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March 29, 2022

Congressional Committees

Patient-Centered Outcomes Research Institute: Review of the Audit of the FY 2021 Financial Statements

This report presents the results of our review of the Patient-Centered Outcomes Research Institute’s (PCORI) fiscal year (FY) 2021 financial statement audit.¹ The Patient Protection and Affordable Care Act (PPACA or “the act”) created PCORI in 2010² as a federally funded,³ nonprofit corporation that is neither an agency nor an establishment of the United States government.⁴ According to the act, 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.

The act 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 review the audit and report the results to the Congress annually.⁵

An independent public accounting firm (IPA) issued an unmodified opinion on PCORI’s FY 2021 and 2020 financial statements. The IPA found PCORI’s financial statements were presented

¹We reported on the results of our review of PCORI’s FY 2020 financial statement audit in GAO, *Patient-Centered Outcomes Research Institute: Review of the Audit of the Financial Statements for FY 2020*, [GAO-21-392R](#) (Washington, D.C.: Mar. 31, 2021).

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

³The Further Consolidated Appropriations Act, 2020, appropriated funds and certain fee revenues to PCORI through FY 2029. See Pub. L. No. 116-94, div. N, tit. I, § 104(a), 133 Stat. 2534, 3097-98 (2019), *classified at* 26 U.S.C. § 9511(b)(1)(F), (4).

⁴PPACA established PCORI 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.

⁵Pub. 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). GAO is also required to review (1) certain PCORI activities, such as processes established, training activities, barriers encountered, and overall effectiveness, every 5 years and (2) the adequacy and use of funding, no later than March 23, 2018. See 42 U.S.C. § 1320e(g)(2)(A)(ii)-(vi). GAO completed reviews and issued reports in 2015, 2018, and 2020. See GAO, *Comparative Effectiveness Research: HHS Needs to Strengthen Dissemination and Data-Capacity-Building Efforts*, [GAO-15-280](#) (Washington, D.C.: Mar. 3, 2015); *Comparative Effectiveness: Initial Assessment of the Patient-Centered Outcomes Research Institute*, [GAO-15-301](#) (Washington, D.C.: Mar. 9, 2015); *Comparative Effectiveness Research: Activities Funded by the Patient-Centered Outcomes Research Trust Fund*, [GAO-18-311](#) (Washington, D.C.: Mar. 23, 2018); and *Comparative Effectiveness Research: Patient-Centered Outcomes Research Institute and HHS Continue Activities and Plan New Efforts*, [GAO-21-61](#) (Washington, D.C.: Nov. 18, 2020).

fairly, in all material respects, in accordance with U.S. generally accepted accounting principles.⁶ The IPA also reported that for FY 2021, it did not identify any (1) deficiencies in internal control over financial reporting it considered to be material weaknesses⁷ or (2) reportable noncompliance with selected provisions of laws, regulations, contracts, and grant agreements it tested.⁸ In addition, the IPA reported it conducted its audit and prepared its report in accordance with U.S. generally accepted government auditing standards. PCORI agreed with the IPA report's conclusions.

Objective, Scope, and Methodology

Our objective was to review the results of PCORI's FY 2021 financial statement audit. 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,⁹ dated December 5, 2019, which indicated a pass rating;¹⁰
 - the request for proposal PCORI sent out when seeking an audit organization to conduct the audit of its financial statements;
 - the proposal the IPA submitted;
 - the IPA's certification of independence;
 - the engagement letter between the IPA and PCORI, which described each of their responsibilities, and set forth the audit services' scope and objectives;¹¹
 - résumés of key audit team members; and

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.

⁷A material weakness is a deficiency, or combination of deficiencies, in internal control over financial reporting, 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 over financial reporting 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.

⁸U.S. generally accepted government auditing standards (GAGAS), which the Comptroller General of the United States issues, incorporate U.S. generally accepted auditing standards and constitute the professional standards under which the IPA was to perform PCORI's financial statement audit. 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 certain provisions of laws, regulations, contracts, or grant agreements.

⁹GAGAS requires each audit organization to have a periodic external peer review conducted 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.

¹⁰There 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 its system of quality control.

¹¹An 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.

- documentation related to the continuing professional education of the IPA staff members assigned to the PCORI audit.
- 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 the IPA developed as a result of this assessment, and the key audit completion documents summarizing the results and conclusions the IPA reached.
- We read PCORI's FY 2021 and 2020 financial statements, the IPA's audit report on the 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 FY 2021 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 nor conclude on the effectiveness of its internal control over financial reporting. Further, we do not express an opinion on PCORI's compliance with laws, regulations, contracts, and grant agreements. The IPA is responsible for its report on PCORI dated February 18, 2022, and the conclusions expressed therein.

We conducted this performance audit from December 2021 through March 2022 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 with the Audit of PCORI's FY 2021 Financial Statements

Based on the limited procedures we performed regarding the IPA's financial audit of PCORI's FY 2021 financial statements, we did not identify any significant issues 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. PCORI's Director of Finance and an IPA partner responded that they had no comments on the draft 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 <https://www.gao.gov>.

If you or your staffs have any questions about this report, please contact me at (202) 512-2623 or davisbh@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 Ted Hu (Assistant Director), Arsenio Jones, and Brian Koning.

A handwritten signature in cursive script that reads "Beryl H. Davis".

Beryl H. Davis
Director
Financial Management and Assurance

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United States Senate

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