

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

Background

Section 4801 of the 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. Section 1894(e)(4) and Section 1934(e)(4) of the Social Security Act, and 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 years (during the trial period), and then at least every 2 years following the trial period. There are currently 119 POs.

Historically, the PACE audit protocols have been included in the Medicare Advantage (MA) and Medicare Part D audit protocols PRA package (CMS 10191, OMB 0938-1000). However, in examining previous submissions, we do not believe that including it with the MA and Part D audit protocols allowed for an accurate representation of the burden. Due to PACE audits being substantially different from MA and Part D audits, we have separated the PACE audit protocols out from the MA and Part D protocols and created a new PRA package. We believe creating this will allow us to tailor the burden estimates more accurately for PACE organizations undergoing a CMS audit.

PACE Organizations (POs) are required to comply with all PACE program requirements. The growth of these PACE organizations led CMS to develop an audit strategy to ensure we continue to obtain meaningful audit results. As a result, CMS’ audit strategy reflected a move to a more targeted, data-driven and outcomes-based audit approach. We focused on high-risk areas that have the greatest potential for participant harm.

CMS has developed an audit protocol and will post it to the CMS website each year for use by POs to prepare for their audit. The data collected for audit is detailed in this protocol and the exact fields are located in the record layouts, at the end of the protocol. In addition, a questionnaire will be distributed as part of our audit. This questionnaire is also included in this package. Any proposed changes to this package will be resubmitted for approval through the appropriate Paperwork Reduction Act process.

A. Justification

1. Need and Legal Basis

Section 1894(e)(4) and 1934(e)(4) of the Social Security Act (Act), and implementing regulations at 42 CFR 460.190 and 460.192 states 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.

2. Information Users

Section 1894(e)(4) and Section 1934(e)(4) of the Social Security Act, and implementing regulations at 42 CFR 460.190 and 460.192 mandate that CMS, in conjunction with the SAA, audit PACE organizations (POs) annually for the first 3 years (during the trial period), and then at least every 2 years 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) and CMS Regional Offices, as well as the SAA, to assess PO's compliance with PACE program requirements. If outliers or other data anomalies are detected, 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 Health Plan Management System (HPMS). HPMS is a system that was developed and is maintained by CMS and that all POs have access too. This system is also secure, requiring users to request and gain access via CMS personnel and then must create and maintain a secure user id and password.

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 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

Section 1894(e)(4) and Section 1934(e)(4) of the Social Security Act, and implementing regulations at 42 CFR 460.190 and 460.192 mandate that CMS, in conjunction with the SAA, audit PACE organizations (POs) annually for the first 3 years (during the trial period), and then at least every 2 years following the trial period.

7. Special Circumstances

There are no special circumstances that would require an information collection to be conducted in a manner that requires 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.

8. Federal Register Notice/Outside Consultation

Federal Register

The 60-day notice published in the Federal Register on August 5, 2016 (81 FR 51916). Comments were received and are attached to this package along with our response. A Crosswalk which sets out the changes from the 60-day package to this 30-day package is also attached.

The 30-day notice published on December 2, 2016 (81 FR 87039). Comments were received and are attached to this package along with our response.

Outside Consultation

We receive year round feedback from POs and outside entities on our protocol at conferences and through external communications (i.e., emails or letters). We will post the protocol on our website 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 described 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 2015 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	50.99	50.99	101.98
Executive Assistants	43-6011	26.66	26.66	53.32

Compliance Officer	13-1041	33.26	33.26	66.52
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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 and divided by the total number of positions to get the average hourly rate. We sought industry feedback on our estimates, and in response to comments received during the 60 day comment period, we revised our burden estimate to reflect the following staff and salaries:

Nurse Manager	\$102
2 Executive Assistants	\$53/assistant
Quality Assurance Specialist	\$67

Total Salary/hour: \$275

$\$275 / 4 \text{ positions} = \68.75

Taking the average of the above rates, we estimate an average hourly rate of **\$68.75**.

Because every PACE organization varies in size, staff availability, and number of staff involved in a CMS audit, we created a burden estimate that we believe accurately reflects the average number of staff, salaries and an hourly time estimate for staff when undergoing a CMS PACE audit. PACE organizations commented on our burden estimate during the 60 day comment period, and we adjusted the totals based on those comments. We did not receive any additional comments during the 30 day comment period, which we believe shows we accurately reflected the average staff, salary, and hourly burden for a PACE organization during audit. We will continue asking for industry feedback in future packages to ensure we are accurately representing the burden for a PACE organization to undergo a CMS audit.

12.2 Burden Estimates

Trial Year and Routine Audits

Trial year and routine audits will use the same audit protocol, so the burden estimate is the same regardless of whether or not the audit is during the trial year or a routine audit. For each PO that receives an audit in 2017, we estimate an average of 80 hours prior to the audit start to assemble and review the information for completeness, 40 hours for the actual administration of the audit, and 40 hours to review and respond to the draft

audit report. We believe an additional 80 hours is spend on corrective action and audit close out activities.

This is a total of approximately 240 hours for each PO. The average number of POs that will receive an audit annually is 72.

In aggregate we estimate 17,280 hours (72 POs x 240 hr/PO) at \$1,188,000.050 (17,280 hr x \$68.75/hr).

12.3 Burden Summary

Information Collection	Respondents	Responses (per Respondent)	Total Responses	Burden per Response (hours)	Total Annual Burden (hours)	Labor Cost of Reporting (\$/hr)	Total Cost (\$)
Audits	72	1	72	240	17,280	68.75	1,188,000

12.4 Information Collection Instruments and Instruction/Guidance Documents

Document Title	Description	Purpose	Respondents	Reporting Frequency	Time Per Response
(2) PACE_AuditProcess_DataRequest	PACE Audit Process and Data Request Protocol	To evaluate compliance with PACE requirements	PACE organizations	We audit approx. 72 PACE organizations annually	These collection tools are administered simultaneously and responses do not exceed 60 days
(4) PACE_Supplemental Questions	PACE Supplemental Questionnaire	To evaluate compliance with PACE requirements	PACE organizations	We audit approx. 72 PACE organizations annually	These collection tools are administered simultaneously and responses do not exceed 60 days
(5) Pre-Audit Issue Summary	Summary of any pre-audit issues	To evaluate PACE organizations	PACE organizations	We audit approx. 72 PACE organizations annually	No more than 1 week

(8) Service Delivery Impact Analysis	Service Delivery Impact Analysis Template	To assess participant impact	PACE organizations	We audit approx. 72 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) Appeals Impact Analysis	Appeals Impact Analysis Template	To assess participant impact	PACE organizations	We audit approx. 72 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) Grievances Impact Analysis	Grievances Impact Analysis Template	To assess participant impact	PACE organizations	We audit approx. 72 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) Root Cause Analysis	Root Cause Analysis Template	To assess impact to PACE organizations	PACE organizations	We audit approx. 72 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) Clinical Appropriateness Impact Analysis_Comp. Care	Clinical Appropriateness for Comprehensive Care Impact Analysis Template	To assess participant impact	PACE organizations	We audit approx. 72 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) Clinical Appropriateness Impact Analysis_Emergency	Clinical Appropriateness for Emergencies Impact Analysis Template	To assess participant impact	PACE organizations	We audit approx. 72 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) Clinical Appropriateness Impact Analysis_IDT Documentation	Clinical Appropriateness for IDT Documentation Impact Analysis Template	To assess participant impact	PACE organizations	We audit approx. 72 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) Clinical Appropriateness Impact Analysis_Med Rec Documentation	Clinical Appropriateness for Medical Record Documentation Impact Analysis Template	To assess participant impact	PACE organizations	We audit approx. 72 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) Clinical Appropriateness Impact Analysis_Restraints	Clinical Appropriateness for Restraints Impact Analysis Template	To assess participant impact	PACE organizations	We audit approx. 72 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) Clinical Appropriateness Impact Analysis_Care Plan	Clinical Appropriateness for Care Planning Impact Analysis Template	To assess participant impact	PACE organizations	We audit approx. 72 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) Clinical Appropriateness Impact Analysis_Assessments	Clinical Appropriateness for Assessments Impact Analysis Template	To assess participant impact	PACE organizations	We audit approx. 72 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) Clinical Appropriateness Impact Analysis_Infections	Clinical Appropriateness for Infections Impact Analysis Template	To assess participant impact	PACE organizations	We audit approx. 72 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) Clinical Appropriateness Impact Analysis_Providers	Clinical Appropriateness for Providers Impact Analysis Template	To assess participant impact	PACE organizations	We audit approx. 72 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) Clinical Appropriateness Impact Analysis_Transportation	Clinical Appropriateness for Transportation Impact Analysis Template	To assess participant impact	PACE organizations	We audit approx. 72 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) Personnel Impact Analysis	Personnel Impact Analysis Template	To assess impact on personnel	PACE organizations	We audit approx. 72 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)

While there is no capital cost associated with this collection, we are accounting for a one-time start up to build systems.

More specifically, we believe there will be a one-time burden of \$43,312.50 for each of the 119 POs to implement systems to capture, track and submit data as requested by CMS. This estimate includes building or creating systems to capture data in each of the seven requested universes.

Specifically, we believe it will take 75 hours for a PO to build the service delivery requests universe, 40 hours to build the appeals universe, 75 hours for the grievance universe, 40 hours for the personnel universe, 100 hours for the quality assessment universe, 250 hours for the participant universe, and 50 hours for the on-call universe.

This is a total of approximately 630 hours per PO to build the universes included in the PACE protocol. With an estimated hourly wage of \$68.75/hr we project a one-time estimate of \$43,312.50 per PO.

In aggregate we estimate 74,970 hours (119 POs x 630 hr/PO) at \$5,154,187.50 (74,970 hr x \$68.75/hr).

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 72 PO audits under current regulations.

Occupation Title	Federal Salary Scale*	Hourly Wage (\$/hr)	Fringe Benefit (\$/hr)	Adjusted Hourly Wage (\$/hr)
2 CMS Auditor(s)	GS-13/Step 1	44.15	44.15	88.30
CMS Audit Manager	GS-15/Step 1	61.37	61.37	122.74

*The hourly wage estimate is based on OPM’s 2016 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/2016/DCB_h.pdf).

Based on the table above, we then added the estimated hourly rate (rounded to the nearest whole dollar) for each position and divided by the total number of positions to get the average hourly rate.

CMS Audit Manager	\$123
2 CMS Auditors	\$88/assistant

Total Salary/hour: \$299
 \$299 / 3 positions = \$99.67

Taking the average of the above rates, we estimate an average hourly rate of \$99.67/hr.

For each audit we estimate 80 hours prior to the audit start to review the information for completeness and prepare for audit, 40 hours for the actual administration of the audit, and 80 hours to review audit documentation, discuss findings, and draft the report. We believe an additional 20 hours is spend on audit close out activities, such as reviewing and monitoring the corrective actions. This is a total of approximately 220 hours for each audit. The average number of audits annually will be 72.

Additionally, the average cost per trip for CMS auditors to go onsite is \$1,395. This is based on our experiences across several geographic regions.

The cost per audit is 220 hours x \$99.67 (average salary for auditors) + \$1,395 air-fare = \$23,322.40. Hence the total cost is \$23,322.40 x 72= **\$1,679,212.80**.

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 team lead duties, acting as the documenter (i.e., documenting all audit findings) for each audit team, providing clinicians for portions of the audit, receiving, and analyzing and ensuring completeness of all audit data collected from POs. Based on invoices received by the government, each audit costs CMS approximately \$23,000 in contracted resources. Contractors assist with approximately 20 PACE audits each year.

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

\$23,000 per audit x 20 audits = **\$460,000**.

Adding up the costs to the government of staff time, travel and contractor costs we can estimate total cost to the government as follows:

Government Staff Cost	\$1,679,212.80
Contractor Costs:	\$460,000
Total Cost:	\$2,139,212.80

15. Program or Burden Changes

The PACE audit protocols have been included in the Medicare Advantage (MA) and Medicare Part D audit protocols PRA package (CMS 10191, OMB 0938-1000). However, we do not believe that including PACE with the MA and Part D audit protocols allowed for an accurate representation of the burden. Due to PACE audits being

substantially different from MA and Part D audits, we have separated the PACE audit protocols out from the MA and Part D protocols and created this new PRA package. We believe that by separating PACE audit protocols from MA and Part D audit protocols, we have created a burden estimate that more accurately reflects what PACE organizations experience when undergoing a CMS audit.

Outside of separating PACE audit protocols into a new PRA package, and creating a separate burden estimate for PACE audits, we also significantly modified the PACE audit process. Specifically, we greatly reduced the administrative burden of PACE audits by eliminating over 80 distinct policies and procedures that were previously collected, and instead focusing our efforts on collecting participant data and universes. Additionally, we reduced the number of audit elements from 20 elements to 5 which reduces the amount of data requested. Since much of the participant data included in this package was already collected in prior audits, we believe that overall PACE organizations will spend less time and money during the pre-audit portion of the audit. Specifically, under the old audit process PACE organizations spent at least 120 hours during the pre-audit portion of the audit and instead will only spend about 80 hours during the pre-audit portion preparing data. . Using the same salary figures as mentioned above (an average salary of \$68.75), that would be a reduction in cost for PACE organizations from \$8,250 during the pre-audit portion to \$5,500 under this new process for the pre-audit portion.

The revised burden estimate referenced in this supporting statement reflects the reduced administrative burden of our new audit protocol and, we believe, accurately reflects the true burden on PACE organizations based on our audit experience and comments received during the 60 day comment period.

16. Publication and Tabulation Dates

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 to 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

The expiration date is displayed.

18. Certification Statement

There are no exceptions.

B. Collection of Information Employing Statistical Methods

There has been no statistical method employed in this collection.