

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

Note: This information collection request is currently approved by OMB under the title, “The PACE Organization (PO) Monitoring and Audit Process in 42 CFR 460”. This iteration revises the title as set out above. The OMB control number and the CMS ID number are unchanged. Additional changes are discussed below under section 15.

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 145 POs.

In 2020, 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 our data-driven and participant outcomes-based audit approach, and improve transparency.

On January 19, 2021, 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 appeals processes, responsibilities of the interdisciplinary team (IDT), required services, and documentation requirements. The 2023 PACE audit protocol was modified with two goals; first, to implement the new regulatory provisions that were effective in March of 2021, and second, to incorporate the lessons learned from our audit experiences in 2020 and 2021. These revisions include modifying elements and data requests in regard to the new regulatory requirements, collecting information on contracted entities (including specialists), incorporating a review of the POs’ implementation of compliance oversight activities, and adding a new documentation request related to corrective action plans (CAPs). As with the 2020 PACE audit protocol, CMS continued to consider stakeholder feedback and audit outcomes data to streamline audit elements, refine our data-driven and participant outcomes-based audit approach, and improve transparency.

CMS currently uses 22 data collection instruments for conducting PACE audits. These instruments are categorized as a PACE audit protocol, a questionnaire, a pre-audit issue summary, an onsite participant sample collection document, a Root Cause Analysis template, 16 impact analyses templates, and a voluntary audit feedback questionnaire.

Beginning in audit year 2023, the number of data collection instruments will increase from 22 to the following 24 documents:

- A PACE Audit Protocol,
- A Pre-audit issue summary document,
- A PACE supplemental questionnaire,
- A Corrective Action Plan Process document,
- A root cause analysis template (for use as-needed),
- 18 Impact Analyses templates (for use as-needed), and
- An audit feedback questionnaire (voluntary).

Based on comments CMS received during the 60-day comment period regarding the burden of the participant observation sample collection document, we removed this collection tool from this collection request.

A more detailed description of the collection instrument changes from 2020 to 2023 and their impact on overall burden is outlined in section 15 below.

CMS intends to continue using the PACE 2020 Audit Protocol (CMS-10630, OMB: 0938-1327) to conduct audits through the end of calendar year 2022. CMS will begin using the updated audit protocol in 2023. Delaying the implementation of the revised audit protocol until 2023 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.

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 2023 protocol provided in this package was published alongside the 60-day Federal Register Notice (86 FR 72244) on 12/21/2021. We received 38 unique comments following the 60-day comment period. Comments, and our responses, are attached to this package. A crosswalk which sets out the changes from the 60-day package to this 30-day package is also attached. The 2023 protocol will be published for the 30-day Federal Register comment period. This package can be updated with specific dates when publication dates are known.

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). We will post the protocol on our 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. While POs are required during audit to provide CMS access to records, data and other participant information, CMS will ensure that the information is maintained and used in a confidential format. Any sensitive or personal information will be transferred and/or stored through the Health Plan Management System (HPMS) which is a secure site. The SORN for the HPMS is located here: <https://www.cms.gov/Research-Statistics-Data-and-Systems/Computer-Data-and-Systems/Privacy/Downloads/0500-HPMS.pdf>

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)

42 CFR §§ 460.190 and 460.192 describe CMS’s regulatory authority to monitor, through audit or other means, the PACE. Monitoring includes review of books, contracts, medical records, patient care documentation and any other records that pertain to any aspect of services performed, reconciliation of benefit liabilities, and determination of amounts payable. CMS developed a strategy to address our oversight and audit responsibilities.

We continue to combine both the trial year and ongoing audit protocols into one universal audit protocol to reduce the financial and administrative burdens for both CMS and POs.

12.1 Wage Estimates

To derive average costs, we used data from the U.S. Bureau of Labor Statistics’ May 2021 National Occupational Employment and Wage Estimates for all salary estimates (https://www.bls.gov/oes/current/oes_nat.htm). In this regard, the following table presents the mean hourly wage, the cost of fringe benefits (calculated at 100 percent of salary), and the adjusted hourly wage.

National Occupational Mean Hourly Wage and Adjusted Hourly Wage

Occupation Title	Occupation Code	Mean Hourly Wage (\$/hr)	Fringe Benefit (\$/hr)	Adjusted Hourly Wage (\$/hr)
Medical and Health Services Managers	11-9111	\$57.61	\$57.61	\$115.22
Executive Secretaries and Executive Administrative Assistants	43-6011	\$32.15	\$32.15	\$64.30
Medical Records Specialists	29-2072	\$23.23	\$23.23	\$46.46
Compliance Officers	13-1041	\$36.45	\$36.45	\$72.90

As indicated, we are adjusting our 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 we believe that doubling the hourly wage to estimate total cost is a reasonably accurate estimation method.

Occupation Title	Adjusted Hourly Wage (\$/hr)
Medical and Health Services Managers (Nurse Manager)	\$115
Executive Secretaries and Executive Administrative Assistants	\$64
Medical Records Specialists	\$46
Compliance Officer (Quality Assurance Specialist)	\$73
Average Adjusted Hourly Wage (\$/hr)	\$75

Based on our experience implementing this audit protocol in 2020 and 2021, and based on the feedback provided to us from POs that underwent an audit using this protocol, we created a burden estimate that we believe accurately reflects the number of staff, salaries and an hourly time estimate for staff when undergoing a CMS PACE audit. For this burden estimate, we are assuming each individual identified works simultaneously during the course of the audit.

We continue to seek industry feedback to ensure we are accurately representing the burden for a PACE organization to undergo a CMS audit, and as such, we continue to request feedback related to the audit burden as a part of our audit survey.

12.2 Burden Estimates

Trial Year and Routine Audits

Trial year and routine audits will use the same audit protocol. As a result, the burden estimate is the same for both trial year and routine audits.

Based on revisions to the audit protocol, CMS has revised burden estimates for the PACE audits beginning in 2023. CMS estimates a total of four people (identified above) from each PO, working simultaneously, will be used for each audit. We estimate 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 and implement corrective action and audit close out activities.

This is a total of approximately 195 hours per person for each PO, or 780 hours total per PO. The average number of POs that will receive an audit annually is 40.

In aggregate, we estimate 31,200 hours of burden for POs (40 POs x 780 hours per PO) at \$2,340,000 (40 POs x 780 hours per PO x \$75 per hour). We further estimate that the cost for a single PO to undergo a CMS PACE audit is \$58,500 (\$2,340,000 total cost ÷ 40 POs).

12.3 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	\$75	\$2,340,000

12.4 Information Collection Instruments and Instruction/Guidance Documents

Document Title	Description	Purpose	Respondents	Reporting Frequency	Response Timeframes
1. AttachmentIPA CEAudit Protocol	Description of the PACE Audit Protocol	To evaluate compliance with PACE requirements	PACE organizations	We audit 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. AttachmentIIP ACESupplemental Questions	PACE Supplemental Questionnaire	To evaluate compliance with PACE requirements	PACE organizations	We audit approx. 40 PACE organizations annually	Responses to this collection tool do not exceed 1 week following the issuance of the engagement letter.
3. AttachmentIIIP reAuditIssueSummary	Summary of any pre-audit issues	To determine pre-disclosed non-compliance	PACE organizations	We audit approx. 40 PACE organizations annually	Responses to this collection tool do not exceed 1 week following the issuance of the engagement letter.

Document Title	Description	Purpose	Respondents	Reporting Frequency	Response Timeframes
4. AttachmentIVA uditSurvey	Audit Survey	A short summary to improve the audit process	PACE organizations	We audit 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.
5. AttachmentVC orrectiveAction PlanProcess	Description of the Corrective Action Plan process	To assist organization with implementation of correction	PACE organizations	We audit 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	We audit 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. Appeals1P651P 661P681P73	Appeals Impact Analysis Template	To assess participant impact	PACE organizations	We audit 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. Assessments1P 491P501P82	Provision of Services Impact Analysis Template	To assess participant impact	PACE organizations	We audit 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
9. Coordination of Care 1P95	Coordination of Care Impact Analysis Template	To assess participant impact	PACE organizations	We audit 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.
10. Effectuation 1P02 1P11 1P30	Service Determination Request and Appeals Impact Analysis Template	To assess participant impact	PACE organizations	We audit 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. Emergency Care 1P07	Provision of Services Impact Analysis Template	To assess participant impact	PACE organizations	We audit 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. Grievances 1P31 1P75 1P77	Grievances Impact Analysis Template	To assess participant impact	PACE organizations	We audit 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. Home Care 1P02	Provision of Services Impact Analysis Template	To assess participant impact	PACE organizations	We audit 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	Respon dents	Reporting Frequency	Response Timeframes
14. MedErrors1P02	Provision of Services Impact Analysis Template	To assess participant impact	PACE organiza tions	We audit approx. 40 PACE organization s 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. Personnel	Personnel Impact Analysis Template	To assess participant impact	PACE organiza tions	We audit approx. 40 PACE organization s 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. ProvisionofServ ices1P021P81	Provision of Services Impact Analysis Template	To assess participant impact	PACE organiza tions	We audit approx. 40 PACE organization s 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.
17. RequiredServic es1P93	Provision of Services Impact Analysis Template	To assess participant impact	PACE organiza tions	We audit approx. 40 PACE organization s 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. Restraints1P09	Provision of Services Impact Analysis Template	To assess participant impact	PACE organiza tions	We audit approx. 40 PACE organization s 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. RootCauseTemplate	Root Cause Analysis Template	To assess impact to PACE organizations	PACE organizations	We audit 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.
20. SDRIdentification1P76	Service Determination Request Impact Analysis Template	To assess participant impact	PACE organizations	We audit 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. SDRs1P601P611P85	Service Determination Request Impact Analysis Template	To assess participant impact	PACE organizations	We audit 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. SpecialistRecommendations1P94	Alert to Specialist Recommendations Impact Analysis Template	To assess participant impact	PACE organizations	We audit 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. SrvcRestrict1P90	Provision of Services Impact Analysis Template	To assess participant impact	PACE organizations	We audit 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. WoundCare1P02	Provision of Services Impact Analysis Template	To assess participant impact	PACE organizations	We audit 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 Cost (Maintenance of Capital Costs)

There is no capital cost associated with this collection.

14. Cost to Federal Government

The costs to the federal government include staff time to participate in 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.

We expect 5 PO audits staffed by CMS employees under current regulations.

Occupation Title	Federal Salary Scale*	Hourly Wage (\$/hr)	Fringe Benefit (\$/hr)	Adjusted Hourly Wage (\$/hr)
7 CMS Auditor(s)	GS-13/Step 1	\$51.18	\$51.18	\$102.36
CMS Audit Manager	GS-15/Step 1	\$71.15	\$71.15	\$142.30
1 CMS Account Manager	GS-13/Step 1	\$ 51.18	\$51.18	\$102.36

*The hourly wage estimate is based on OPM's 2021 General Schedule (GS) Locality Pay Table for DC-MD-VA-WV-PA (see https://www.opm.gov/policy-data-oversight/pay-leave/salaries-wages/salary-tables/pdf/2022/DCB_h.pdf).

Based on the table above, we then determined the costs for conducting the audit, oversight of audit processes, and audit monitoring.

Conducting Audit Activities

Occupation Title	Adjusted Hourly Wage (\$/hr)
7 CMS Auditors	\$102/auditor
Total salary/hour	\$714

For each of the 5 audits staffed by CMS, we estimate 30 hours per person prior to the audit start to review the information for completeness and prepare for audit, 80 hours per person for the actual administration of the audit, and 90 hours per person to review audit documentation, discuss findings, and draft the report, respond to draft comments (if applicable), revise the final report, and review and accept CAPs. The total amount of time estimated to conduct an audit is 200 hours per person. The total hours for CMS to staff an audit is 1,400 hours.

7 CMS Auditors x \$102/hour x 200 hours per person = \$142,800 per audit

Management Oversight

Occupation Title	Adjusted Hourly Wage (\$/hr)
1 CMS Audit Manager	\$142
Total salary/hour	\$142

Oversight of CMS audits typically involves one CMS audit manager. We estimate that the total amount of time spent on audit management activities is 60 hours per audit.

1 CMS Audit Manager x \$142/hour x 60 hours = \$8,520 per audit

Audit Close Out Activities

Occupation Title	Adjusted Hourly Wage (\$/hr)
1 CMS Account Manager	\$102
Total salary/hour	\$102

We believe an additional 20 hours is spent on audit close out activities, such as monitoring the CAPs. Audit close out activities typically involve one CMS Account Manager.

1 CMS Account Manager x \$102/hour x 20 hours = \$2,040

Travel

The average cost per trip for CMS auditors to go onsite is \$13,662. This is based on our experiences across several geographic regions.

Total for Audits Conducted by CMS Staff

We anticipate using CMS staff to conduct 5 audits per year using the 2023 audit protocol, plus CMS staff will conduct close out activities for all 40 audits. The following table summarizes the costs for the 5 audits conducted by CMS staff on a per audit basis and, separately, the total cost of audit close out activities for all 40 audits.

Audit Process	Cost per audit	Total Cost
Conducting Audit Activities	\$142,800	\$714,000 for 5 audits
Audit Oversight Activities	\$8,520	\$42,600for 5 audits
Travel	\$13,662	\$68,310 for 5 audits
Audit Close Out Activities	\$2,040	\$81,600 for 40 audits
Total cost	\$167,022 (per audit for the 5 audits with all audit activities)	\$906,510 for 40 audits (35 with audit close out activities only)

The cost per audit is \$167,022 for the 5 audits with all audit process activities. The total annual cost for audits conducted by CMS staff is \$906,510.

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 include serving as audit lead, providing additional clinical support for audit related analyses, and receiving, analyzing, and ensuring completeness of all audit data collected from POs.

Based on invoices received by the government, the cost to complete a CMS PACE Audit exclusively by CMS contractor staff is \$258,388 on average. CMS anticipates utilizing contractor staff to fully conduct approximately 35 PACE audits each year.

Consequently, the total cost to the government in contracted resources is as follows:

\$258,388 per audit x 35 audits = **\$9,043,580**.

The total estimated costs to the government for staff time, travel, and contractor costs is:

Contractor Costs: \$9,043,580
Government Staff Cost: \$906,510
Total Cost: **\$9,950,090**

15. Program or Burden Changes

Changes to PACE Organization Burden

In 2020, CMS implemented a revised PACE audit protocol that was designed to account for the continued growth of the PACE program and CMS' 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 2023, CMS has updated the PACE audit protocol with an approach similar to 2020 PACE audit protocol updates, plus addressing PACE regulatory changes introduced in 2021.

We received comments on these estimates during the 60-day comment period. Most commenters indicated that they believed we had underestimated the burden of audits on POs. These commenters also offered specific suggestions on how to reduce the burden. We addressed these comments, and we made a number of changes to the audit protocol that would reduce the burden for organizations undergoing a CMS PACE audit. Based on the revisions, we believe the original burden estimates now more accurately reflects the cost of the audits and therefore we are not making adjustments to the burden estimates in response to comments other than to change hourly wages and contractor costs based on updated data, as reflected in the calculations here and in Section 12.

In 2020, CMS estimated a total burden of 600 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. For pre-audit activities, CMS estimated that per audit, 4 PO staff would spend 80 hours (20 hours per person) prior to the audit start to assemble and review information for completeness, 160 hours (40 hours per person) for the administration of the audit, 160 hours (40 hours per person) to review and respond to documentation requests, and 200 hours (50 hours per person) for corrective action and audit close out activities. Based on our proposed revisions to the 2023 PACE audit protocol, we continue to explain the burden estimate in reference to the audit lifecycle. Overall, we increased the burden estimate for the 2023 audit protocol to take into account the additional requirements CMS will review in response to regulatory changes to 42 CFR § 460 that went into effect March 22, 2021 and additional or modified documentation and data requests for high risk areas CMS has proposed to assess in 2023. We continue to seek industry feedback on these assumptions.

In 2020, CMS estimated an average of 80 hours (20 per person) prior to the start of the audit for assembling and reviewing data and document submissions. For 2023, CMS has increased the number of hours needed to assemble and review information prior to the start of the audit from 20 hours per person to 25 hours per person. When considering these numbers, we took into account the addition of a new universe, Contracted Entities and Providers (CEP) and additional pre-audit documentation related to POs' compliance oversight efforts and provision of services tracking. For the additional pre-audit documentation, CMS does not anticipate a significant increase in burden, as CMS expects POs to already have the requested information tracked and maintained in their records, in accordance with PACE regulations. Any additional burden would be a matter of providing the requisite information within the timeframe requested by CMS.

Additionally, the CEP universe has a narrow scope, requires few data points per entry, and per regulations POs are already required to maintain a list of contracts. For the above stated reasons, CMS estimates an additional 5 hours per person, or 25 hours per person, in relation to pre-audit activities for a total of 100 hours per PO.

For 2023, CMS has increased the timeframe for administration of the audit from 40 hours per person to 80 hours per person, or from 160 to 320 hours total per PO. Based on our audit experiences in 2020 and 2021, we believe we underestimated the time required to respond to documentation requests during the administration of the audit, and we believe the work during audit fieldwork lasts two weeks rather than one.

For the 2020 audit protocol, we estimated that a PO would spend 40 hours per person on audit activities that follow audit fieldwork, such as submitting supporting documentation, compiling and submitting root cause analyses and impact analyses, and responding to draft audit reports. The time spent on an audit following audit fieldwork varies significantly from PO to PO depending on how many issues of non-compliance were identified during the audit, and how much additional documentation requests or analyses need to be conducted in response. We recognize that the more issues or conditions of non-compliance identified during the audit, the more hours are required by PO staff in the post-audit activities. Based on our experiences conducting audits in 2020 and 2021, we will maintain the estimate of 40 hours per person or 160 hours total per PO for responding to documentation following audit fieldwork.

Finally, for the 2020 audit protocol, we estimated 50 hours per person, or a total of 200 hours per PO, on audit close out activities. For 2023, we are estimating the same, 200 hours total per PO for submitting CAPs, then implementing and monitoring CAPs to ensure adequate correction. For transparency into the CAP process, CMS added Attachment V: Corrective Action Plan Process to the protocol for 2023. We did not increase the close out audit activity burden, because under regulations POs are required to correct noncompliance, and Attachment V clarifies a process and workload that has been in place since the implementation of the 2017 audit protocol, and thus does not change the PO burden.

To summarize the change in estimated staff hours across the audit life cycle, for 2023, we assume that POs will continue to assign four individuals to work on audit activities, which will increase from 150 to 195 hours per person. As a result, the total number of hours spent on audit from 2020 to 2023 will increase from 600 hours total to 780 hours total per PO.

CMS would like to note that the number of documents in Section 12.4 of this statement has increased from 22 documents for the 2020 audit protocol to 24 documents for the 2023 audit protocol. For 2023, CMS added three impact analyses templates and Attachment V, the Corrective Action Plan Process document. The additional impact analyses will only be used if a deficiency is identified on audit. Also, the 2020 impact analysis template AppealExt1P71 was not included in 2023 documents. As mentioned previously, Attachment V: Corrective Action Plan Process, clarifies a process that has been in place since 2017. As with the impact analysis, only POs with deficiencies would be subject to Attachment V. Therefore, the three additional

documents introduced in the 2023 audit protocol do not equate to a meaningful increase in PO burden.

Since the implementation of the 2020 audit protocol, CMS has continued to collect feedback and data from POs that allows us to more accurately estimate the costs of a PACE audit to an organization. The previously estimated cost to conduct 35 audits using the 2020 protocol was \$1,470,000. Based on our experience and additional cost analysis, CMS has revised the estimated cost to conduct 40 audits using the 2023 protocol to be \$2,340,000.

We believe that the cost estimate for 2023 does not represent a significant increase in cost to POs. Instead, we believe that the estimates for 2023 reflect a more accurate representation of the actual cost for conducting PACE audits than what was published in 2020. Lastly, cost increases reflect inflation adjustments and necessary changes to the protocol to ensure POs implemented 2021 regulatory updates and have established robust compliance oversight. We invite the industry to comment on these new burden estimates to ensure we are accurately representing the audit cost for POs.

Changes to Federal Government Burden

Since the implementation of the 2020 PACE audit protocol, CMS continually monitored resource allocation and utilization and, as a result, has updated the estimated costs to CMS in the 2021 audit protocol. The previously estimated cost to conduct 35 PACE audits using the 2020 protocol was \$5,247,020. Based on our experience and additional cost analysis, CMS has revised the estimated cost to conduct 40 audits using the 2023 protocol to be \$9,950,090. We believe that the increased cost estimate for 2023 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.