

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 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 Social Security Act and the implementing regulations at 42 CFR §§ 460.190 and 460.192 mandate that CMS, in cooperation 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 131 PACE organizations.

In 2017, CMS developed and implemented a revised PACE audit protocol. The audit protocol 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.

Since the implementation of the 2017 PACE audit protocol, CMS has utilized stakeholder feedback and audit outcomes to continually evaluate and improve the audit process. The 2020 PACE audit protocol has been revised, using stakeholder feedback and audit outcomes data, to streamline the elements, clarify CMS expectations, refine our data-driven and participant outcomes-based audit approach, and improve transparency.

CMS currently uses 18 data collection instruments for conducting PACE audits. These instruments are categorized as a PACE audit process and data request, a questionnaire, a pre-audit issue summary, a Root Cause Analysis template and 14 impact analyses templates.

Beginning in audit year 2020, the number of data collection tools will increase from 18 to the following 22 documents:

- A PACE Audit Process and Data Request,
- A Pre-audit issue summary document,
- A PACE supplemental questionnaire,
- One onsite participant sample collection document,
- One root cause analysis template (for use as-needed),
- 16 Impact Analyses templates (for use as-needed), and
- One voluntary audit feedback questionnaire

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

We are requesting revision approval with changes from OMB for this currently approved collection.

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 cooperation 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 PACE organizations' 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 cooperation with the SAA, audit PACE organizations (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 PACE organizations' compliance with PACE program requirements. If outliers or other data anomalies are detected, CMS' Regional Offices will work in collaboration with MOEG and other divisions within CMS 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 PACE organizations. All POs have access to HPMS. Users must request and gain access via CMS personnel and users must create and maintain a secure user id and password that are used each time the 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

This collection will not impact small businesses or other small entities.

6. Less Frequent Collection

Sections 1894(e)(4) and 1934(e)(4) of the Social Security Act and the implementing regulations at 42 CFR §§ 460.190 and 460.192 mandate that CMS, in cooperation with the 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. CMS determines by risk how often organizations are subject to audits following the trial period.

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

7. Special Circumstances

In general, CMS collects information in a manner that would not require respondents to:

- Report information to the agency more often than quarterly;
- Prepare a written response to a collection of information in fewer than 30 days after receipt of it;
- Submit more than an original and two copies of any document;
- Retain records, other than health, medical, government contract, grant-in-aid, or tax records for more than three years;
- Collect data in connection with a statistical survey that is not designed to produce valid and reliable results that can be generalized to the universe of study,
- Use a statistical data classification that has not been reviewed and approved by OMB;
- Include a pledge of confidentiality that is not supported by authority established in statute or regulation that is not supported by disclosure and data security policies that are consistent with the pledge, or which unnecessarily impedes sharing of data with other agencies for compatible confidential use; or
- Submit proprietary trade secret, or other confidential information unless the agency can demonstrate that it has instituted procedures to protect the information's confidentiality to the extent permitted by law.

However, as outlined in our data request tools, 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 published in the Federal Register on March 28, 2019 (84 FR 11800). We received 15 unique commenters 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 2020 protocol, provided in this package will be published for the 30-day Federal Register comment period. This package can be updated with specific dates when the publication date is 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 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 Programs for All-Inclusive Care of the Elderly (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 have combined both the trial year and ongoing audit protocols into one universal audit protocol that is streamlined and outcomes based to reduce the financial and administrative burdens for both CMS and PACE organizations.

12.1 Wage Estimates

To derive average costs, we used data from the U.S. Bureau of Labor Statistics' May 2018

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)
Nurse Manager	11-9111	54.68	54.68	109.36
Executive Assistant	43-6011	29.59	29.59	59.18
Medical Records and Health Information Technician	29-2071	21.16	21.16	42.32
Compliance Officer	13-1041	34.86	34.86	69.72

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.

Based on the table above, we then added the estimated hourly rate (rounded to the nearest whole dollar) for each position identified below.

Occupation Title	Adjusted Hourly Wage (\$/hr)
Nurse Manager	\$109
Executive Assistants	\$59
Medical Records and Health Information Technicians	\$42
Quality Assurance Specialist	\$70
Total salary/hour	\$280

Total Salary/hour: \$280

Based on our experience implementing this audit protocol in 2017 and 2018, we created a burden estimate that we believed to accurately reflect the number of staff, salaries and an hourly time estimate for staff when undergoing a CMS PACE audit. We are no longer averaging the salaries, but instead we are assuming each individual identified works simultaneously during the course of the audit. 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 PACE organizations. 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 package that would greatly reduce the burden organizations would experience when undergoing a CMS PACE audit. Based on the revisions, we believe the original estimate for PACE organizations now more accurately reflects the cost of the audit and therefore we are not making adjustments to the burden estimate in response to

comments.

We continue to seek industry feedback to ensure we are accurately representing the burden for a PACE organization to undergo a CMS audit.

12.2 Burden Estimates

Trial Year and Ongoing Audits

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

CMS estimates an average of 20 hours per person prior to the audit start to assemble data and review the information for completeness, 40 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 150 hours per person for each PO, or 600 hours total per PACE organization. The average number of POs that will receive an audit annually is 35.

In aggregate we estimate 5,250 hours per person (35 POs x 150 hr/per person) at \$1,470,000 (5,250 hr x \$280/hr). We further estimate that the cost for a single PACE organization to undergo a CMS PACE audit is \$42,000 ($\$1,470,000 \div 35$).

12.3 Burden Summary

Information Collection	Respondents	Responses (per Respondent)	Total Responses	Burden per person per Response (hours)	Total Annual Burden (hours)	Labor Cost of Reporting (\$/hr)	Total Cost (\$)
Audits	35	1	35	150	5,250	\$280	\$1,470,000

12.4 Information Collection Instruments and Instruction/Guidance Documents

Document Title	Description	Purpose	Respondents	Reporting Frequency	Response Timeframes
1. Attachment I PACE Audit Process Data Request	Description of the PACE Audit Process and Data Request Protocol	To evaluate compliance with PACE requirements	PACE organizations	We audit approx. 35 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. Attachment II PACE Supplemental Questions	PACE Supplemental Questionnaire	To evaluate compliance with PACE requirements	PACE organizations	We audit approx. 35 PACE organizations annually	Responses to this collection tool do not exceed 1 week following the issuance of the engagement letter.
3. Attachment III Pre Audit Issue Summary	Summary of any pre-audit issues	To determine pre-disclosed non-compliance	PACE organizations	We audit approx. 35 PACE organizations annually	Responses to this collection tool do not exceed 1 week following the issuance of the engagement letter.
4. Attachment IV Onsite Obs Part List	List of participants receiving care the week of the onsite audit	To evaluate compliance with PACE requirements	PACE organizations	We audit approx. 35 PACE organizations annually	Responses to this collection tool do not exceed 2 weeks following the start of audit fieldwork.
5. Attachment V Audit Survey	Audit Survey	A short summary to improve the audit process	PACE organizations	We audit approx. 35 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.
6. Root Cause Template	Root Cause Analysis Template	To assess impact to PACE organizations	PACE organizations	We audit approx. 35 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.
7. Home Care IP02	Clinical Appropriateness and Care Planning Impact Analysis Template	To assess participant impact	PACE organizations	We audit approx. 35 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. Med Errors IP02	Clinical Appropriateness and Care Planning Impact Analysis Template	To assess participant impact	PACE organizations	We audit approx. 35 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	Response Timeframes
9. Provision of Services 1P021P81	Clinical Appropriateness and Care Planning Impact Analysis Template	To assess participant impact	PACE organizations	We audit approx. 35 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. Wound Care 1P02	Clinical Appropriateness and Care Planning Impact Analysis Template	To assess participant impact	PACE organizations	We audit approx. 35 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	Clinical Appropriateness and Care Planning Impact Analysis Template	To assess participant impact	PACE organizations	We audit approx. 35 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. Restraints 1P09	Clinical Appropriateness and Care Planning Impact Analysis Template	To assess participant impact	PACE organizations	We audit approx. 35 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. Alert IDT 1P14	Clinical Appropriateness and Care Planning Impact Analysis Template	To assess participant impact	PACE organizations	We audit approx. 35 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.
14. Assessments 1P491P501P82	Clinical Appropriateness and Care Planning Impact Analysis Template	To assess participant impact	PACE organizations	We audit approx. 35 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. Svc Restrict 1P90	Clinical Appropriateness and Care Planning Impact Analysis Template	To assess participant impact	PACE organizations	We audit approx. 35 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. Personnel	Personnel Impact Analysis Template	To assess participant impact	PACE organizations	We audit approx. 35 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.
17. Effectuation 1P021P111P30	Service Delivery Request and Appeals Impact Analysis Template	To assess participant impact	PACE organizations	We audit approx. 35 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
18.Grievances1P311P751P77	Grievances Impact Analysis Template	To assess participant impact	PACE organizations	We audit approx. 35 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.
19.SDRs1P601P611P85	Service Delivery Request Impact Analysis Template	To assess participant impact	PACE organizations	We audit approx. 35 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.Appeals1P651P661P681P73	Appeals Impact Analysis Template	To assess participant impact	PACE organizations	We audit approx. 35 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. AppealExt1P71	Appeals Impact Analysis Template	To assess participant impact	PACE organizations	We audit approx. 35 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. SDR Identification1P76	Service Delivery Request Impact Analysis Template	To assess participant impact	PACE organizations	We audit approx. 35 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 two audit support contracts that are used as staff extenders during audits, but that also perform a host of other audit, enforcement and data analytic activities outside of activities related to this collection effort.

We expect 35 PO audits under current regulations.

Occupation Title	Federal Salary Scale*	Hourly Wage (\$/hr)	Fringe Benefit (\$/hr)	Adjusted Hourly Wage (\$/hr)
6 CMS Auditor(s)	GS-13/Step 1	47.52	47.52	95.04
CMS Audit Manager	GS-15/Step 1	66.05	66.05	132.10

1 CMS Account Manager	GS-13/Step 1	47.52	47.52	95.04
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*The hourly wage estimate is based on OPM's 2019 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/2019/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)
6 CMS Auditors	\$95/auditor
Total salary/hour	\$570

For each audit 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 corrective action plans. The total amount of time estimated to conduct an audit is 200 hours per person. The total hours for CMS to conduct an audit is 1200 hours.

6 CMS Auditors x \$95/hour x 200 hours = \$114,000 per audit

Management Oversight

Occupation Title	Adjusted Hourly Wage (\$/hr)
1 CMS Audit Manager	\$132
Total salary/hour	\$132

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 \$132/hour x 60 hours = \$7,920 per audit

Audit Close Out and Ongoing Monitoring Activities

Occupation Title	Adjusted Hourly Wage (\$/hr)
1 CMS Account Manager	\$95
Total salary/hour	\$95

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

1 CMS Account Manager x \$95/hour x 20 hours = \$1,900

Travel

The average cost per trip for CMS auditors to go onsite is \$10,584. 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 2020 audit protocol. The following table summarizes the costs for the 5 audits conducted by CMS staff.

Audit Process	Cost
Conducting Audit Activities	\$114,000 per audit
Audit Oversight Activities	\$7,920 per audit
Travel	\$10,584 per audit
Audit Close Out and Ongoing Monitoring	\$1,900 per audit
Total cost per audit	\$134,404

The cost per audit is \$134,404. The total annual cost for audits conducted by CMS staff is $\$134,404 \times 5 = \mathbf{\$672,020}$.

Contractor Costs

CMS has two audit support contractors that perform a variety of duties beyond just the performance of the audit. The duties performed related to this collection effort include performing audit lead duties, audit team members (conducting the review of audit elements) for each audit team, providing clinicians for portions of the audit, and receiving, analyzing, and ensuring completeness of all audit data collected from POs.

Based on invoices received by the government, we are estimating the cost to complete a CMS PACE Audit exclusively by CMS contractor staff under this revised package is \$152,500. CMS anticipates utilizing contractor staff to fully conduct approximately 30 PACE audits each year.

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

$\$152,500 \text{ per audit} \times 30 \text{ audits} = \mathbf{\$4,575,000}$.

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

Government Staff Cost	\$672,020
<u>Contractor Costs:</u>	<u>\$4,575,000</u>
Total Cost:	\$5,247,020

15. Program or Burden Changes

Changes to PACE Organization Burden

Beginning in 2017, CMS developed and implemented a PACE audit protocol PRA package that was separated from MA and Part D audit PRA packages. The revised audit protocol 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.

In 2017, CMS estimated a total burden of 240 hours per audit for each PACE organization. Specifically, CMS estimated 80 hours prior to the audit start to assemble and review information for completeness, 40 hours for the actual administration of the audit, 40 hours to review and respond to the draft audit report, and 80 hours for corrective action and audit close out activities. Additionally, we estimated that while 4 individuals would be involved in the audit, they would not work simultaneously, and therefore we averaged salaries and assumed that the PO would spend 240 hours total (split between 4 individuals). Based on CMS' experience implementing the 2017 protocol, we believe our estimate did not appropriately account for the staff a PO may need to utilize during the course of the audit. Based on our experience conducting over 130 audits under this protocol, we believe staff generally work simultaneously during the course of an audit. For our proposed revisions to the 2020 PACE audit protocol, we have therefore revised the burden estimates for 2020 to more accurately reflect the burden for PACE organizations and the government when undergoing an audit. We continue to seek industry feedback on these assumptions.

In 2017, CMS estimated an average of 80 hours prior to the start of the audit for assembling and reviewing data and document submissions. CMS believes that the vast majority of the 80 hours spent during the pre-audit timeframe was utilized assembling and reviewing universe data. For 2020, CMS has clarified the number of hours needed to assemble and review information prior to the start of the audit from 80 hours to 20 hours per person. When considering these numbers, we took into account our change from a one year look-back or audit review period to a 6 month period. This reduces the amount of data that an organization needs to compile and submit by 50%. However, we also believe we underestimated the amount of time that an organization took to submit this data in our last package, so we are keeping the total hours the same for the 2020 package.

For 2020, CMS has increased the timeframe for administration of the audit from 40 hours total (per PO) to 40 hours per person. Based on our experiences, we believe that multiple individuals work simultaneously during the audit fieldwork, and that we underestimated the costs in the 2017 package.

Additionally, we increased the amount of time spent reviewing and responding to the draft audit report to include any activities following the audit fieldwork, including responding to documentation requests such as root cause analyses and Impact Analyses. In 2017 we estimated that a PO spent 40 hours total responding to the draft report. We now know that the time spent on an audit following audit fieldwork varies significantly from PO to PO depending on how many conditions of non-compliance were cited, and how much additional documentation or

analyses need to be conducted in response. For the 2020 package we are erring on the side of over-estimating costs to account for those organizations that have multiple conditions of non-compliance that require data and documentation submissions in response. We are therefore increasing our estimate from 40 hours per PO to 40 hours per person following audit fieldwork. These hours include the time it takes to submit supporting documentation, compile and submit root cause analyses and impact analyses, and respond to the draft audit report. Additionally, because part of our audit process includes the period of time it takes for an organization to submit and implement corrective action plans, we are increasing the amount of time we estimate an organization spends on post-audit corrective action and close out activities.

In 2017, we estimated that a PO spent a total of 80 hours (20 hours per person) on audit close out activities. For 2020, we are estimating that a PO spends 50 hours per person (200 hours total) submitting corrective action plans (CAPs), and then implementing and monitoring CAPs to ensure adequate correction. In summary, for 2020, we are assuming that all four PACE organization individuals identified above will work simultaneously during the audit, for a total of 150 hours per person. As a result, the number of hours spent on audit went from 240 hours total to 600 hours total per PO.

CMS would like to note that the number of documents in Section 12.4 of this statement has increased from 18 documents in the 2017 audit protocol to 22 documents in the 2020 audit protocol. The primary reason for this change is the number of Impact Analysis templates is increasing from 14 in the 2017 protocol to 16 in the 2020 protocol to accommodate condition-specific Impact Analyses. CMS believes that utilizing condition specific Impact Analyses will clarify CMS expectations and result in improved data collection and analysis while reducing PO and CMS burden overall. It is important to note that Impact Analyses are only requested when a condition of non-compliance is noted during an audit. Additionally, each condition of non-compliance does not always result in a request for an impact analysis. As a result, an increase in the number of Impact Analysis templates does not equate to an increase in PO burden.

We received numerous comments on the burden of completing impact analyses during the post-audit phase, and as a result we made a number of changes to the process for requesting impact analyses, including reducing the number of IAs we would collect from 25 to 16, and reducing the scope of the impact analysis review from 100% of participant medical records, to 50% of the remaining participant medical records. We discussed these changes in more detail in our response to comments. Commenters indicated that we had underestimated the burden of audits on PACE organizations. We believe the changes made in the revised package related to our collection tools and sample selection will reduce burden and more generally address the overarching concerns about the burden of PACE audits on organizations. Based on the revisions, we believe the original estimate for PACE organizations now more accurately reflects the cost of the audit and therefore we are not making modifications to the PACE organization estimates in this supporting statement other than adjustments to the mean average salaries of personnel based on the 2018 BLS wage estimates instead of the 2017 wage estimates. Additionally, since publishing this package for the 60-day comment period, a new regulation has gone into effect which allows CMS to conduct ongoing audits using a risk assessment. This new regulation allows CMS to reduce the number of audits conducted annually from approximately 70 audits a year to approximately 35 audits a year. Based on these changes,

CMS has revised the estimated cost to conduct 35 audits using the 2020 protocol to be \$1,470,000.

We invite the industry to comment on these new burden estimates to ensure we are accurately representing the audit cost for PACE organizations.

Changes to Federal Government Burden

As noted previously, 2017 was the first attempt by CMS to develop and implement a PACE audit protocol which was separated out from the MA and Part D protocols. This allowed CMS to tailor burden estimates more accurately for POs undergoing a CMS audit and also provided CMS with an opportunity to more accurately reflect the costs and burden to CMS.

Since the implementation of the 2017 audit protocol, CMS continually monitored resource allocation and utilization and, as a result, has updated the estimated costs to CMS in the 2020 audit protocol. The previously estimated cost to conduct 72 audits using the 2017 protocol was \$2,139,213. Based on comments received, we made changes to our audit protocol which increases CMS' burden when conducting these audits, including increasing the number of staff needed to conduct an audit based on increased sample size and number of auditors needed to review the additional samples. We also reduced the number of annual audits from 70 to 35. Based on these modifications, we believe the cost to the federal government to conduct 35 audits is \$5,247,020.

16. Publication and Tabulation Dates

The information collected during audits will be made available to PACE organizations. 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. 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

CMS will continue to display the expiration date and OMB control number on all documents.

18. Certification Statement

There are no exceptions.

B. Collection of Information Employing Statistical Methods

There has been no statistical method employed in this collection.