Research Institute: Review of the Audit of the Financial Statements for 2011 and 2010

This report presents the results of our review of the Patient-Centered Outcomes Research Institute’s (PCORI) 2011 and 2010 financial statement audit.1 PCORI was created by the Patient Protection and Affordable Care Act (PPACA) as a federally funded, nonprofit corporation that is neither an agency nor establishment of the United States government.2 PCORI’s purpose is to assist patients, clinicians, purchasers, and policymakers 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 other items.

PPACA requires PCORI to provide for the conduct of its financial audits on an annual basis by a private entity with expertise in conducting financial audits, and requires the Comptroller General of the United States to annually perform a review of the audit of such financial statements. We are required to report the results of our review to the Congress annually.3 This is the first year PCORI has prepared financial statements and contracted with an independent public accountant (IPA) to conduct the financial statement audit, and consequently, the first year in which we have reviewed the audit.

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1 Unlike the federal fiscal year-end of September 30, PCORI has a fiscal year-end of December 31. PCORI was incorporated in November 2010, thus its 2010 operations span only 2 months. The first full year of PCORI’s operations was 2011.


3 On March 30, 2012, we provided the Congress with a status letter that indicated that the PCORI 2011 and 2010 financial statement audit was ongoing. The IPA completed the audit on April 20, 2012.
Results in Brief

PCORI received an unqualified audit opinion on its 2011 and 2010 financial statements. In its audit of PCORI’s financial statements, the IPA found that the financial statements were presented fairly, in all material respects, and there was no reportable noncompliance with selected provisions of laws and regulations the IPA tested as part of its audit. However, the IPA identified a deficiency in PCORI’s internal control over financial reporting related to PCORI reporting on its receipt of appropriated funds. The IPA determined the deficiency to be significant enough to constitute a material weakness.4 We found no instances in which the IPA did not comply, in all material respects, with U.S. generally accepted auditing standards and generally accepted government auditing standards in the conduct of the financial statement audit. In e-mailed comments from PCORI’s Director of Finance, PCORI stated that the identified deficiency in financial reporting related to appropriations received resulted from uncertainty over differences between the federal government’s and PCORI’s fiscal years and cited action taken to adjust its records to correct the deficiency.

Background

PCORI was established as a nonprofit corporation, neither an agency nor establishment of the U.S. government. PCORI was incorporated pursuant to the District of Columbia Non-Profit Corporation Act and organized within the meaning of Section 501(c)(1) and 501(l) of the Internal Revenue Code of 1986, as amended. PCORI’s operations are funded by appropriations from the Congress that are maintained in a trust fund established by PPACA known as the Patient-Centered Outcomes Research Trust Fund (PCORTF). The Congress appropriated funds to the PCORTF for the fiscal years ending September 30, 2010 through 2019.5 The investments of the PCORTF are managed by the U.S. Treasury’s Bureau of the Public Debt. These funds are available to PCORI without further appropriation through September 30, 2019, subject to transfer.6

Financial Reporting and Audit Requirements

PCORI is required under PPACA to annually prepare and have its financial statements audited by a private entity with expertise in conducting financial audits. PCORI’s financial statements consist of the statements of financial position (balance sheet), statements of activities and changes in net assets, statements of cash flows,

4 A material weakness is a deficiency, or combination of deficiencies, in internal control such that there is a reasonable possibility that a material misstatement of the entity’s financial statements will not be prevented, or detected and corrected, on a timely basis. A deficiency in internal control exists when the design or operation of a control does not allow management or its employees, in the normal course of performing their assigned functions, to prevent, or detect and correct, misstatements on a timely basis.


6 PPACA mandates that the Secretary of the Treasury as trustee of the PCORTF transfer to the Secretary of Health and Human Services 20 percent of the amounts appropriated or credited to the PCORTF for each of the fiscal years 2011 through 2019.
statements of functional expenses, and accompanying notes to the financial statements. The Management’s Discussion and Analysis (MD&A) accompanies the financial statements in PCORI’s annual report; however, the MD&A is not a required part of the basic financial statements, but rather is considered supplementary information under generally accepted accounting principles.7

Objectives, Scope, and Methodology

Our objectives were to (1) summarize the results of the IPA’s audit of PCORI’s 2011 and 2010 financial statements and (2) determine whether the IPA conducted the audit of PCORI’s 2011 and 2010 financial statements in accordance with U.S. generally accepted auditing standards and generally accepted government auditing standards.8

To satisfy these objectives, we reviewed the IPA’s audit report, the audited 2011 and 2010 PCORI financial statements, the IPA’s audit documentation, and the IPA’s professional qualifications. We also met with IPA representatives and PCORI management officials to discuss issues pertinent to our objectives.

Our review, as differentiated from an audit of the financial statements, was not intended to enable us to express, and we do not express, an opinion on PCORI’s financial statements or conclude on the effectiveness of its internal control over financial reporting and on its compliance with laws and regulations. The IPA is responsible for its report on PCORI dated April 20, 2012, and the conclusions expressed therein. We performed our review in accordance with Section 650 of the GAO/President’s Council on Integrity and Efficiency Financial Audit Manual. This guidance requires us to

- evaluate the IPA’s independence and objectivity,
- evaluate the IPA’s qualifications, and
- review and evaluate the IPA’s work.

We evaluated the IPA’s independence, objectivity, and qualifications by reviewing the following:

- the most recent peer review9 report for the IPA, dated December 2, 2010;

7 The purpose of the MD&A is to provide a narrative explanation, through the eyes of management, of how an entity has performed in the past, its financial condition, and its future prospects. Management prepares the MD&A to enhance the overall financial disclosure and provide the context within which financial information should be analyzed.
8 U.S. generally accepted auditing standards and generally accepted government auditing standards, issued by the Comptroller General of the United States (GAGAS) constitute the professional standards under which financial statement audits are performed.
9 GAGAS require each audit organization to have an external peer review conducted at least once every 3 years by reviewers independent of the organization being reviewed. The external peer review should determine whether, during the period under review, the reviewed audit organization’s internal quality control system was adequate and whether quality control policies and procedures were being complied with to provide the audit organization with reasonable assurance of conforming with applicable professional standards.
the request for proposal sent out by PCORI when seeking an audit firm to conduct the audit of its financial statements for 2011 and 2010; the engagement letter\textsuperscript{10} between the IPA and PCORI; and résumés for the IPA staff assigned to the PCORI audit.

To determine whether the financial statement audit was conducted in accordance with professional standards, we reviewed the IPA’s planning, testing, and reporting audit documentation to determine whether the auditor appropriately assessed risk for the audit and designed appropriate audit procedures to address the identified risk and to determine whether sufficient audit work was performed to support the IPA’s opinion and conclusions.

We conducted this performance audit from January 2012 to May 2012 in accordance with generally accepted government auditing standards. Those standards require that we plan and perform the audit to obtain sufficient, appropriate evidence to provide a reasonable basis for our findings and conclusions based on our audit objectives. We believe that the evidence obtained provides a reasonable basis for our findings and conclusions based on our audit objectives.

Results of PCORI Financial Audit

PCORI received an unqualified opinion on its 2011 and 2010 financial statements. The IPA found that PCORI’s financial statements were presented fairly, in all material respects, in conformity with U.S. generally accepted accounting principles. The IPA found no instances of noncompliance with laws and regulations that have a direct and material effect on the determination of financial statement amounts. However, the IPA identified a deficiency in PCORI’s internal control over financial reporting related to the accounting period in which to report its receipt of appropriated funds. The IPA determined the deficiency to be significant enough to constitute a material weakness. Because PCORI’s annual accounting period begins on January 1, PCORI was uncertain when it would recognize funding the PCORTF received in November 2010 and October 2011. The IPA determined that the funding received by the PCORTF that was available to PCORI on December 31, 2011, was available without fiscal year limitation, which necessitated an audit adjustment that PCORI recorded in its accounting records to appropriately report revenue of $120 million and $50 million for calendar years 2011 and 2010, respectively.

Audit Was Performed in Accordance with Professional Standards

We determined that the IPA was independent and objective in its audit of PCORI by reviewing its certification to PCORI management. We reviewed the engagement letter between the IPA and PCORI, which described the responsibilities of the IPA and those of PCORI and set forth the objectives of the audit service. Under peer review, the IPA received a rating of pass in its system review report dated

\textsuperscript{10} An engagement letter describes the nature and scope of the work performed and includes a reference to the professional standards governing the conduct of the engagement.
December 2, 2010. Additionally, our review of the IPA staff’s qualifications determined that the IPA was qualified to perform the audit of PCORI.

Our review of the audit of PCORI’s financial statements disclosed no instances in which insufficient audit work was performed by the IPA to support its audit opinion. Our review also disclosed no instances in which the IPA did not comply, in all material respects, with U.S. generally accepted auditing standards and generally accepted government auditing standards.

**PCORI Comments and Our Evaluation**

We provided a draft of this report to PCORI for comment. We received comments through e-mail from PCORI’s Director of Finance. The Director of Finance noted that based on advice and input from a broad range of organizations and experts, PCORI established a revenue recognition policy that matched the government fiscal year appropriation to PCORI’s calendar year accounting period. That methodology was challenged under audit, and PCORI made corresponding adjustments to its records. The Director of Finance further noted that there was never any confusion or disagreement regarding the nature of the PCORTF or the amount of funds contained in it, only that there was uncertainty as to when the funds should be reflected as revenue.

Our report does not indicate that there was confusion or disagreement with respect to the nature of the trust fund or its funding. However, as we stated in our draft report, because of the difference in fiscal years, PCORI did not recognize appropriation funding received by the PCORTF in October 2010 and November 2011 that was available to PCORI as revenue at year-end. This ultimately led to the IPA’s conclusion that this constituted a material weakness in PCORI’s internal control over financial reporting and the audit adjustment PCORI made to its accounting records.

We are sending copies of this report to the executive director of PCORI and other interested parties. In addition, the report is available at no charge on the GAO website at [http://www.gao.gov](http://www.gao.gov).

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11 There are two types of peer reviews: system reviews and engagement reviews. System reviews focus on a firm’s system of quality control, while engagement reviews focus on work performed on particular selected engagements. Firms can receive a rating of pass, pass with deficiency(ies), or fail.
If you or your staff have any questions about this report, please contact me at (202) 512-3406 or sebastians@gao.gov. Contact points for our Offices of Congressional Relations and Public Affairs may be found on the last page of this report. GAO staff who made key contributions to this report are listed in enclosure I.

Steven J. Sebastian  
Managing Director  
Financial Management and Assurance

Enclosure
List of Committees

The Honorable Max Baucus  
Chairman  
The Honorable Orrin G. Hatch  
Ranking Member  
Committee on Finance  
United States Senate

The Honorable Tom Harkin  
Chairman  
The Honorable Michael B. Enzi  
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Committee on Health, Education, Labor, and Pensions  
United States Senate

The Honorable Fred Upton  
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The Honorable Henry A. Waxman  
Ranking Member  
Committee on Energy and Commerce  
House of Representatives

The Honorable Dave Camp  
Chairman  
The Honorable Sander Levin  
Ranking Member  
Committee on Ways and Means  
House of Representatives
Enclosure I: GAO Contact and Staff Acknowledgments

GAO Contact

Steven J. Sebastian, (202) 512-3406 or sebastians@gao.gov

Staff Acknowledgments

In addition to the contact named above, Chanetta R. Reed, Assistant Director; Katherine Lenane, Assistant General Counsel; Omyra M. Ramsingh, Assistant General Counsel; Jehan Abdel-Gawad; Maria M. Morton; and Mary V. Osorno made key contributions to this report.
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