



2020 Programs of All-Inclusive Care for the Elderly (PACE) Audit Overview

Medicare Parts C and D Oversight and
Enforcement Group

Division of Analysis, Policy, and
Strategy

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I. Executive Summary – 2020 Audit Phase Timeline

Phase I: Audit Engagement and Universe Submission

- **Engagement Letter** – CMS notification to PACE organizations of audit selection; identification of audit scope and logistics; and instructions for PACE organizations audit document submissions.
- **Universe Submission** – PACE organization submission of requested universes and supplemental documentation to CMS.
- **Audit Sample Selection** – CMS selection of samples of cases to be tested during field work.

Phase II: Audit Field Work

- **Entrance Conference** – Discussion of CMS audit objectives and expectations; PACE organization voluntary presentation on organization.
- **Week 1 Webinar/Desk Review** – CMS testing of sample cases via desk review or live webinar review with the PACE organization; PACE organization submission of supplemental documentation (screenshots, root cause analyses, etc.)
- **Week 2 Onsite Audit, +/- Desk Review** – CMS testing of remaining audit elements; PACE organization submission of supplemental documentation (screenshots, root cause analyses, impact analyses, etc.); CMS documentation analysis; Continuation of desk review or live webinar as needed.
- **Exit Conference** – CMS review and discussion of preliminary issues of non-compliance with PACE organization.

Phase III: Audit Analysis and Reporting

- **Condition Classification** – CMS classification of non-compliance.
- **Notification of Immediate Corrective Action Required (ICAR) conditions (as applicable)** – CMS notification to PACE organization of any conditions requiring corrective action prior to the issuance of the final report; PACE organization Corrective Action Plan (CAP) submission within three business days of ICAR notification.
- **Draft Report Issuance** – CMS issuance of draft audit report, inclusive of condition classifications, to PACE organization approximately 60-180 days after the exit conference.
- **Draft Report Response** – PACE organization submission of comments to the draft report within 10 business days of draft report receipt.
- **Final Report Issuance** – CMS responds to PACE organization comments and updates audit conditions (if applicable); Final report is issued approximately 15-60 days after receipt of the PACE organization's draft report comments.

Phase IV: Audit CAPs and Close Out

- **Non-ICAR Corrective Action Plan (CAP) Submission** – PACE organization submission of CAPs for all conditions classified as a Corrective Action Required within 10 business days of receiving the final audit report.
- **CAP Review and Acceptance** – CMS performance of CAP reasonableness review and notification to PACE organization of acceptance or need for revision.
- **CAP Implementation and Release** – The PACE organization's account manager will monitor the implementation of CAPs to ensure the PACE organization is effectively executing corrective action as required. Once CAPs have been implemented, the account manager will release the CAPs.
- **Audit Close Out** – Once all CAPs have been released, CMS will close the audit.

II. Background

The Medicare Parts C and D Oversight and Enforcement Group (MOEG) is the group within the Centers for Medicare & Medicaid Services (CMS) responsible for creating and administering the audit strategy for the Programs of All-Inclusive Care for the Elderly (PACE) audits¹. MOEG also oversees, coordinates and conducts the audits of all PACE organizations. These audits measure a PACE organization's compliance with the terms of its contract with CMS, in particular, the regulatory requirements associated with access to services, drugs, and other protections required by Medicare. CMS solicits feedback on the audit process from industry stakeholders through a variety of mediums. CMS uses the feedback to update and improve audit operations as well as to explore new areas that may require oversight.

This document outlines the audit phases for 2020. Engagement letters to initiate PACE audits will be issued beginning in March of 2020 and will continue through September 2020. Engagement letters for unscheduled audits may be sent at any time throughout the year.

III. Summary of Audit Phases

The PACE audit consists of four phases:

- I. Audit Engagement and Universe Submission
- II. Audit Field Work
- III. Audit Analysis and Reporting
- IV. Audit CAPs and Close Out

The following sections describe important milestones in each phase of the audit.

¹ MOEG also oversees, coordinates, and conducts program audits which includes audits of Medicare Advantage Organizations (MAOs), Prescription Drug Plans (PDPs), and Medicare-Medicaid Plans (MMPs). Information regarding program audits is posted on the CMS PACE Audits Website located at <https://www.cms.gov/Medicare/Compliance-and-Audits/Part-C-and-Part-D-Compliance-and-Audits/ProgramAudits>.

Phase I: Audit Engagement and Universe Submission

The Audit Engagement and Universe Submission phase is the six-week period² prior to the field work portion of the audit. During this phase, the PACE organization is notified that it has been selected for an audit and is required to submit the requested data, which is outlined in the PACE audit process and data request document. Key milestones within Phase I include:

Engagement Letter – CMS issues an audit engagement letter via the Health Plan Management System (HPMS). Notification of the engagement letter is sent to the PACE organization’s CEO - CMS Administrator Contact designated in HPMS. The engagement letter contains instructions for downloading important audit documents from HPMS as well as key dates and timeframes for documentation submission.

Engagement Letter Follow-Up Call – Within two business days from the date of the engagement letter, the CMS audit team conducts a follow-up call with the PACE organization. The purpose of this call is to provide an opportunity for the PACE organization to ask questions about the engagement letter and audit process, as well as for CMS to emphasize important information within the engagement letter and outline next steps in the audit process.

Pre-Audit Issue Summary – Within five business days of the date of the engagement letter issuance, the PACE organization is asked to provide a list of all disclosed issues of non-compliance that are relevant to and may be detected during the audit. A disclosed issue is one that has been reported to CMS prior to the date of the audit engagement letter. Issues identified by CMS or the State Administering Agency through ongoing monitoring or other account management, and oversight activities and PACE Quality data reported during or prior to the audit year are not considered disclosed. PACE organizations must provide a description of each disclosed issue and the status of correction using the Pre-Audit Issue Summary template. The PACE organization’s account manager will review the template to validate that disclosed issues were reported to CMS prior to receipt of the audit engagement letter.

PACE Supplemental Questions – Within five business days of the date of the engagement letter issuance, the PACE organization is asked to provide responses to the PACE Supplemental Questions document.

Universe Submission – Within 20 business days of the date of the engagement letter, the PACE organization must submit all requested universes to CMS following the instructions in the PACE audit process and data request document. CMS may request revised universes if data issues are identified. PACE organizations will have a maximum of 3 attempts to provide complete and accurate universes, regardless of when the universes are submitted. When multiple attempts are made, CMS will only use the last universe submitted. If the PACE organization fails to provide accurate and timely universe submissions, CMS will document it in the PACE organization’s audit report and this may impact condition classifications.

² Audit engagement letters are typically issued approximately 45 calendar days prior to the start of audit fieldwork. In some instances, CMS may determine that an unannounced audit is necessary. In these instances, the audit engagement letter may not be issued until the start of audit fieldwork.

Universe Analysis – CMS will complete data entry tests on all of the universes to ensure there are no blank entries and data is properly formatted. CMS will also analyze universes throughout the audit for varying compliance standards including the timeliness of service delivery requests and appeals.

Audit Sample Selection –CMS selects targeted samples from information submitted by the PACE organization to evaluate during audit field work. Specific sample sizes vary by element and are listed within the PACE audit process and data request document.

Coordination of Audit Fieldwork Schedule – The audit team coordinates with the PACE organization to schedule the fieldwork phase of the audit, including what elements will be reviewed via desk review and the elements that will be reviewed onsite. CMS aims to adhere to the PACE organization’s normal business hours, but may request alternative hours depending on the progress of audit field work.

Phase II: Audit Fieldwork

PACE audit field work is conducted over a period of two weeks. Key milestones within Phase II include:

Entrance Conference – Audit field work begins with an entrance conference held on the morning of the first day of fieldwork. The audit lead conducts the meeting, reviews the schedule, and discusses expectations for the audit. The PACE organization will also have an opportunity to make a presentation about its organization.

Audit Fieldwork Week 1 – The first week of the audit includes a review of the service delivery, appeals and grievances element and may include a review of additional elements, when possible, via a desk review or webinar (this may also include remote access to the PACE organization’s medical records). During the desk review/webinar, the audit team will evaluate sample cases remotely and determine whether the cases are compliant or non-compliant. During the desk review/webinar, auditors may request supporting documentation for non-compliant cases. PACE organizations must upload all supporting documentation requested by auditors to HPMS. Classification of audit conditions is determined after the conclusion of audit fieldwork. This is discussed in more detail in the Audit Analysis and Reporting section.

Audit Fieldwork Week 2 – The second week of audit fieldwork includes an in-person audit conducted at one or more PACE centers (or Alternative Care Settings). The location(s) of the in-person audit will be determined by CMS. The second week will include a review of all elements not conducted during the first week of audit fieldwork, in-person participant observations and, when necessary, a review of sample cases or medical records for elements started, but not completed, during the first week of audit fieldwork. At the beginning of the second week, the PACE organization must submit the information identified in the Onsite Observation Participant List. The PACE organization may submit a completed Onsite Observation Participant List template or may submit using other formats so long as all requested information is included.

Daily Debriefs – Debriefs will be held on a daily basis during the audit fieldwork phase (weeks 1 and 2). The purpose of the debrief is to inform PACE organization staff of the status of the audit, review conditions of non-compliance identified in sample cases, and address any questions staff may have.

Root Cause Analysis Submissions – A root cause analysis must be submitted for any non-compliance identified during the audit, as requested by auditors. The PACE organization’s root cause analysis must identify the core problem(s) or issue(s) that resulted in non-compliance with regulatory requirements and a description of why the non-compliance occurred. Root cause analyses are due within 24 to 48 hours of the request (depending on the number requested) and must be uploaded to the HPMS as instructed by CMS. CMS will attempt to request all root cause analyses prior to the exit conference; however, we reserve the right to make requests after the exit conference has concluded. CMS will review the submission and instruct the PACE organization on next steps for completing an impact analysis, as applicable.

Impact Analysis Submissions – CMS may request impact analyses for conditions in order to determine the scope of non-compliance. The impact analysis must identify the participants or personnel subject to or impacted by the issue of non-compliance as instructed by CMS. Within 10 business days of the request or the date of the exit conference (whichever is later), PACE organizations must upload the impact analyses to the HPMS as instructed by CMS. CMS may validate the accuracy of the impact analysis submission(s). In the event an impact analysis cannot be produced, is incomplete, or is invalidated, CMS will report that the scope of the non-compliance could not be fully measured and impacted an unknown number of participants/personnel during the audit review period.

Exit Conference – The final day of fieldwork concludes with an exit conference (conducted onsite if possible). The audit team will walk through the preliminary conditions of non-compliance with the PACE organization and discuss any outstanding requests for information. These findings are subject to additional review and evaluation after all supporting documentation has been received and evaluated, at which point classification occurs. During the exit conference, the PACE organization may ask questions about the findings and provide any follow-up information as appropriate. PACE organizations will have an opportunity to formally respond or provide comments for CMS’ consideration during the draft audit report process.

Phase III: Audit Analysis and Reporting

Audit reporting occurs in multiple stages beginning with the findings identified and discussed during the audit fieldwork stage (i.e., daily debriefs, exit conference) and through root cause/impact analysis requests, followed by more formal notification of conditions classified as Immediate Corrective Action Required (ICAR) and issuance of the draft and final reports. Key milestones within Phase III include:

Root Cause/Impact Analysis Submission and Validation – PACE organizations submit remaining requested root cause and impact analyses. Audit team members review and analyze submitted impact analyses to determine the effect of non-compliance. If CMS believes that one or more impact analyses may be incomplete or inaccurate, CMS may validate the accuracy of the

impact analysis submission(s) and may require the organization to submit additional case files or provide access to participant medical records.

Condition Classification– Upon receipt of all audit documentation, auditors meet with the PACE Audit Consistency Team (PACT). The PACT serves as subject matter experts for PACE and audit policy and ensures consistency in classification of audit conditions across all audits in accordance with the following definitions:

- **Immediate Corrective Action Required (ICAR)** – An ICAR is a deficiency that requires prompt correction prior to the issuance of the final report. These conditions of non-compliance result in a lack of access to care and/or services, may pose an immediate threat to participant health and safety, and/or result in harm or the potential for harm. Situations that restrict, hinder, or limit a participant’s ability to request or advocate for care and/or services are considered a lack of access to care or services³.
- **Corrective Action Required (CAR)** – A CAR is a deficiency that must be corrected, but the correction can wait until the final audit report is issued. These issues may impact participants, but are not of a nature that immediately affects their health and safety or their ability to advocate for care and/or services. Generally, they involve deficiencies with respect to lacking or inadequate policies and procedures, systems, internal controls, training, operations, or staffing.
- **Observations** – Observations are conditions of non-compliance that do not require submission of a corrective action plan based on the nature of the deficiency and why the deficiency occurred (for example there was one case misclassified as a result of human error).

Referral for Enforcement Action – Conditions noted in the audit may be referred to the Division of Compliance Enforcement (DCE). DCE will conduct an independent review of audit documentation to determine if an enforcement action (Civil Money Penalty, sanction, or contract termination) is warranted.

Notification of Immediate Corrective Action Required (ICAR) Conditions – If one or more conditions are classified as an ICAR, the PACE organization will receive notification and prompt corrective action must be implemented in order to remediate non-compliant activity and prevent future non-compliance. PACE organizations are required to submit Corrective Action Plans describing the actions taken to remediate non-compliance within three business days of being informed of the ICAR condition.

Draft Audit Report Preparation and Issuance to the PACE Organization – CMS prepares a draft audit report (inclusive of condition classifications) with a target for issuance between 60 and 180 calendar days from the date of the exit conference.

³ If CMS determines that a disclosed issue was promptly identified, corrected, and the risk to participants has been mitigated, CMS will not apply the Immediate Corrective Action Required condition classification to that condition. CMS may require organizations to submit a completed root cause analysis and/or impact analysis for any disclosed issue of non-compliance.

Draft Report Response: The PACE organization has 10 business days to respond to the draft audit report with comments to CMS. This is an organization's opportunity to request reconsideration of a condition or classification. CMS reviews and responds to any comments the PACE organization submits in the HPMS and determines if the comments warrant a change in the final audit report.

Issuance of the Final Audit Report– CMS aims to issue the final audit report between 15 and 60 days from receipt of the PACE organization's comments to the draft audit report. The final report contains the final classification of conditions noted during the audit.

Audit Feedback – Following issuance of the final audit report, CMS will send PACE organizations an optional audit survey. CMS will use feedback collected from the survey to improve the PACE audit process.

Phase IV: Audit CAPs and Close Out

The final phase of the PACE audits occurs over a period of approximately 60 to 90 days. Once the final audit report is issued, PACE organizations develop, implement, and monitor corrective action plans. Key milestones within Phase IV include:

Non-ICAR Corrective Action Plan (CAP) Submission – PACE organizations have 10 business days from the issuance of the final audit report to submit CAPs associated with conditions classified as Corrective Action Required.

CAP Review and Acceptance – Upon receipt of the CAPs, CMS performs a reasonableness review and notifies the PACE organization of either CAP acceptance or the need for additional information. CMS continues the reasonableness review process until it deems all CAPs acceptable.

CAP Implementation and Release – CMS requires that PACE organizations undertake correction of conditions noted in the final audit report. The PACE organization's account manager will conduct monitoring of all CAPs to ensure corrective actions are being implemented as required to effectively address the non-compliance. Once the CAPs have been implemented, the account manager will release all CAPs.

Audit Close Out – Once CAPs are released, CMS will close the audit and send an audit close out letter to the PACE organization. The PACE organization should continue to monitor the implemented corrective actions to ensure and maintain full compliance with CMS requirements.