

Supporting Statement - A
The PACE Organization (PO) Monitoring and Audit Process in Part 460 of 42 CFR
CMS-10630, OMB 0938-1327

Background

Section 4801 of the Balanced Budget Act of 1997 (BBA) authorized coverage of Program of All-Inclusive Care for the Elderly (PACE) under the Medicare program by amending Title XVIII of the Social Security Act (“the Act”) and adding section 1894, which addresses Medicare payments and coverage of benefits under PACE. Section 4802 of the BBA authorized the establishment of PACE as a state option under Medicaid by amending Title XIX of the Act and adding Section 1934, which directly parallels the provisions of section 1894. Sections 1894(e)(4) and 1934(e)(4) of the Act and the implementing regulations at 42 CFR §§ 460.190 and 460.192 mandate that CMS, in conjunction with the State Administering Agency (SAA), audit PACE organizations (POs) annually for the first 3 contract years (during the trial period), and then on an ongoing basis following the trial period. There are currently 179 POs.

In 2023, CMS developed and implemented a revised PACE audit protocol. The audit protocol utilized stakeholder feedback and audit outcomes data to streamline the audit elements, clarify CMS expectations, refine its data-driven and participant outcomes-based audit approach, and improve transparency.

On April 23, 2024, CMS finalized updates to the PACE regulations in 42 CFR § 460, which strengthened and improved the PACE program with respect to service determination request and grievance processes, responsibilities of the interdisciplinary team (IDT) for coordination of care, participant rights, timeframes for provision of services, and care planning requirements. The 2026 PACE audit protocol was modified with two goals; first, to implement the new regulatory provisions that were effective in June of 2024, and second, to incorporate the lessons learned from CMS’s audit experiences in 2023 and 2024. These revisions include modifying element data requests and compliance standards to align with the new regulatory requirements, introducing case file cover sheets and new impact analysis templates, providing templates with instructions for responding to requests for additional information and for submitting corrective action plans (CAPs), and removing burdensome collections. As with the 2023 PACE audit protocol, CMS continued to consider stakeholder feedback and audit outcomes data to streamline audit elements, refine its data driven and participant outcomes-based audit approach, and improve transparency. CMS solicited comments on the collection for the updated audit protocol in the Federal Register (89 FR 104545) on December 23, 2024, for the 60-day public comment period. Based on comments received during the 60-day public comment period, CMS made minor technical corrections or clarifications to elements of the data collection package.

Beginning in audit year 2026, the number of data collection instruments will increase from 24 to the following 34 documents. This increase primarily reflects the addition of seven impact analysis templates. However, of the seven new templates, three are the result of splitting existing impact analysis templates to provide clarity and the other 4 are necessary to align with result of new regulations. The remaining three new documents include instructions for supporting documentation submitted as part of the audit process to evaluate potential non-compliance and develop corrective action plans, as required.

- A PACE Audit Protocol,
- A Pre-audit issue summary document,
- A PACE supplemental questionnaire,
- A case file cover sheet document,
- A Request for Additional Information template (for use as needed),
- A Root Cause Analysis template (for use as needed),
- 25 Impact Analyses templates (for use as needed),
- A Corrective Action Plan Process document (for use as needed),
- A Corrective Action Plan template (for use as needed), and
- An audit feedback questionnaire (voluntary).

A more detailed description of the collection instrument changes from 2023 to 2026 and their impact on overall burden is outlined in section 15 below.

CMS intends to continue using the PACE 2023 Audit Protocol (CMS-10630, OMB: 0938-1327) for any audit where fieldwork was conducted in calendar year 2025. CMS will begin using the updated audit protocol for fieldwork conducted in 2026 and will continue using this protocol for any audits initiated in the calendar year associated with the expiration date. Delaying the implementation of the revised audit protocol until 2026 will provide POs with sufficient time to make all necessary system changes once the next audit protocol is finalized through the Paperwork Reduction Act (PRA) notice and comment process.

CMS is requesting a Revision approval from OMB due to the 10 additional documents and edits made to the PACE audit protocol. Thus the changes introduced in this 2026 audit protocol do not equate to a meaningful increase in PO burden and the burden reducing revisions to the data collection are more impactful and better align burden with our original estimates.

A. Justification

1. Need and Legal Basis

Sections 1894(e)(4) and 1934(e)(4) of the Act and the implementing regulations at 42 CFR §§ 460.190 and 460.192 state that CMS, in conjunction with the State Administering Agency

(SAA), must oversee a PACE organization's continued compliance with the requirements for a PACE organization. The data collected with the data request tools included in this package allow CMS to conduct a comprehensive review of POs' compliance in accordance with specific federal regulatory requirements.

2. Information Users

Sections 1894(e)(4) and 1934(e)(4) of the Act and the implementing regulations at 42 CFR §§ 460.190 and 460.192 mandate that CMS, in conjunction with the SAA, audit POs annually for the first 3 years (during the trial period), and then on an ongoing basis following the trial period. The information gathered during this audit will be used by the Medicare Parts C and D Oversight and Enforcement Group (MOEG) within the Center for Medicare (CM), as well as the SAA, to assess POs' compliance with PACE program requirements. If outliers or other data anomalies are detected, other offices within CMS will work in collaboration with MOEG for follow-up and resolution. Additionally, POs will receive the audit results, and will be required to implement corrective action to correct any identified deficiencies.

3. Improved Information Technology

Information collected from the POs for use in the audit is obtained electronically through the Health Plan Management System (HPMS). HPMS is a system that was developed and is maintained by CMS, and is used to securely transmit information between CMS and POs. All POs have access to HPMS, and users create and maintain a secure user id and password that is used each time HPMS is accessed.

4. Duplication of Similar Information

This information collection does not duplicate any other effort and the information cannot be obtained from any other source.

5. Small Business

The collection of information will have a minimal impact on small businesses since applicants to the PACE program must possess an insurance license and be able to accept substantial financial risk. Generally, state statutory licensure requirements effectively preclude small business from being licensed to bear risk needed to serve Medicare enrollees.

6. Less Frequent Collection

Sections 1894(e)(4) and 1934(e)(4) of the Act and the implementing regulations at 42 CFR §§ 460.190 and 460.192 mandate that CMS, in cooperation with the SAA, audit POs annually for the first 3 contract years (during the trial period), and then on an ongoing basis

following the trial period. CMS determines by risk how often organizations are subject to audits following the trial period.

CMS would be non-compliant with statutory and regulatory oversight requirements if information was collected less frequently.

7. Special Circumstances

There are several instances in which CMS requests submission of data in fewer than 30 days, including data universe submissions, questionnaires, and clarifications surrounding submitted data (e.g., screen shots, root cause and impact analyses). In addition, CMS could request submission of data in fewer than 30 days when conducting a focused audit.

8. Federal Register Notice/Outside Consultation

Federal Register

The 60-day notice for this data collection was published in the Federal Register on December 23, 2024 (89 FR 104545). CMS received 7 unique commenters following the 60-day public comment period. Changes made to the data collection based on these comments are listed in the attached Crosswalk of Changes, along with the proposed data collection instruments for the 30-day public comment period. This package can be updated with specific dates when publication dates are known.

The 30-day notice for this data collection was published in the Federal Register (90 FR 31209) on July 14, 2025.

Outside Consultation

CMS continues to receive year-round feedback from POs and outside entities on the existing PACE audit protocol. Feedback has been received at conferences and through external communications (i.e., emails, surveys, or letters). CMS will post the protocol on its website (https://www.cms.gov/Medicare/Compliance-and-Audits/Part-C-and-Part-D-Compliance-and-Audits/PACE_Audits.html) and in the HPMS system, so POs can access them year round.

9. Payment/Gift to Respondent

There are no payments or gifts associated with this collection.

10. Confidentiality

CMS will adhere to all statutes, regulations, and agency policies regarding confidentiality. Privacy will be maintained to the extent provided by law. While POs are required during

audit to provide CMS access to records, data and other participant information, CMS will ensure that the collected information is maintained and used in a confidential format and any sensitive or personal information will be transferred and/or stored through the Health Plan Management System (HPMS) which is a secure site.

11. Sensitive Questions

There are no sensitive questions associated with this collection. Specifically, the collection does not solicit questions of a sensitive nature, such as sexual behavior and attitudes, religious beliefs, and other matters that are commonly considered private.

12. Burden Estimate (Total Hours & Wages)

To derive cost estimates, CMS used data from the most recent U.S. Bureau of Labor Statistics' National Occupational Employment and Wage Estimates for all salary estimates (https://www.bls.gov/oes/current/oes_nat.htm) from May 2024. In this regard, the following table presents the median hourly wage, the cost of fringe benefits (calculated at 100 percent of salary), and the adjusted hourly wage. CMS selected the following personnel for the burden estimate based on CMS's previous experiences conducting PACE audits, feedback from PACE organizations, and audit protocol data collection and processes.

National Occupational Median Hourly Wage and Adjusted Hourly Wage

Occupation Title	Occupation Code	Median Hourly Wage (\$/hr)	Fringe Benefit (\$/hr)	Adjusted Hourly Wage (\$/hr)
Medical and Health Services Managers	11-9111	\$56.71	\$56.71	\$113.42
Executive Secretaries and Executive Administrative Assistants	43-6011	\$35.70	\$35.70	\$71.40
Medical Records Specialists	29-2072	\$24.16	\$24.16	\$48.32
Compliance Officers	13-1041	\$37.70	\$37.70	\$75.40

As indicated, CMS is adjusting employee hourly wage estimates by a factor of 100 percent. This is necessarily a rough adjustment, both because fringe benefits and overhead costs vary significantly from employer to employer, and because methods of estimating these costs vary widely from study to study. Nonetheless, there is no practical alternative, and CMS believes that doubling the hourly wage to estimate total cost is a reasonably accurate estimation method.

Wage Estimates

CMS determined the median hourly wage for a PACE organization to conduct a PACE audit based on the positions selected in the table above.

Occupation Title	Adjusted Hourly Wage (\$/hr)
Medical and Health Services Managers (Nurse Manager)	\$113
Executive Secretaries and Executive Administrative Assistants	\$71
Medical Records Specialists	\$48
Compliance Officer (Quality Assurance Specialist)	\$75

Based on the above adjusted hourly wages (rounded to the nearest whole dollar), CMS estimated a median hourly wage of \$73/hr for PACE organizations' activities related to CMS PACE audits.

Burden Estimates

Trial Year and Routine Audits

Trial year and routine audits will use the same audit protocol; therefore, the burden estimate is the same for both types of audits. Based on audit experience and revisions to the audit protocol, CMS estimates a total of four people (identified above) from each PO, working simultaneously for each audit. CMS estimates an average of 25 hours per person prior to the audit start to assemble data and review the information for completeness, 80 hours per person for the actual administration of the audit, 40 hours per person to review and respond to the documentation requests, impact analyses (as applicable) and the draft audit report, and 50 hours per person to submit corrective action plans. The total burden per PACE organization equals 780 hours. CMS estimates the annual number of PACE organizations that will undergo a PACE audit to be approximately 40.

Burden Summary

Information Collection	Respondents	Responses (per Respondent)	Total Responses	Burden per Respondent (hours)	Total Annual Burden for Respondents (hours)	Labor Cost of Reporting (Average \$/hr)	Total Cost (\$)
Audits	40	1	40	780	31,200	\$73	\$2,277,600

Information Collection Instruments and Instruction/Guidance Documents

Document Title	Description	Purpose	Respondents	Reporting Frequency	Response Timeframes
1.AttachmentIPACE Audit Protocol	Description of the PACE Audit Protocol	To evaluate compliance with PACE requirements	PACE organizations	CMS audits approx. 40 PACE organizations annually	The collection tools described in this protocol are provided simultaneously and response timeframes do not exceed 60 days following the issuance of the engagement letter.
2. AttachmentIIPACE Supplemental Questions	PACE Supplemental Questionnaire	To evaluate compliance with PACE requirements	PACE organizations	CMS audits approx. 40 PACE organizations annually	Responses to this collection tool do not exceed 1 week following the issuance of the engagement letter.
3. AttachmentIIIPre AuditIssueSummary	Summary of any pre-audit issues	To determine pre- disclosed non-compliance	PACE organizations	CMS audits approx. 40 PACE organizations annually	Responses to this collection tool do not exceed 1 week following the issuance of the engagement letter.

4. AttachmentIVAudit Survey	Audit Survey	A short summary to improve the audit process	PACE organizations	CMS audits approx. 40 PACE organizations annually	This is an optional survey and is not required to be completed. POs have 30 days following the issuance of the Final Audit Report to respond to the survey.
Document Title	Description	Purpose	Respondents	Reporting Frequency	Response Timeframes

5. AttachmentV CorrectiveAction PlanProcess	Description of the Corrective Action Plan process	To assist organizations with developing corrective actions	PACE organizations	CMS audits approx. 40 PACE organizations annually	Only used if a deficiency is cited during audit. Responses to this collection tool will not exceed 70 days following issuance of the final audit report.
6. AlertIDT1P14	Provision of Services Impact Analysis Template	To assess participant impact	PACE organizations	CMS audits approx. 40 PACE organizations annually	Only used if a deficiency is cited during the audit. Response time can vary based on the size of the impact. It is usually 10 days.
7. AppealRecognition 1P65	Appeals Impact Analysis	To assess participant impact	PACE organizations	CMS audits approx. 40 PACE organizations annually	Only used if a deficiency is cited during the audit. Response time can vary based on the size of the impact. It is usually 10 days.

8. Appeals1P321P 661P681P73	Appeals Impact Analysis Template	To assess participant impact	PACE organizations	CMS audits approx. 40 PACE organizations annually	Only used if a deficiency is cited during the audit. Response time can vary based on the size of the impact. It is usually 10 days.
9. AppealsEffectuation 1P111P30	Appeals Impact Analysis Template	To assess participant impact	PACE organizations	CMS audits approx. 40 PACE organizations annually	Only used if a deficiency is cited during the audit. Response time can vary based on the size of the impact. It is usually 10 days.
Document Title	Description	Purpose	Respondents	Reporting Frequency	Response Timeframes

10. ArrangingServices 1P101	Provision of Services Impact Analysis Template	To assess participant impact	PACE organizations	CMS audits approx. 40 PACE organizations annually	Only used if a deficiency is cited during the audit. Response time can vary based on the size of the impact. It is usually 10 days.
11. Assessments1P49 1P50	Provision of Services Impact Analysis Template	To assess participant impact	PACE organizations	CMS audits approx. 40 PACE organizations annually	Only used if a deficiency is cited during the audit. Response time can vary based on the size of the impact. It is usually 10 days.

12. CAPTemplate	CAP Template	To record and assess corrective action plans	PACE organizations	CMS audits approx. 40 PACE organizations annually	Only used if a deficiency is cited during audit. Responses to this collection tool usually will not exceed 30 days following issuance of the final audit report.
13. CaseFileCoverSheet	Coversheet for PACE organization sample case files	To determine compliance with PACE requirements for specific findings	PACE organizations	CMS audits approx. 40 PACE organizations annually	Only used for the case files selected for SDAG or Personnel samples. Response time can vary based on the finding identified. It is usually 1 day.
Document Title	Description	Purpose	Respondents	Reporting Frequency	Response Timeframes

14. Coordinationof Care1P95	Provision of Services Impact Analysis Template	To assess participant impact	PACE organizations	CMS audits approx. 40 PACE organizations annually	Only used if a deficiency is cited during the audit. Response time can vary based on the size of the impact. It is usually 10 days.
15. Effectuation1P02	Service Determination Request and Appeals Impact Analysis	To assess participant impact	PACE organizations	CMS audits approx. 40 PACE organizations annually	Only used if a deficiency is cited during the audit. Response time can vary based on the size of the impact. It is usually 10 days.
16. EmergencyCare 1P07	Provision of Services Impact Analysis	To assess participant impact	PACE organizations	CMS audits approx. 40 PACE organizations	Only used if a deficiency is cited during the audit. Response time

	Template			annually	can vary based on the size of the impact. It is usually 10 days.
17. Grievance Recognition and Notification 1P751P77	Grievances Impact Analysis Template	To assess participant impact	PACE organizations	CMS audits approx. 40 PACE organizations annually	Only used if a deficiency is cited during the audit. Response time can vary based on the size of the impact. It is usually 10 days.
18. Grievances 1P1031P1041P105	Grievances Impact Analysis Template	To assess participant impact	PACE organizations	CMS audits approx. 40 PACE organizations annually	Only used if a deficiency is cited during the audit. Response time can vary based on the size of the impact. It is usually 10 days.
Document Title	Description	Purpose	Respondents	Reporting Frequency	Response Timeframes

19. HomeCare 1P02	Provision of Services Impact Analysis Template	To assess participant impact	PACE organizations	CMS audits approx. 40 PACE organizations annually	Only used if a deficiency is cited during the audit. Response time can vary based on the size of the impact. It is usually 10 days.
20. MedErrors 1P02	Provision of Services Impact Analysis Template	To assess participant impact	PACE organizations	CMS audits approx. 40 PACE organizations annually	Only used if a deficiency is cited during the audit. Response time can vary based on the size of the impact. It is usually 10 days.

21. Participant Rights1P1061P107	Provision of Services Impact Analysis Template	To assess participant impact	PACE organizations	CMS audits approx. 40 PACE organizations annually	Only used if a deficiency is cited during the audit. Response time can vary based on the size of the impact. It is usually 10 days.
22. Personnel	Personnel Impact Analysis Template	To assess participant impact	PACE organizations	CMS audits approx. 40 PACE organizations annually	Only used if a deficiency is cited during the audit. Response time can vary based on the size of the impact. It is usually 10 days.
23. PlanofCare1P151P201P84	Provision of Services Impact Analysis Template	To assess participant impact	PACE organizations	CMS audits approx. 40 PACE organizations annually	Only used if a deficiency is cited during the audit. Response time can vary based on the size of the impact. It is usually 10 days.
Document Title	Description	Purpose	Respondents	Reporting Frequency	Response Timeframes

24. Provisionof Services1P02	Provision of Services Impact Analysis Template	To assess participant impact	PACE organizations	CMS audits approx. 40 PACE organizations annually	Only used if a deficiency is cited during the audit. Response time can vary based on the size of the impact. It is usually 10 days.
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25. Recommended Services1P94	Provision of Services Impact Analysis Template	To assess participant impact	PACE organizations	CMS audits approx. 40 PACE organizations annually.	Only used if a deficiency is cited during the audit. Response time can vary based on the size of the impact. It is usually 10 days.
26. RequestAdditional InformationTemplate	Request for Additional Information Template	To determine compliance with PACE requirements for specific findings	PACE organizations	CMS audits approx. 40 PACE organizations annually	Only used if a deficiency is cited during the audit. Response time can vary based on the finding identified. It is usually 1 day.
27. RequiredServices 1P931P100	Provision of Services Impact Analysis Template	To assess participant impact	PACE organizations	CMS audits approx. 40 PACE organizations annually	Only used if a deficiency is cited during the audit. Response time can vary based on the size of the impact. It is usually 10 days.
28. RequiredSpecialistContract1P100	Provision of Services Impact Analysis Template	To assess participant impact	PACE organizations	CMS audits approx. 40 PACE organizations annually	Only used if a deficiency is cited during the audit. Response time can vary based on the size of the impact. It is usually 10 days.
Document Title	Description	Purpose	Respondents	Reporting Frequency	Response Timeframes
30. RootCauseTemplate	Root Cause Analysis Template	To assess impact to PACE organizations	PACE organizations	CMS audits approx. 40 PACE organizations annually	Only used if a deficiency is cited during the audit. Response time can vary based on the size of the impact. It is usually 1 day.

31. SDRIdentification 1P76	Service Determination Request Impact Analysis Template	To assess participant impact	PACE organizations	CMS audits approx. 40 PACE organizations annually	Only used if a deficiency is cited during the audit. Response time can vary based on the size of the impact. It is usually 10 days.
32. SDRs1P041P601P611 P85	Service Determination Request Impact Analysis Template	To assess participant impact	PACE organizations	CMS audits approx. 40 PACE organizations annually	Only used if a deficiency is cited during the audit. Response time can vary based on the size of the impact. It is usually 10 days.
33. SrvRestrict1P90	Provision of Services Impact Analysis Template	To assess participant impact	PACE organizations	CMS audits approx. 40 PACE organizations annually	Only used if a deficiency is cited during the audit. Response time can vary based on the size of the impact. It is usually 10 Days.
34. WoundCare1P02	Provision of Services Impact Analysis Template	To assess participant impact	PACE organizations	CMS audits approx. 40 PACE organizations annually	Only used if a deficiency is cited during the audit. Response time can vary based on the size of the impact. It is usually 10 days.

13. Capital Costs

There is no capital cost associated with this collection.

14. Cost to Federal Government

The costs to the federal government include updating the Health Plan Management System (HPMS) used for collecting information, staff time to participate in the audit and oversee the audit, travel expenses and money used to fund contractor support during audits. Additionally,

federal and contractor staff perform a host of other audit, enforcement and data analytic activities outside of activities related to this collection effort.

*Federal Government Staff Time**

CMS estimated the cost for the federal government to conduct the CMS PACE audits starting with the personnel and hourly wage table below. CMS selected the following personnel for the burden estimate based on CMS's previous experiences conducting PACE audits.

Occupation Title	Federal Salary Scale*	Hourly Wage (\$/hr)	Fringe Benefit (\$/hr)	Adjusted Hourly Wage (\$/hr)
CMS Auditor	GS-13/Step 1	\$57.78	\$57.78	\$116
CMS Audit Manager	GS-15/Step 1	\$80.31	\$80.31	\$161

*The hourly wage estimate is based on OPM's 2025 General Schedule (GS) Locality Pay Table for DC-MD-VA-WV-PA (https://www.opm.gov/policy-data-oversight/pay-leave/salarieswages/salary-tables/pdf/2025/DCB_h.pdf).

CMS expects the federal government to staff approximately 40 annual PACE audits under current regulations

and estimate the median hourly wage for federal government staff to conduct and oversee audit related activities based on the above wage table and number of staff positions indicated below.

PACE Audit Activities

Occupation Title	Total Number of Positions (\$/hr.)	Adjusted Hourly Wage (\$/hr)
CMS Auditor	3	\$116
CMS Manager	1	\$161

Based on the above hourly wages (rounded to the nearest whole dollar) and number of positions, CMS estimates a median hourly wage of \$138/hr. for the federal government to conduct PACE audit activities, including audit oversight.

For each of the 40 PACE audits staffed by the federal government, CMS estimates that staff will take 30 hours to review submitted information and prepare for the audit, 100 hours for the actual administration of the audit, and 150 hours to analyze the data, issue non-compliance notices and reports, respond to report comments from organizations (if applicable), accept corrective action plans and close-out audits. The total burden equals 280 hours per PACE audit. Therefore, the total annual

hours for the federal government to conduct all 40 audits is 11,200 hours (40 PACE audits x 280 staff hours per audit).

Audit Cost to the Federal Government The following table summarizes the per audit cost to the federal government.

Federal Government Staff	Adjusted Hourly Wage (\$/hr)	Hours per Audit	Total Cost Per Audit (\$)
4 Audit Staff	\$138	280	\$154,560

The cost per PACE audit is \$154,560 for all federal government audit activities. The total cost for the 40 annual PACE audits conducted by the federal government is \$6,182,400 (40 PACE audits per year x \$154,560 cost per PACE audit).

Travel Cost to the Federal Government

CMS expects the federal government to travel for approximately 10 audits annually. Based on CMS's experiences across several geographic regions, CMS estimates the cost per trip at \$1800 per auditor or a total cost of \$3600 for two audit staff. Therefore, the travel total cost for the 10 annual PACE audits conducted by the federal government is \$36,000 (10 PACE audits per year x \$3600 travel cost per audit).

Total Costs to the Federal Government

Based on the preceding methodology, CMS estimates the total cost of the federal government as follows:

Total Audit Cost	\$6,182,400
<u>Total Travel Cost</u>	<u>\$36,000</u>
<u>Total Cost</u>	<u>\$6,218,400</u>

Contractor Costs

CMS utilizes audit support contractors with a variety of roles and responsibilities with duties beyond just conducting the audit. The roles and responsibilities related to this collection effort includes but it not limited to serving as audit leads and team members, analyzing data and ensuring completeness of all audit data collected from POs, developing draft notices and reports, reviewing corrective action plans, and providing additional support for audit related analyses.

Based on invoices received by the government, the contractor cost per CMS PACE Audit is \$212,204. CMS anticipates utilizing contractor staff to fully conduct approximately 40 PACE audits each year.

Overall Audit Cost to the Federal Government

Based on the preceding methodology, CMS estimates the overall cost to the federal government as follows:

Total Contractor Cost	\$8,488,160
<u>Total Government Staff Cost</u>	<u>\$6,218,400</u>
 Overall Cost	 <u>\$14,706,560</u>

15. Changes to Burden

Changes to PACE Organization Burden

In 2023, CMS implemented a revised PACE audit protocol that was designed to account for the continued growth of the PACE program and CMS's commitment to a more targeted, data-driven and outcomes-based audit approach, focused on high-risk areas that have the greatest potential for participant harm. For 2026, CMS has updated the PACE audit protocol with an approach similar to the 2023 PACE audit protocol updates, which includes addressing PACE regulatory changes introduced in 2024. As described above, the total hourly burden for PACE organizations is 31,200 hours for the PACE audits (780 hours per PO).

In 2023, CMS estimated a total burden of 780 hours per audit for each PO and explained hours of burden according to the PACE audit lifecycle: pre-audit activities, audit administration (audit fieldwork), responding to documentation requests, and audit close out activities. Based on CMS's experiences conducting audits in 2023 and 2024 and changes to the protocol, CMS estimates the total burden for the 2026 protocol to be 31,200 hours (780 hours per audit).

CMS notes that the number of documents in Section 12 of this statement has increased from 24 documents for the 2023 audit protocol to 34 documents for the 2026 audit protocol. For 2026, CMS added 7 impact analyses templates, a cover sheet for element case files, a request for additional information template, and a corrective action plan template. Four additional impact analyses were added based on regulatory changes and three were split out from existing approved templates for clarity and to reduce the potential for completing unnecessary data fields. As noted previously, these templates will only be used if a related deficiency is identified

on audit. The other new documents provide instructions and a framework to help POs simplify and organize supporting documentation already submitted as part of the audit process. Specifically, the case file cover sheets serve as a documentation checklist for element samples to help organizations ensure they have submitted all necessary documents and help streamline the audit review process. The request for additional information template provides instructions for responding to questions regarding potential issues of non-compliance identified during an audit, and the corrective action plan template provides instructions to assist organizations with submitting the required corrective action plans more efficiently and effectively.

CMS has omitted two collection requirements included in the 2023 protocol, that we believe necessitated considerable PO resources to complete and delayed closing the audit, thus extending the time commitment for POs. The first eliminated requirement was for monitoring reports for the provision of services and the second was for CAP implementation and monitoring submissions.

Overall, we believe that the 10 additional documents and other minor changes introduced in the 2026 audit protocol do not equate to a meaningful increase in PO burden. Furthermore, the burden reducing revisions to the data collection are more impactful and better align burden with our original estimates.

Based on CMS's experience and additional cost analysis, CMS estimated the cost to conduct 40 audits using the 2026 protocol to be \$2,277,600. CMS made no changes to the data collection burden estimates based on the 60-day public comments received. Multiple commenters considered the collection burdensome and expressed concern that CMS may have underestimated the collection burden. CMS addressed these concerns in the 30-day Response to Comments document associated with this package. CMS believes that the burden reducing revisions better align burden with the original estimates included in the 60-day comment package. Therefore, CMS determined that the data collection burden estimate for this 30-day public comment period would not change.

Changes to Federal Government Burden

Since the implementation of the 2023 PACE audit protocol, CMS finalized two rules with new PACE provisions and continually monitored resource allocation and utilization and as a result, has updated the estimated costs to CMS in the 2026 audit protocol. The previously estimated cost to conduct 40 PACE audits using the 2023 protocol was \$9,950,090. Based on CMS's experience and additional cost analysis, CMS has revised the estimated cost to conduct 40 audits using the 2026 protocol to be \$14,706,560. CMS believes that the increased cost estimate for 2026 is necessary to adequately assess PO's compliance with new regulatory requirements and ensure participants are adequately protected.

16. Publication and Tabulation Dates

The review results based on the information collected during audits will be made available to POs. In accordance with 42 CFR § 460.196(d), POs are required to make the results of the review available for examination in a place that is readily accessible by participants, caregivers, family members and authorized representatives. Additionally, in accordance with 42 CFR § 460.196(b), CMS or the SAA will make results available to the public upon request.

17. Expiration Date

The expiration date will be displayed once this package is approved.

18. Certification Statement

There are no exceptions.

B. Collections of Information Employing Statistical Methods

No statistical methods are applied to any of the audit information collected.