

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

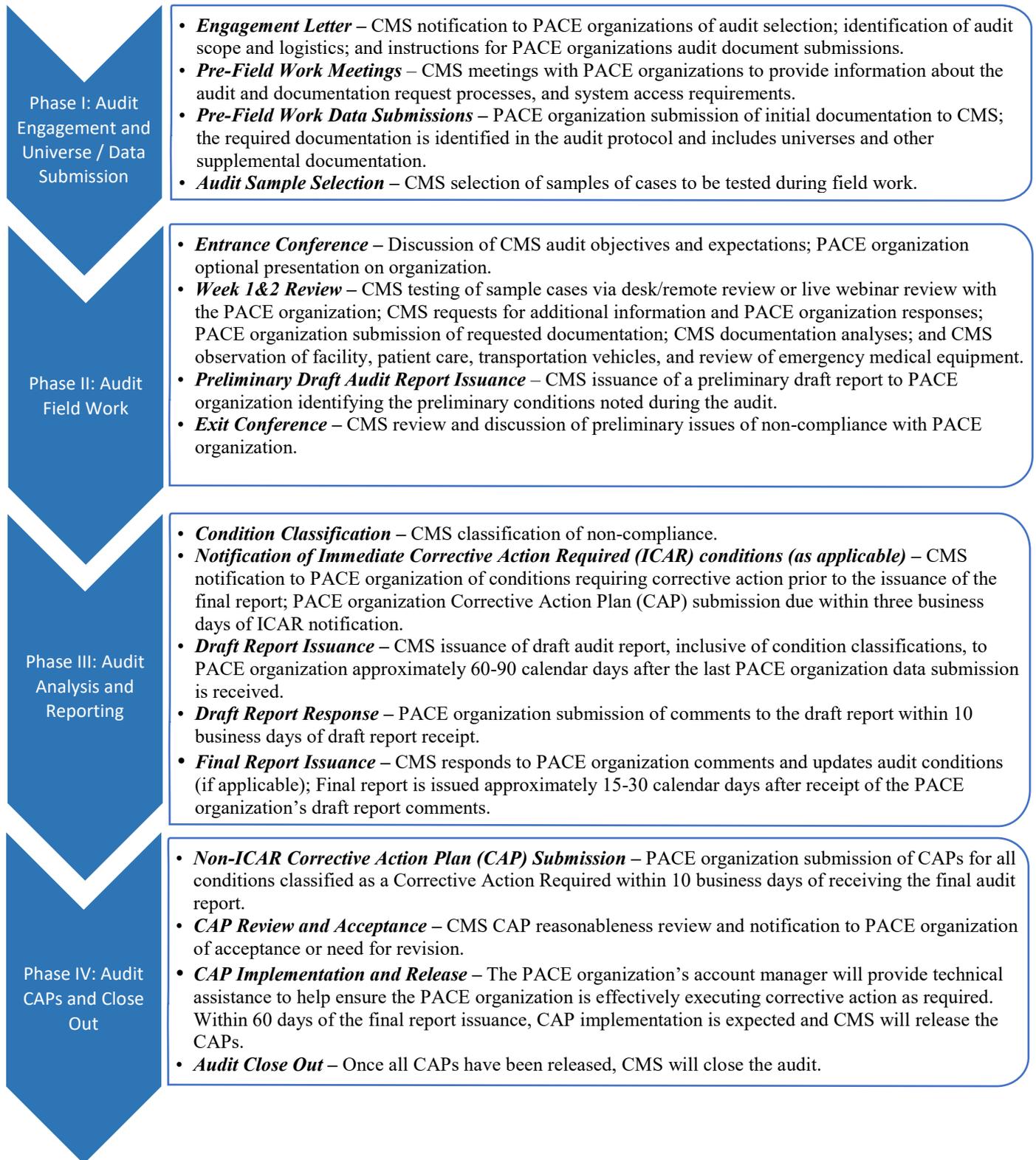
Medicare Parts C and D Oversight and
Enforcement Group

Division of Analysis, Policy, and
Strategy

Table of Contents

I. Executive Summary – PACE Audit Phase Timeline.....	3
II. Background.....	4
III. Summary of Audit Phases	4
Phase I: Audit Engagement and Universe Submission.....	5
Phase II: Audit Field Work.....	6
Phase III: Audit Analysis and Reporting	8
Phase IV: Audit CAPs and Close Out.....	10

I. Executive Summary – PACE Audit Phase Timeline



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 (POs). 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 PACE audits. CMS will typically issue engagement letters for scheduled audits from January through September, but this could vary from year to year. 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/Data 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 Program 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 for scheduled audits 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 Chief Executive Officer - 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.

Document Request Log (DRL) and Element Overview Call – Approximately one week after the engagement letter follow-up call, the CMS audit team conducts a call with the PACE organization to discuss the document request process, requests for additional information, medical records systems access requirements, and the review of elements³.

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/or PACE quarterly 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.

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

³ CMS conducts the DRL and Element overview call with all first-year trial period and routine audits. This call is optional for organizations undergoing second and third-year trial period audits.

Quality and Compliance Documentation Submission – Within 20 business days of the date of the engagement letter, the PACE organization must submit quality improvement plans that were in use during the data collection period, Participant Advisory Committee (PAC) minutes for the data collection period, and documentation demonstrating the measures developed as part of the PO’s compliance oversight program to prevent, detect, and correct noncompliance with regulatory requirements and fraud, waste, and abuse.

Monitoring Reports – Within 20 business days of the date of the engagement letter, the PACE organization must submit monitoring reports for 30 participants, selected by CMS, that detail the organization’s monitoring and tracking of all services across all care settings that were ordered, approved, or care planned during the data collection period.

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.

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, but not limited to, the timeliness of service determination requests and appeals. 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.

Audit Sample Selection – CMS selects targeted samples using 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 Field Work – The audit team works with the PACE organization to coordinate, schedule and conduct audit field work; this includes, but is not limited to, coordinating remote access to medical records, scheduling observations, and scheduling meetings with the PACE organization. CMS aims to adhere to the PACE organization’s normal business hours when conducting audit field work activities, but may request alternative hours depending on the progress of audit field work.

Phase II: Audit Field Work

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

Entrance Conference – Audit field work begins with an entrance conference held on the morning of the first day of field work. 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.

Notification of Sample Selections – Sample selections for the Service Determination Requests, Appeals and Grievances (SDAG) and Personnel elements will be uploaded to HPMS by the audit team two business days before the reviews of the elements begin. Sample selections for medical record samples will be uploaded to HPMS by the audit team one hour before the review of medical records begins. The audit team will work with the PACE organization to select samples for participant observations; therefore, observation samples will be uploaded to HPMS by the audit team once the observation samples are finalized.

Audit Field Work Weeks 1 and 2 – During field work, the audit team will evaluate sample cases and determine whether the samples are compliant with regulatory requirements. In order to determine compliance, auditors may request additional information and documentation. Auditors may also request that organizations provide supporting documentation for non-compliant or potentially non-compliant cases. PACE organizations must upload all information requested by auditors to HPMS.

The first week of the audit field work typically includes a review of the SDAG, Personnel, and Provision of Services elements, but may also include a review of the Compliance and Quality Improvement element. The review of these elements is accomplished through desk reviews, remote access to the PACE organization's medical records, and when applicable, webinars. The first week of audit field work will also include participant and other observation reviews. Observations may be conducted in-person or remotely at PACE centers, Alternative Care Settings, and/or participants' homes. The location(s) of observations will be determined by CMS in collaboration with the PACE organization.

During the second week, the audit team will continue to review samples for elements started, but not completed, during the first week of audit field work. Auditors will also conduct a review of the Compliance and Quality Improvement element if not already completed in week one. The review of the Compliance and Quality Improvement element is typically conducted remotely, via webinar.

CMS may extend the duration of field work beyond two weeks to accommodate holidays or when additional time is needed to complete the review of samples and/or to collect additional information or documentation from the PACE organization.

Daily Debriefs – The purpose of the debrief is to inform PACE organization staff of the status of the audit, review potential conditions of non-compliance identified in sample cases, and address any questions staff may have. Debriefs will be held on a daily basis during the audit field work phase, unless there is no new information, status updates, or questions to discuss or the organization requests not to hold the debrief meeting.

Root Cause Analysis Submissions – A root cause analysis must be submitted, as requested by auditors, for all non-compliance identified during the audit. CMS may also require organizations to submit a completed root cause analysis for any disclosed issue of non-compliance. 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 may grant additional time when requested by the organization. CMS will attempt to request all root cause analyses prior to the exit conference; however, CMS reserves 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.

Issuance of Preliminary Draft Audit Report – At the conclusion of the audit field work phase, CMS will issue a preliminary draft audit report to the PACE organization, identifying conditions noted during the audit as of the exit conference. The audit lead issues this report via the HPMS prior to the exit conference. Please note that additional conditions may be added as a result of Root Cause Analyses, Impact Analyses or other submitted data.

Exit Conference – The final day of field work concludes with an exit conference. The audit team will walk through the preliminary conditions of non-compliance with the PACE organization and discuss any outstanding requests for information. During the exit conference, the PACE organization may ask questions about the findings and provide any follow-up information as appropriate. Preliminary conditions of non-compliance are subject to additional review and evaluation after the exit conference when all supporting documentation and requested analyses have been received and evaluated. Classification of conditions will occur once the review and evaluation of all documentation is completed. PACE organizations will have an opportunity to formally respond or provide comments for CMS’s consideration during the draft audit report process.

Impact Analysis Submissions – CMS may request impact analyses for conditions identified during the audit in order to determine the scope of non-compliance. CMS may also require organizations to submit a completed impact analysis for any disclosed issue 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 grant additional time when requested by the organization. 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.

Phase III: Audit Analysis and Reporting

Audit analyses and reporting occurs in multiple stages beginning with the findings identified and discussed during the audit field work 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 for scheduled audits 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 additional 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 services⁴.
- **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, conditions may be classified as observations when only one instance of non-compliance is identified and the non-compliance occurred as a result of human error. Although CMS does not require the submission of corrective action plans for observations, CMS does expect PACE organizations to ensure the non-compliance is addressed and corrected.

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

⁴ If CMS determines that a disclosed issue was promptly identified, corrected, and the risk to participants has been mitigated, CMS may not apply the Immediate Corrective Action Required 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.

future non-compliance. This notification typically is issued in advance of the draft audit report, but may occur with the draft audit report. 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 90 calendar days from the date of the last data submission received from the PACE organization.

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 30 calendar 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. There is no additional opportunity to comment on the conditions of non-compliance after this report is issued.

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 for scheduled audits 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 provide technical assistance and education to help the organization ensure that their implemented corrective actions will effectively address non-compliance. This may include collection and review of documentation submitted by the organization. Corrective action plans

will be released 60 days after CAPs acceptance by CMS with the expectation that PACE organizations will have fully implemented those corrective action plans by that time.

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.