Centers for Medicare and Medicaid Services Response to Public Comments Received for CMS-10630

The Centers for Medicare and Medicaid Services (CMS) received responses from three commenters on CMS-10630, including existing Programs of All-Inclusive Care for the Elderly (PACE) organizations (POs) and an advocacy organization. This is the reconciliation of the comments.

General Comments

Comment: A commenter expressed appreciation for CMS's consideration and incorporation of PACE stakeholder feedback to improve the audit process and timely update to the audit protocol to reflect new regulatory provisions.

Response: Thank you for these comments.

Comment: A commenter expressed appreciation for CMS's thoughtful review of the comments on the 60-day notice and the modifications to the proposed 2026 PACE Audit protocol, noting these modifications improved clarity, reduced administrative burden on POs, and still allow CMS to identify systemic compliance issues.

Response: Thank you for these comments.

Audit Protocol

Comment: A commenter expressed appreciation for CMS's responsiveness to stakeholder feedback on the Initial Comprehensive Review (ICR) and clarification provided.

Response: Thank you for this comment.

Comment: A commenter recommended that CMS formalize and clearly define the ICR process in the audit protocol. It was also recommended that structured training on the Root Cause Analysis (RCA)-Impact Analysis (IA)-Corrective Action Plan (CAP) process be integrated in the ICRs to improve the POs' understanding of compliance expectations, strengthen audit preparedness, reduce administrative burden, and support participant protection, program integrity, and long-term program success.

Response: The ICR process is effectively the same audit processes and application of compliance standards described in the audit protocol. The only difference is that CMS may not require a PO undergoing an ICR to submit all the data collection elements specified in attachment I. However, during the onsite portion of the ICR, CMS reviews all collection elements with the PO, including the RCA, IA, and CAP templates and processes. CMS

encourages organizations to make use of the audit protocol and supporting documentation available on CMS's website to help ensure they are audit ready.

Comment: A commenter expressed concern about the variability in ICR timing, noting that reviews can occur as early as four months or as late as twelve months after program initiation. The variability can delay Service Area Expansion (SAE) applications and compress timelines impacting adequate data collection and participant engagement.

Response: In accordance with 42 CFR § 460.6, a PACE organization's initial contract year may range from 19 to 30 months in duration. The specific dates for a PO's first contract year of the trial period are available in their program agreement. CMS schedules ICRs based on these dates, taking into account various factors such as enrollment, to ensure that CMS will have sufficient data to conduct its comprehensive review and PACE organizations will have adequate operational experience before being audited.

Comment: A commenter requested clarification on the typos that were corrected in the PACE Audit Protocols.

Response: The CMS-10630 Crosswalk of Changes 2026 document included a list of proposed changes that specified which protocol document was modified and a summary of those changes.

Attachment IV PACE Audit Survey

Comment: A commenter expressed appreciation for CMS's ongoing efforts to gather feedback through the PACE Audit Survey and the opportunity it provides POs to share their experiences and recommendations following an audit.

Response: Thank you for the comment.

Comment: A commenter noted some POs are unaware of the survey or unable to locate the link and suggested CMS improve visibility, potentially through follow up reminders and include targeted questions about roles involved in audit preparation. The commenter acknowledged the value of the PACE Audit Survey in informing burden estimates and improving the audit process, but recommended CMS evaluate response rates and reassess the process to ensure it captures meaningful feedback. The commenter also recommended that CMS clarify how survey results are used to inform audit improvements.

Response: When issuing the final audit report, CMS includes a weblink to the PACE Audit Survey, although completing the survey is voluntary and not required. CMS informs POs about the survey before the final report is issued and invites feedback to help improve processes. Historically, the survey provided an opportunity for POs to submit any comments or suggestions regarding the audit process, including free text responses for feedback that was not specifically requested. However, based on the comments received, CMS has streamlined and enhanced the survey by consolidating, replacing, or adding questions about the audit experience, preparing for audits, and PO resources needed during an audit. CMS also included a question to specify the

audit year to better understand the context of responses. CMS will continue to carefully consider the feedback collected from each survey to improve the audit process and consider other opportunities to encourage survey completion.

Root Cause Analyses (RCAs) and Impact Analyses (IAs)

Comment: A commenter expressed appreciation for CMS's recognition of the burden associated with completing RCAs and IAs and its efforts to limit requests based on the nature of non-compliance. The commenter recommended CMS reassess its methodology for determining the magnitude of potential non-compliance. It was also suggested that staff time may be better spent developing and implementing CAPs, as requiring separate IAs can divert resources from these efforts where meaningful improvements to care and operations are made. To streamline the process, the commenter recommended CMS adopt a tiered sampling approach for IAs, integrate participant remediation into the CAP, and use CAPs to identify impacted participants.

Response: IAs continue to be an effective mechanism to determine the magnitude of an issue, and to allow a PO to identify participants that may need remediation. CMS is sensitive to the burden that producing IAs creates, which is why CMS carefully considers all information received from the PO prior to deciding whether to request an IA and the IA scope. Following an audit, the PO is required to submit CAPs that fully address how the PO will remediate all identified noncompliance and prevent future noncompliance. Because the IAs typically include a small proportion of potentially impacted participants, CMS encourages organizations to consider conducting additional analyses after an audit to ensure full correction of the non-compliance.

Root Cause Analyses (RCAs)

Comment: A commenter recommended that CMS consider an enrollment-based algorithm for RCA sample sizes. The commenter stated that while the RCA process is beneficial, it remains manual and labor intensive, and the addition of new RCA templates increases burden. The commenter also noted that it often takes fewer records to identify patterns of non-compliance and necessary corrections, and requiring up to "no more than 50%" of the sample doesn't make sense.

Response: RCAs are requested for each condition of non-compliance identified during the audit and are critical to understanding the cause and potential impact of non-compliance identified during an audit. In addition, RCAs can provide the PO additional opportunities to submit documentation that may address or mitigate identified non-compliance and can improve a PO's ability to develop Corrective Action Plans (CAPs) targeted at fixing the cause of non-compliance to prevent it from recurring. Lastly, CMS did not add new RCA templates to the protocol that would increase burden.

Burden

Comment: A commenter expressed appreciation for CMS's efforts to revise the burden estimate for the 2026 Audit Protocol and reiterated concerns regarding both the overall burden estimate and its underlying assumptions. Another commenter emphasized that the estimated 780 hours does not reflect the actual time and resources required for PACE audits, which involve extensive data collection, manual review of narrative electronic medical records, and significant cross-department coordination. The commenter stated that, due to limited structured data extraction capabilities, many POs must rely on labor intensive manual abstraction, pulling staff away from direct participant care. The commenter recommended that CMS reassess the burden estimate to fully account for all audit-related activities, including internal corrective action planning and manual data abstraction, clarify which activities are included and excluded from the estimate, particularly those related to CAP development, and engage with POs to collect real-world data on time and resource use during audits.

Response: CMS appreciates the commenter's concerns. CMS acknowledged that the previous burden estimate may have been too low; however, CMS made multiple modifications that substantially reduce the burden of audits conducted in 2026 and beyond. For example, CMS removed the collection of monitoring reports, removed the collection of information during CAP implementation and monitoring, and has provided templates designed to assist POs through the audit process. This includes templates for CAP development to help POs more efficiently submit successful CAPs needed to close the audit. Upon further review of the revised data collection instruments and audit procedures, CMS determined that the burden-reducing revisions meaningfully decrease respondent time and effort beyond what was reflected in the original estimates. Accordingly, CMS has revised the estimated burden to 563 hours per audit.CMS understands that some POs do not have systems that are capable of easily compiling information for audits about the provision of care and services for participants. However, because PACE is a direct care provider, it is even more critical that POs have the ability to maintain information on requested and approved services to ensure services are being provided to participants. Since 2017, CMS has made many improvements to the audit process in response to comments about the burden of audits. With each protocol update, the agency has sought to strike a better balance between ensuring participants are receiving appropriate and timely care and services, while not overwhelming organizations with intensive data requests over the course of the audit. CMS will continue working with POs to identify opportunities to streamline the audit process while maintaining CMS's ability to effectively oversee organizations for compliance with regulatory requirements.