Supporting Statement Part-A
Programs of All-Inclusive Care for the Elderly (PACE)
Quality Data Monitoring and Reporting
(CMS-10525, OMB 0938-1264)

Background

As outlined in §§ 1894 and 1934 of the Social Security Act (the Act) and Title 42 of the Code of Federal Regulations (CFR) § 460, the Programs of All-Inclusive Care for the Elderly (PACE) program is a unique model of managed care service delivery for the frail elderly, most of whom are dually eligible for Medicare and Medicaid benefits. To be eligible to enroll in PACE, an individual must be 55 or older, live in the service area of a PACE organization (PO), need a nursing home-level of care (as certified by the state in which he or she lives), and be able to live safely in the community at the time of enrollment (42 CFR § 460.150).

PACE organizations are responsible for providing all required Medicare and Medicaid covered services, and any other service that the interdisciplinary team (IDT) determines necessary to improve and maintain a participant's overall health condition (42 CFR § 460.92). The IDT is responsible for providing as well as coordinating the care and services for each participant enrolled in the program based on his or her individual needs, with the goal of enabling older individuals to remain in their community.

In addition to these requirements, POs must also comply with the quality monitoring and reporting requirements outlined in §§460.130(d), 460.200(b)(1), 460.200(c) and 460.202. POs are also required to report certain unusual incidents to other Federal and State agencies consistent with applicable statutory or regulatory requirements (see 42 CFR § 460.136(a)(5)). Specific reporting requirements and timeframes can be found on the respective Federal or State agency websites. Note that POs have been collecting and reporting PACE Quality Data to CMS and State Administering Agencies (SAA) since 1999.

Because PACE organizations are both an insurer and health care provider, it is vital that CMS have a mechanism to monitor POs performance and identify areas for quality improvement and need for technical assistance.

POs should regularly monitor their PACE Quality Data for quality improvement purposes using a standardized methodology (e.g., Plan, Do, Study, Act, known as PDSA) to:

- Identify, track and trend opportunities and/or areas in need of improvement.
- Develop and implement a plan(s) of action to improve or maintain quality of care and services.
- Institute Quality Improvement-driven change in policies, procedures, systems, or training as appropriate.
- Evaluate the effectiveness of interventions.
- Monitor for sustained improvement.

- Report and discuss findings with oversight committees including the PO's governing body, and
- Document evidence of a performance improvement activity(s) for review by the PACE organization, CMS, and the SAA.

Currently, all PACE Quality Data is reported in the PACE Quality Monitoring Module in the Health Plan Management System (HPMS). There are two types of data:

PACE Quality Data without Root Cause Analysis

This type of quality data is related to administrative processes, such as appeals, grievances, enrollments, disenrollments, enrollment denials, etc., and does not require a root cause analysis (RCA)[1]. Other areas reported under this category include utilization of services, for example, emergency care, hospital admissions, and preventive care, e.g., immunizations. The frequency for reporting PACE Quality Data without RCA is quarterly.

PACE Quality Data with Root Cause Analysis

This type of quality data is related to unusual incidents that result in serious adverse outcomes, or negative national or regional notoriety related to PACE, and requires an RCA for quality improvement purposes and to mitigate further and/or future incidence. Reportable incidents include, but are not limited to, unexpected deaths, infectious disease outbreaks, falls with injury and/or serious traumatic injuries while enrolled in the PACE program. For more information, please see the PACE Quality Monitoring and Reporting Guidance Document located on the PACE portal website at https://pace.lmi.org.

CMS notes that in the currently approved PRA, the frequency for reporting PACE Quality Data with RCA is within three working days of identifying the incident, followed by the RCA data within 45 days of identifying the incident. CMS has not yet implemented this standard but will keep the industry informed regarding future implementation and updated guidance. In the meantime, PACE organizations are required to report PACE Quality with RCA on a quarterly basis but are not precluded from submitting it prior to the end of the quarter.

In this revised PRA package, we made modifications to the burden and cost estimates for POs based on PACE Quality Data volumes in HPMS. We also made modifications regarding the cost to the Federal Government and adjusted the labor rates to reflect current wages for both POs and government employees.

CMS requests an extension with minor changes type of renewal for the three-year clearance from the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 for POs to collect PACE Quality Data and

[1] A root cause analysis is defined as a multi-disciplinary process of study or analysis that uses a detailed and

structured process to examine factors contributing to a specific outcome (e.g., an adverse event).

submit it to HPMS for purposes related to improving the quality of care and ensuring participant protection from adverse events.

Justification

Need and Legal Basis

CMS is focused on providing high quality health care to PACE participants. It is critical that POs have established benchmarks to compare quality outcomes against other organizations with identical or similar populations. Quality data collection and monitoring will enable POs and CMS to identify opportunities for improving the quality of care and health outcomes for PACE participants.

The legal basis is as follows: Statute

- 1894(b)(2)(A) of the Act mandates that the PACE program agreement shall require the PACE provider to have in effect at a minimum a written plan of quality assurance and improvement, and procedures implementing such a plan, in accordance with regulations.

Regulations at 42 CFR Part 460

- §460.130(d) requires a PO to meet external quality assessment and reporting requirements, as specified by CMS or State administering agency, in accordance with §460.202.
- §460.200(a) requires a PO to collect data, maintain records, and submit reports as required by CMS and the State administering agency.
- §460.200(b) requires a PO to allow CMS and the State administering agency access to data and records including, but not limited to, Participants Health Outcomes Data.
- §460.202 requires that a PACE organization must establish and maintain a health information system that collects, analyzes, integrates, and reports data necessary to measure the organization's performance, including outcomes of care furnished to participants. A PACE organization must furnish data and information pertaining to its provision of participants' care in the manner and at the time intervals specified by CMS and the SAA. The items collected are specified in the PACE program agreement.

2. Information Users

To ensure and promote quality of care and services to PACE participants, CMS and the POs will use the information collected in the PACE Quality Monitoring Module to monitor and analyze data to identify areas in need of quality improvement and technical assistance.

3. Use of Information Technology

The data is collected at the PACE site and then submitted into HPMS via excel file uploads, drop down selection menus and/or limited text fields. All data submissions will occur electronically in the CMS web based HPMS system. CMS requires that all HPMS users be registered and have a secure password.

No signatures are required for these submissions.

4. Duplication of Effort

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

5. Small Businesses

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

6. Less Frequent Collection

Quality improvement and participant safeguards are at risk without the collection of PACE Quality Data. PACE programs are required to submit quality data on a quarterly basis and more frequently in some cases (i.e., adverse events), for the purposes of identifying risk for harm and areas for quality improvement. If this data is not submitted, CMS and POs cannot adequately assess their performance and participants are at increased risk for potentially inadequate care, adverse events and/or harm.

7. Special Circumstances

CMS requires PACE organizations to report adverse events more frequently than on a quarterly basis. As indicated on page 2, the currently approved PRA requires PACE Quality Data with RCA be reported within three working days of identifying the incident, followed by the RCA data within 45 days of identifying the incident. CMS has not yet implemented this standard but will keep the industry informed regarding future implementation and updated guidance. In the meantime, PACE organizations are required to report PACE Quality with RCA on a quarterly basis but are not precluded from submitting it prior to the end of the quarter.

There are no additional special circumstances that would require this information collection to be conducted in a manner that requires respondents to:

- 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 confidentiality of information to the extent permitted by law.

8. Federal Register/Outside Consultation

The 60-day Federal Register Notice published in the Federal Register on 09/08/2023 (88 FR 62088). During the comment period, we received comments from one PO, a state administering agency, and an anonymous source for a total of three comments. CMS' responses to the comments can be found in Appendix A "CMS Response to Public Comments Received for CMS-10525."

In summary, one commenter conveyed concerns around the burden of reporting PACE quality data with RCA within three days. There were no other substantive comments, and therefore no changes have been made to the Supporting Statement or reporting requirements.

The 30-day Federal Register Notice published in the Federal Register 12/01/2023 (88 FR 83947).

9. Payments/Gifts to Respondents

The collection of PACE Quality Data does not include incentive payments or gifts.

10. Confidentiality

POs are aware and informed that their data collection, recording, and data entry under 42 U.S.C. 1306, 20 CFR parts 401 and 422, 5 U.S.C. 552 (Freedom of Information Act), 5 U.S.C. 552a (Privacy Act of 1974), and OMB Circular No. A-130. Data will be kept private to the extent allowed by law.

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 Estimates (Hours & Wages)

Wage Estimates

To derive average costs, we used data from the U.S. Bureau of Labor Statistics' May 2022 National Occupational Employment and Wage Estimates for industry personnel salary estimates (https://www.bls.gov/oes/current/oes_stru.htm). We identified the position of Compliance Officer because this is the PACE personnel that usually compiles the PACE Quality Data and submits it to HPMS. 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.)
Compliance Officer	13-1041	37.01	37.01	74.02

Burden Estimates

Exhibit 1 shows the estimated annual time for collecting and submitting PACE Quality Data.

Exhibit 1

Data Entry	Average number of data entries/PO Annually	Hours per data entry	Annual Burden Hours (per PO)	Annual Burden Hours (Aggregate for 152 POs)
PACE Quality Data Without RCA	1,215	1.0	1,215	184,680

PACE Quality Data With RCA	64	4.0	256	38,912

Total	1,279	5	1,472	223,592

Exhibit 2 shows the annualized cost for compliance officers to enter PACE Quality Data into HPMS.

Exhibit 2

Data Entry	Annual Burden Hours (per PO)	Hourly Wage	Annual Cost Per PO ($)	Total Aggregate Cost ($) 152 POs
PACE Quality Data Without RCA	1,215	$74.02/hr	89,934	13,670,014
PACE Quality Data With RCA Review	256	$74.02/hr	18,949	2,880,266
Total	1,471	74.02/hr	108,883	16,550,280

This information collection request is currently approved by OMB 0938-1264 under the title "PACE Quality Data Monitoring and Reporting" and sets out a cost estimate of $ 90,357 per PO annually, based on the assumption of a total of 1,296 hours by PO personnel at a cost of $69.72/hr. This accounts for 134 POs collecting and submitting PACE Quality Data, for an aggregate estimated cost of $12,107,838.

For this PRA package, we estimate that approximately 152 POs will submit PACE Quality Data per the frequency requirements outlined above. For each PO, we estimate 1,471 hours of work by PO personnel at a cost of $108,883 (1,471 hrs x $74.02/hr) annually. This represents an increase in burden hours of 175 hours (1,471 hrs - 1,296 hrs), and an increase in cost of $18,526 ($108,883 – $90,357) annually per PO.

CMS also notes that we increased the total number of POs from 134 to 152. As a result, the aggregated estimated cost for POs has increased by $4,442,442 (16,550,280 - $12,107,838), for a total estimated cost of $16,550,280 ($108,883 x 152 POs).

Information Collection Instruments/Instruction/Guidance Documents

- PACE Quality Monitoring and Reporting Guidance, Issued March 2021
- HPMS PACE Quality Monitoring Integrated User Guide, Issued May 11, 2021

13. Capital Costs

There is no capital cost for this data collection and entry.

14. Cost to the Federal Government

For the cost estimates provided below, wages correlate to government employees who monitor and analyze HPMS PACE Quality Data on a routine basis.

Exhibit 3 shows the annualized cost burden to the Federal Government to analyze PACE Quality Data. We estimate that quarterly reviews (four times annually) for the PACE Quality Data without RCA will require 8 hours by a nurse consultant (8 x 4=32) multiplied by 152 POs, equals 4,864 hours annually.

In addition, we estimate that weekly reviews (fifty-two times annually) for the PACE Quality Data with RCA will require 2 hours per PO by a nurse consultant (2 x 52=104), multiplied by 152 POs, equals 15,808 hours annually. In aggregate, we estimate 20,672 hours (4,864 + 15,808) at an estimated cost of $ 1,109,466 (20,672 hrs x $53.67) to CMS. This is an increase of 2,448 hours (20,672 -18,224 hrs), and an increase in cost of $213,027 ($1,109,466 - $896,439).

Exhibit 3

PACE Quality Data Review	**Total Burden Hours Annually**	**Hourly Wage** Rate*	**Total Burden Cost ($)**
PACE Quality Data Without RCA	4,864	$53.67	261,051
PACE Quality Data With RCA	15,808	$53.67	848,415
Total	20,672	----------	1,109,466

*The hourly rate is based on Office of Personnel Management's General Schedule for the Washington-Baltimore-Arlington locality (effective January 2023) for a GS-13 step 1 nurse consultant (see SALARY TABLE 2023-DCB (opm.gov)).

15. Program and Burden Changes

This information collection request is currently approved by OMB under the title "PACE Quality Data Monitoring and Reporting." This is a renewal of the currently approved collection package as we are not making any substantive changes.

We do note that CMS made minor revisions in 2021 to the PACE Quality Monitoring & Reporting Guidance Document to reflect a few minor policy clarifications, such as how to report enrollment data, infectious disease outbreaks, etc. We also updated the HPMS Integrated User Guide to streamline the technical guidance for data entry. These changes do not impact the burden estimates and are considered routine in nature.

Burden Estimate

We made modifications to the burden and cost estimates using the average number of data entries per PO annually based on PACE Quality Data volumes in HPMS. All data is collected largely through drop down menus and minimal narrative text. The estimated burden hours associated with entering data for each of the PACE Quality Data categories are as follows:

- PACE Quality Data without RCA: The estimate for data entry is 1 hour as this data is administrative in nature.
- PACE Quality Data with RCA: The estimate for data entry is 4 hours.

In addition, we adjusted the number of POs from 134 POs to 152 POs. We also modified the hourly wage for the applicable PO staff based on data from the U.S. Bureau of Labor Statistics' May 2022 National Occupational Employment and Wage Estimates and adjusted it for fringe/benefits and overhead.

For this iteration of the Supporting Statement, the revised estimate represents an increase in burden by 175 hours (1,471 hrs - 1,296 hrs) as we now estimate 1,471 hours of work by PO personnel at a cost of $108,883 (1,471 hrs x $74.02/hr) annually per PO. This is an increase in cost of $18,526 ($108,883 - $90,357) annually per PO. In aggregate, this represents an increase in burden hours of 49,928 (223,592 (1472 hrs x 152 POs)) – (173,664 hrs. (1,296 x 134 POs)).

We also increased the total number of POs from 134 to 152. As a result, the aggregated estimated cost has increased by $$4,442,442 ($16,550,280 - $12,107,838) for a total estimated cost of $ 16,550,280 ($108,883 x 152 POs).

Lastly, we increased the burden estimate for the cost incurred by the Federal Government to account for 152 POs submitting PACE Quality Data to CMS annually. We increased the estimated burden hours to CMS from 18,224 hrs to 20,672 hrs, which reflects an increase of 2,448 hrs (20,672 - 18,224 hrs). Likewise, we increased the cost estimate to CMS from $896,439 to $1,109,466, which reflects an increase of $213,027 ($1,109,466 - $896,439).

16. Publication/Tabulation Dates

CMS does not plan to publish PACE Quality Data for public viewing. However, aggregate data at the regional level is available in HPMS for POs to establish and evaluate quality initiatives, benchmarking and comparison among POs and other like services and programs.

17. Expiration Date

The expiration date will be displayed in the PACE Quality Monitoring and Reporting Guidance document, which is located on the PACE portal webpage located at https://pace.lmi.org.

18. Certification Statement

There are no exceptions to the certification statement.

B. Collections of Information Employing Statistical Methods

CMS will not be employing statistical methods or surveys for this data collection.

Appendix A

PACE Quality

Data

PACE Quality Data Without Root Cause Analysis

- Appeals
- Emergency Room and/or Urgent Care Visits
- Enrollment Data (including denials of prospective enrollees)
- Falls without Injury
- Grievances
- Immunizations-Influenza
- Immunizations-Pneumococcal
- Medication Administration Errors

PACE Quality Data With Root Cause Analysis

- Abuse
- Adverse Drug Reaction
- Adverse Outcome
- Burns 2nd degree or higher
- Elopement
- Equipment-Related Occurrences
- Falls with Injury

- Fires/Other Disasters

- Foodborne Outbreak
- Infectious Disease Outbreak
- Media Related Event
- Medication Related Occurrence
- Motor Vehicle Accidents
- Pressure Injury
- Restraint Use
- Suicide Attempt/Suicide
- Unexpected Death