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March 31, 2017

Congressional Committees

Patient-Centered Outcomes Research Institute: Review of the Audit of the Financial Statements for Fiscal Year 2016

This report presents the results of our review of the Patient-Centered Outcomes Research Institute's (PCORI) fiscal year 2016 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 review the audit of PCORI's financial statements and report the results to the Congress.⁴

PCORI received an unmodified opinion from an independent public accounting firm (IPA) on its fiscal years 2016 and 2015 financial statements. The IPA found that PCORI's financial statements were presented fairly, in all material respects, in accordance with U.S. generally accepted accounting principles.⁵ The IPA also reported that for fiscal year 2016, it did not identify any (1) deficiencies in internal control that the IPA considered to be material

¹We reported on the results of our review of PCORI's fiscal year 2015 financial statement audit in GAO, *Patient-Centered Outcomes Research Institute: Review of the Audit of the Financial Statements for Fiscal Year 2015*, [GAO-16-458R](#) (Washington, D.C.: Mar. 30, 2016).

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), (2)(B). PPACA also mandated GAO to review certain PCORI activities in 2015 (and every 5 years thereafter) and 2018. See *id.*, *classified at* 42 U.S.C. § 1320e(g)(2)(A)(ii)-(A)(v). GAO completed two reviews and issued the reports in 2015. See GAO, *Comparative Effectiveness Research: HHS Needs to Strengthen Dissemination and Data-Capacity-Building Efforts*, [GAO-15-280](#) (Washington, D.C.: Mar. 3, 2015), and *Comparative Effectiveness: Initial Assessment of the Patient-Centered Outcomes Research Institute*, [GAO-15-301](#) (Washington, D.C.: Mar. 9, 2015).

⁵PCORI'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.

weaknesses⁶ or (2) reportable noncompliance with selected provisions of laws, regulations, contracts, and grant agreements it tested.⁷ In addition, the IPA reported that it conducted its audit and prepared its report in accordance with U.S. generally accepted government auditing standards. PCORI did not disagree with the IPA report's conclusions.

Objective, Scope, and Methodology

Our objective was to review the financial audit of PCORI's fiscal year 2016 financial statements. To satisfy this objective, we performed the following procedures:

- We read and considered the following with respect to the IPA's independence, objectivity, and qualifications:
 - the results of the IPA's most recent peer review,⁸ dated December 2, 2016, which indicated a passing rating;⁹
 - the request for proposal PCORI sent out when seeking an audit organization to conduct the audit of its financial statements;
 - the proposal submitted by the IPA;
 - the IPA's certification of independence;
 - the engagement letter 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;¹⁰
 - résumés of key audit team members; and
 - documentation related to the continuing professional education of the IPA staff members assigned to the PCORI audit.

⁶A 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 employees, in the normal course of performing their assigned functions, to prevent, or detect and correct, misstatements on a timely basis.

⁷U.S. generally accepted government auditing standards (GAGAS), 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 to be performed. For 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.

⁸GAGAS 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.

⁹There are two types of peer reviews: system reviews and engagement reviews. System reviews focus on an audit organization's system of quality control, while engagement reviews focus on work performed on particular selected engagements. An audit organization can receive a rating of pass, pass with deficiency(ies), or fail. The IPA's audit organization received a rating of pass on a system review.

¹⁰An 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.

- 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.
- We read PCORI's fiscal years 2016 and 2015 financial statements, the IPA's audit report on such financial statements, and the IPA's report on internal control over financial reporting and on compliance. We also met with IPA representatives and PCORI management officials to discuss matters pertinent to our objective.

Our review of PCORI's fiscal year 2016 financial statement audit, 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 2, 2017, and the conclusions expressed therein.

We conducted this performance audit from January 2017 to March 2017 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.

No Significant Issues Identified Related to the Audit of PCORI's Financial Statements for Fiscal Year 2016

Based on the limited procedures we performed regarding the IPA's financial audit of PCORI's fiscal year 2016 financial statements, we did not identify any significant issues related to the financial statement audit that we believe require attention. Had we performed additional procedures, other matters might have come to our attention that we would have reported.

Agency Comments and Third-Party Views

We provided a draft of this report to PCORI and the IPA for review and comment. In response, PCORI's Executive Director and an IPA Partner had no comments in regard to our report.

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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 include Charles Fox (Assistant Director), Diana Lee, Curtis Lim, Lisa Motley, and Carrie Wehrly.

A handwritten signature in black ink that reads "J. Lawrence Malenich". The signature is written in a cursive style with a large, prominent initial "J".

J. Lawrence Malenich
Director
Financial Management and Assurance

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