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March 27, 2015

Congressional Committees

Patient-Centered Outcomes Research Institute: Review of the Audit of the Financial Statements for 2014 and 2013

This report presents the results of our review of the Patient-Centered Outcomes Research Institute’s (PCORI) 2014 and 2013 financial statement audit.¹ PCORI was created in 2010 by the Patient Protection and Affordable Care Act (PPACA)² as a federally funded, nonprofit corporation that is neither an agency nor establishment of the United States government.³ According to PPACA, 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.

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.⁴ This is the fourth year PCORI has prepared financial statements and engaged an independent public accountant (IPA) to conduct the financial statement audit. Accordingly, this is the fourth year we have reviewed this audit.⁵

PCORI received an unmodified opinion from the IPA on its 2014 and 2013 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.⁶ For 2014, the IPA did not identify any

¹PCORI’s audited financial statements for fiscal years 2014 and 2013 are presented in a 2-year comparative format, displaying 12 months of activity for both 2014 and 2013. In 2013, the PCORI Board of Governors voted to change the financial reporting period for PCORI from a year-end of December 31 to a year-end of September 30. Due to this change in year-end, PCORI’s previously issued audited financial statements for 2013 and 2012 only displayed 9 months of activity for 2013.

²Pub. L. No. 111-148, § 6301(a), 124 Stat. 119, 728 (2010), *classified at* 42 U.S.C. § 1320e(b)(1).

³PCORI was established as a nonprofit corporation subject to the District of Columbia Non-Profit Corporation Act and organized within the meaning of Sections 501(c)(1) and 501(l) of the Internal Revenue Code of 1986, as amended.

⁴Pub. L. No. 111-148, § 6301(a), 124 Stat. 119, 736 (2010), *classified at* 42 U.S.C. § 1320e(g)(1), (2)(A)(i).

⁵We reported on the results of our review of PCORI’s previous financial audits 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); *Patient-Centered Outcomes Research Institute: Review of the Audit of the Financial Statements for 2012 and 2011*, [GAO-13-390R](#) (Washington, D.C.: Mar. 29, 2013); and *Patient-Centered Outcomes Research Institute: Review of the Audit of the Financial Statements for 2013 and 2012*, [GAO-14-415R](#) (Washington, D.C.: Mar. 27, 2014).

⁶PCORI’s financial statements consist of the statements of financial position, statements of activities, statements of cash flows, statements of functional expenses, and accompanying notes to the financial statements.

deficiencies in internal control that it considered to be material weaknesses.⁷ Furthermore, in its report issued as required for performing the audit of the financial statements in accordance with U.S. generally accepted government auditing standards (GAGAS),⁸ the IPA reported that it found no instances of noncompliance with laws, regulations, contracts, and grant agreements that have a direct and material effect on the determination of financial statement amounts.⁹ PCORI did not disagree with the IPA report's conclusions.

Objective, Scope, and Methodology

Our objective was to determine whether the audit of PCORI's 2014 and 2013 financial statements was conducted in accordance with GAGAS, in all material respects. To satisfy this objective, we reviewed the IPA's audit report, PCORI's 2014 and 2013 audited financial statements, the IPA's report on internal control over financial reporting and on compliance, the IPA's audit documentation, and the IPA's professional qualifications. We also met with IPA representatives and PCORI management officials to discuss matters 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. Furthermore, we do not express an opinion on PCORI's compliance with laws, regulations, contracts, and grant agreements. The IPA is responsible for its reports on PCORI dated March 3, 2015, and the conclusions expressed therein. We performed our review using Section 650, "Using the Work of Others," of the GAO/President's Council on Integrity and Efficiency *Financial Audit Manual* as a guide.¹⁰ 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 results of the IPA's most recent peer review,¹¹ dated December 4, 2013;

⁷A 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.

⁸GAGAS, issued by the Comptroller General of the United States, incorporates U.S. generally accepted auditing standards and constitutes the professional standards under which PCORI's financial statement audit was performed.

⁹For an audit of financial statements performed in accordance with 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 does not require the auditor to express opinions on the effectiveness of internal control over financial reporting or compliance.

¹⁰GAO, *Financial Audit Manual*, vol. 2, [GAO-08-586G](#) (Washington, D.C.: July 2008).

¹¹GAGAS requires 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 suitably designed 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.

- the request for proposal sent out by PCORI when seeking an audit firm to conduct the audit of its financial statements;
- the proposal submitted by the IPA;
- the IPA's certification of independence;
- the engagement letters between the IPA and PCORI,¹² which described the responsibilities of the IPA and those of PCORI and set forth the scope and objectives of the audit service;
- résumés of key audit team members; and
- the continuing professional education of the IPA staff members assigned to the PCORI audit.

Additionally, to evaluate the IPA's work in order 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 conclude whether the auditor appropriately assessed risk for the audit and designed appropriate audit procedures to address the identified risk and whether sufficient audit work was performed to support the IPA's opinion and conclusions.

We conducted this performance audit from December 2014 to March 2015 in accordance with U.S. 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.

Audit of PCORI's Financial Statements Was Performed in Accordance with Professional Standards

We found that the IPA's audit of PCORI's 2014 and 2013 financial statements was performed in accordance with professional standards, in all material respects.

We determined that the IPA was independent and objective in its audit of PCORI by reviewing the IPA staff members' certifications of independence. We also reviewed the résumés of key audit team members and continuing professional education transcripts of the IPA staff members assigned to the PCORI audit and determined that its staff members were qualified to perform the audit of PCORI. In addition, the IPA received a passing rating in its peer review report dated December 4, 2013.¹³

Furthermore, we analyzed key audit planning documentation focusing on the IPA's assessment of the risk of material misstatement in PCORI's financial statements, the audit procedures developed in response to this assessment, and the key audit completion documents summarizing the results and conclusions reached by the IPA and 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, regulations, contracts, and grant agreements. Our review also did not identify any instances in which the IPA did not comply, in all material respects, with GAGAS.

¹²An 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.

¹³There 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. A firm 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.

Agency and Third-Party Comments

We provided a draft of this report to PCORI and PCORI's IPA for review and comment. In response, PCORI's management and PCORI's IPA had no comments in regard to 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 malenichi@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 include Shirley Abel (Assistant Director), Gregory Marchand, Carrie Wehrly, Diana Lee, and Kailey Seibert.



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