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United States Government Accountability Office
Washington, DC 20548

March 29, 2013

Congressional Committees

Subject: *Patient-Centered Outcomes Research Institute: Review of the Audit of the Financial Statements for 2012 and 2011*

This report presents the results of our review of the Patient-Centered Outcomes Research Institute's (PCORI) 2012 and 2011 financial statement audits.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 obtain an annual financial statement audit from 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 PCORI's financial statements and report the results of the review to the Congress.³ This is the second year PCORI has prepared financial statements and engaged an independent public accountant (IPA) to conduct the financial statement audit. Accordingly, we have reviewed this audit in order to report the results annually.⁴

¹ Unlike the federal fiscal year-end of September 30, PCORI has a fiscal year-end of December 31. PCORI's audited financial statements are presented in a 2-year comparative format with 2012 as the current year under audit and 2011 as the prior year that was previously audited.

² Pub. L. No. 111-148, §§ 6301(a), 10602, 124 Stat. 119, 727, 1005 (Mar. 23, 2010), *codified at* 42 U.S.C. § 1320e (b)(1).

³ Pub. L. No. 111-148, §§ 6301(a), 10602, 124 Stat. 119, 736, 1005 (Mar. 23, 2010), *codified at* 42 U.S.C. § 1320e(g).

⁴ We reported on the results of our review of PCORI's first financial audit in GAO, *Patient-Centered Outcomes Research Institute: Review of the Audit of the Financial Statements for 2011 and 2010*, GAO-12-663R (Washington, D.C.: May 10, 2012).

Results in Brief

We did not find any instances in which PCORI's IPA did not comply, in all material respects, with U.S. generally accepted auditing standards and generally accepted government auditing standards in conducting PCORI's financial statement audit. PCORI's IPA provided an unmodified audit opinion on its 2012 and 2011 financial statements. The IPA found that PCORI's financial statements were presented fairly, in all material respects, and did not identify any reportable noncompliance with the selected provisions of laws and regulations it tested. Further, the IPA did not identify any new deficiencies in internal control that it considered to be material weaknesses and determined that PCORI resolved the material weakness identified in 2011 regarding a deficiency in its internal control over financial reporting related to its receipt of appropriated funds.⁵ PCORI did not disagree with the report's conclusions.

Background

PCORI was established as a nonprofit corporation subject 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. PPACA established the Patient-Centered Outcomes Research Trust Fund (PCORTF) to fund the operations of PCORI.⁶ The funds in the PCORTF are available to PCORI without further appropriation through September 30, 2019, subject to transfer.⁷

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, statements of functional expenses, and accompanying notes to the financial statements. Management's Discussion and Analysis accompanies the financial

⁵ 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 The PCORTF consists of annual lump-sum appropriated funds for fiscal years 2010 through 2019, appropriations of an amount equivalent to the net revenue received in the Treasury from certain fees assessed on private health insurance policies and self-insured health plans for fiscal years 2013 through 2019, as well as defined transfers from the Federal Hospital Insurance Trust Fund and the Federal Supplementary Medical Insurance Trust Fund for fiscal years 2013 through 2019. See 26 U.S.C. § 9511(b).

⁷ 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 in PCORI's annual report, but is not a required part of PCORI's basic financial statements.⁸

Results of PCORI Financial Audit

PCORI received an unmodified opinion on its 2012 and 2011 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. In its report issued as required for performing the audit of the financial statements in accordance with generally accepted government auditing standards, the IPA reported that it found no instances of noncompliance with laws and regulations that have a direct and material effect on the determination of financial statement amounts. For 2012, the IPA did not identify any deficiencies in internal control that it considered to be material weaknesses.⁹ In performing the audit for 2012, the IPA determined that PCORI resolved the material weakness reported in 2011 regarding a deficiency in PCORI's internal control over financial reporting related to its reporting on its receipt of appropriated funds.

Objective, Scope, and Methodology

Our objective was to determine whether the IPA conducted the audit of PCORI's 2012 and 2011 financial statements in accordance with U.S. generally accepted auditing standards and generally accepted government auditing standards.¹⁰

To satisfy this objective, we reviewed the IPA's audit report, the audited 2012 and 2011 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 objective.

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 reports on PCORI dated March 12, 2013, and the conclusions

⁸ The purpose of the Management's Discussion and Analysis 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 Management's Discussion and Analysis to enhance the overall financial disclosure and provide the context within which financial information should be analyzed.

⁹ For an audit of financial statements performed in accordance with generally accepted government auditing standards (GAGAS), the auditor is required to report on internal control over financial reporting and on compliance with provisions of laws, regulations, contracts, or grant agreements that have a material effect on the financial statements, regardless of whether the auditor identifies internal control deficiencies or instances of noncompliance. GAGAS do not require the auditor to express opinions on the effectiveness of internal control over financial reporting or compliance.

¹⁰ U.S. generally accepted auditing standards and GAGAS, issued by the Comptroller General of the United States, constitute the professional standards under which PCORI's financial statement audits were performed.

expressed therein. We performed our review in accordance with Section 650 of the GAO/President's Council on Integrity and Efficiency *Financial Audit Manual*.¹¹ 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 review¹² report for the IPA, dated December 2, 2010;
- the request for proposal sent out by PCORI when seeking an audit firm to conduct the audits of its financial statements;
- the proposal submitted by the IPA, which included its certification of independence of PCORI;
- the engagement letter¹³ between the IPA and PCORI, which described the responsibilities of the IPA and those of PCORI and set forth the scope and objectives of the audit service; and
- résumés and the continuing professional education of the IPA staff members 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 December 2012 to March 2013 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 objective. We believe that the evidence obtained provides a reasonable basis for our findings and conclusions based on our audit objective.

¹¹ GAO, *Financial Audit Manual*, vol. 2, GAO-08-586G (Washington, D.C.: July 2008).

¹² 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 that it conforms with applicable professional standards.

¹³ An engagement letter describes the objectives and scope of the work performed and includes a reference to the professional standards governing the conduct of the engagement.

IPA's Audit Was Performed in Accordance with Professional Standards

Our review of the audit of PCORI's financial statements did not identify any instances in which the IPA did not perform sufficient audit work to support its audit opinion and its conclusions on internal control and compliance with laws and regulations. Our review also did not identify any 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.

Specifically, we determined that the IPA was independent and objective in its audit of PCORI, it received a passing rating in its peer review report dated December 2, 2010,¹⁴ and its staff members were qualified to perform the audit of PCORI.

PCORI Comments and Our Evaluation

We provided a draft of this report to PCORI for comment. In response, PCORI's Director of Finance provided comments through e-mail noting that PCORI's senior management had no disagreements with the conclusions in our report.

We are sending copies of this report to the Executive Director of the Patient-Centered Outcomes Research Institute and other interested parties. In addition, the report is available at no charge on the GAO website at <http://www.gao.gov>.

If you or your staffs have any questions about this report, please contact me at (202) 512-3406 or malenichj@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 members who made key contributions to this report are listed in enclosure I.



J. Lawrence Malenich
Director
Financial Management and Assurance

Enclosure

¹⁴ 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. The IPA's firm received a rating of pass on a systems review.

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Chairman
The Honorable Sander Levin
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Committee on Ways and Means
House of Representatives

Enclosure I: GAO Contact and Staff Acknowledgments

GAO Contact

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Staff Acknowledgments

In addition to the contact named above, Katherine Lenane (Assistant General Counsel), Jason Kirwan, Werner Miranda-Hernandez, and Maria Morton made key contributions to this report.

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