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

Note: This information collection request is currently approved by OMB under the title, "PACE Quality Data Entry in CMS Health Plan Management System." This iteration revises the title to "PACE Quality Data Monitoring and Reporting." The OMB control number and the CMS ID number are unchanged. Additional revisions to this package are discussed below under section 15.

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 with assistance from PACE (42 CFR 460.150(b)).

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 the 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 State Administering Agency (SAA).

Currently, all PACE Quality Data is reported in the PACE Quality Monitoring Module in the Health Plan Management System (HPMS) on a quarterly basis, and there are two types:

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 will continue on a quarterly basis.

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.

In this revised PRA package, we made edits to the supporting statement to streamline the language and align the terminology with current CMS polices for reporting and monitoring PACE Quality Data.

CMS clarified the two types of PACE Quality Data and updated Appendix A accordingly.

CMS changed the frequency of reporting PACE Quality Data with Root Cause Analysis in

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).

HPMS to occur **within three working days of identifying the incident**, rather than on a quarterly basis. CMS also changed the frequency of reporting RCA data in HPMS to occur **within 45 days of identifying the incident.**

We revised the PACE Quality Monitoring & Reporting Guidance Document to streamline the language, reflect changes to the reporting frequencies, and update expired web links.

We made modifications to the burden and cost estimates for POs based on PACE Quality Data volumes in HPMS, and, the transition of all PACE Quality Data entry from the Division of Medicare Advantage Operations (DMAO) portal (now known as the PACE portal) to 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.

Lastly, we removed the PACE quality measures, which include Falls, Falls with Injury and Pressure Ulcer Prevalence, and the estimated burden hours and cost included in the current PRA package.

CMS requests a 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 submit it to HPMS for purposes related to improving the quality of care and ensuring participant protection from adverse events. Note that CMS initially proposed a renewal of this package on March 24, 2020 through notice to the Federal Register, and retracted the notice on April 15, 2020. In light of the new posting date for this package to the Federal Register and the June 30, 2020 expiration date for the currently approved PRA package, a renewal is no longer feasible and we are instead requesting a reinstatement.

A. Justification

1. 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

No special circumstances apply to this information collection request.

8. Federal Register/Outside Consultation

The 60-day Federal Register Notice published in the Federal Register on June 17, 2020 (85 FR 36590).

During the comment period, we received comments from two POs and an industry advocate. CMS' responses to the comments can be found in Appendix A, "CMS Response to Public Comments Received for CMS-10525". As a result of industry feedback and the concerns regarding additional burden, we have further increased the estimated burden hours for reporting *PACE Quality Data with RCA* from 2 to 4 hours total for each incident, and, increased the estimated aggregate cost from the currently approved PRA of $11,901,600 to $12,107,838. We also modified all burden estimates based on 134 POs instead of 131 POs.

The 30-day Federal Register Notice published in the Federal Register September 28, 2020 (85 FR 60798)

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 of the confidentiality of 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.

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 2018 National Occupational Employment and Wage Estimates for industry personnel salary estimates (https://www.bls.gov/oes/2018/may/oes131041.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	34.86	34.86	69.72

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 134 POs)**
PACE Quality Data Without RCA	1092	1.0	1092	146,328
PACE Quality Data With RCA	51	4.0	204	27,336
Total	1143	5	1296	173,664

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 ($)	Total Cost (aggregate: for 134 POs) ($)
PACE Quality Data Without RCA	1092	$69.72/hr	76,134	10,201,956
PACE Quality Data With RCA Review	204	$69.72/hr	14,223	1,905,882
Total	1296	----------	90,357	12,107,838

This information collection request is currently approved by OMB 0938-1264 under the title "Program of all-Inclusive Care for the Elderly PACE Quality Data Entry in CMS Health Plan Monitoring System," and sets out a cost estimate of $99,180 per PO annually, based on the assumption of a total of 2,115 hours by PO personnel at a cost of $36.00/hr. This accounts for 120 POs collecting and submitting PACE Quality Data, and the proposed implementation of PACE quality measure(s) data, for an aggregate estimated cost of $11,901,600.

For this PRA package, under the revised title "PACE Quality Data Monitoring and reporting," we estimate that approximately 134 POs will submit PACE Quality Data (PACE Quality Data without RCA and PACE Quality Data with RCA) per the frequency requirements outlined above. Note that the estimated burden hours and cost for the PACE quality measure(s) data has been removed, resulting in an aggregate reduction in burden hours of 27,000 and a cost savings of $972,000.

For each PO, we estimate 1,296 hours of work by PO personnel at a cost of $90,357 (1,296 hrs x $69.72/hr) annually. This represents a decrease in burden hours of 819 hours (2,115 hrs – 1,296 hrs), and a decrease in cost of $8,823 ($99,180 – $90,357) annually per PO.

In aggregate, this represents a decrease in burden hours of 80,136 (253,800 (2,115 hrs x 120 POs)) – (173,664 hrs (1,296 x 134 POs)) due to the elimination of the PACE Quality Measures. Note however that CMS adjusted the labor rates to account for fringe and overhead, and increased the estimated burden hours for the *PACE Quality Data With RCA* from 2 hour to 4 hours total for each incident. We also increased the total number of POs from 131 to 134. As a result, the aggregated estimated cost has increased by $206,238 ($12,107,838 – $11,901,600), for a total estimated cost of $12,107,838 ($90,357 x 134 POs) to POs.

Information Collection Instruments/Instruction/Guidance Documents

- PACE Quality Monitoring and Reporting Guidance, Issued April, 2018 (Revised)
- HPMS PACE Quality Monitoring User Guide

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 multiplied by 4=32) multiplied by 134 POs, equals 4,288 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 multiplied by 52=104), multiplied by 134 POs, equals 13,936 hours annually. In aggregate, we estimate 18,224 hours (4,288 + 13,936) at an estimated cost of $896,439 (18,224 hrs x $49.19) to CMS. This is an increase of 17,789 hours (18,224 hrs – 435 hrs), and an increase in cost of $877,234 ($896,439 – $19,205).

Exhibit 3

PACE Quality Data Review	**Total Burden Hours Annually**	**Hourly Wage** Rate*	**Total Burden Cost ($)**
PACE Quality Data Without RCA	4,288	$49.19/hr	210,927
PACE Quality Data With RCA	13,936	$49.19/hr	685,512
Total	18,224	----------	896,439

*The hourly rate is based on Office of Personnel Management's General Schedule for the Washington-Baltimore-Arlington locality (effective January 2020) for a GS-13 step 1 nurse consultant (see https://www.opm.gov/policy-data-oversight/pay-leave/salaries-wages/salary-tables/pdf/2020/DCB_h.pdf).

15. Program and Burden Changes

This information collection request is currently approved by OMB under the title "Program of all-Inclusive Care for the Elderly PACE Quality Data Entry in CMS Health Plan Monitoring System." This iteration revises the title to read "PACE Quality Data Monitoring and Reporting."

As mentioned previously, we made revisions to the supporting statement to streamline the language, eliminate outdated and/or extraneous text, and align the terminology with current CMS polices for reporting and monitoring PACE Quality Data.

Similarly, the term PACE Quality Data is used to reference all PACE Quality Data categories, and the terms Level I and Level II data have been eliminated. We clarified that there are two types of PACE Quality Data: 1). Does not require an RCA, for example appeals, grievances, enrollment data, etc., and 2). Requires an RCA, such as unexpected deaths, falls with injury, etc.

Note that for this PRA package, CMS changed the frequency of reporting PACE Quality Data with Root Cause Analysis in HPMS to occur **within three working days of identifying the incident**, rather than on a quarterly basis. CMS also changed the frequency of reporting RCA data in HPMS to occur **within 45 days of identifying the incident.** The rationale for these changes is that under the currently approved PRA, CMS has identified that reporting this type of data on a quarterly basis, rather than on a more expeditious basis, has resulted in missed opportunities for technical assistance from CMS, and delays in implementing much needed quality improvement efforts. In order to successfully implement participant specific interventions and meaningful quality improvement initiatives, we believe that reporting this data to CMS in a more expeditious manner will promote better collaboration, and improve the health and safety of PACE participants.

We revised the PACE Quality Monitoring & Reporting Guidance Document to streamline the language, reflect changes to the reporting frequencies, and update expired web links.

In addition to clarifying the two types of PACE Quality Data, we updated **Appendix A** accordingly, and made minor edits to reflect current industry terminology and align with current CMS polices for reporting and monitoring PACE Quality Data:

PACE Quality Data Without RCA Category

- Changed the name of Census/Disenrollment to Enrollment Data, which captures enrollments, disenrollments and deaths to align with current reporting policy and to eliminate ambiguity.
- Deleted Denials (of Prospective Enrollees) as a distinct category from Appendix A
- Changed the name of Emergency Visits to Emergency Room Visits, which reflects the current terminology.
- Added Falls Without Injury and Medication Administration Errors Without an Adverse Effect as both were omitted from the current Appendix A, however, they are present in HPMS and the PACE Quality Data Reporting Guidance.
- Added a second Immunization category to clarify the different types, those being Immunizations-Influenza and Immunizations-Pneumococcal, to align with current reporting policy and industry terminology.
- Deleted Readmissions as this is not part of the current reporting requirements.

PACE Quality Data With RCA Category

- Changed the name of Burns to Burns 2nd degree or higher to align with current reporting policy and to eliminate the burden of reporting 1st degree burns.
- Changed the name of Pressure Ulcer/Injury to Pressure Injury to align with current industry terminology.
- Changed the name of Death to Unexpected Death to align with current reporting policy and to eliminate the burden of reporting deaths that are generally expected in PACE due to a frail population.

Burden Estimate

We made modifications to the burden and cost estimates for POs based on PACE Quality Data volumes in HPMS, and, the transition of all data entry from the DMAO portal (now known as the PACE portal) to HPMS. The process for submitting PACE Quality Data is less burdensome than previous data collection efforts, as all data is now collected by one system and largely through drop down menus VS extensive narrative text. As a result, we modified the estimated burden hours associated with entering data for each of the PACE Quality Data categories:

- PACE Quality Data without RCA: The estimate for data entry was modified from 2 hours to 1 hour as this data is administrative in nature.

- PACE Quality Data with RCA: The estimate for data entry was modified from 1 hour to 2 hours. CMS changed the frequency of reporting PACE Quality Data with Root Cause Analysis in HPMS to occur **within three working days of identifying the incident**, rather than on a quarterly basis. CMS also changed the frequency of reporting RCA data in HPMS to occur **within 45 days of identifying the incident,** rather than on a quarterly basis. Note that for this iteration of the supporting statement, based on public comment, CMS has further increased the burden from 2 to 4 hours total for each incident to account for submitting this data in a more expeditious manner and the effort required to conduct a thorough RCA.

Also note that we changed our estimate using the "number of possible data entries/PO" to using the "average number of data entries per PO annually," as CMS is now able to determine how many data entries occur annually across all POs for each of the PACE Quality Data categories, see Exhibit 1. We believe this is a more accurate method to estimate the burden on POs, and have removed the "estimated number of data categories per data entry" entirely as we determined that it was no longer relevant to the burden estimate.

In addition, we adjusted the number of POs from 120 POs to 134 POs. We also significantly modified the hourly wage for the applicable PO staff based on data from the U.S. Bureau of Labor Statistics' May 2018 National Occupational Employment and Wage Estimates, and adjusted it for fringe/benefits and overhead, as such adjustments were not included in the currently approved PRA.

For this iteration of the supporting statement, the revised estimate continues to represent a decrease in burden hours of 819 hours (2,115 hrs - 1,296 hrs) as we now estimate 1,296 hours of work by PO personnel at a cost of $90,357 (1,296 hrs x $69.72/hr) annually per PO. This is a decrease in cost of $8,823 ($99,180 – $90,357) annually per PO. In aggregate, this represents a decrease in burden hours of 80,136 (253,800 (2,115 hrs x 120 POs)) – (173,664 hrs (1,296 x 134 POs)) due to the elimination of the PACE Quality Measures. Note however that CMS adjusted the labor rates for POs to account for fringe and overhead (which are not included in the currently approved PRA and therefore PO labor rates and cost were underestimated), and, based on industry comments, increased the estimated burden hours for the *PACE Quality Data With RCA* from 2 hour to 4 hours total for each incident. We also increased the total number of POs from 131 to 134. As a result, the aggregated estimated cost has increased by $206,238 ($12,107,838 – $11,901,600), for a total estimated cost of $12,107,838 ($90,357 x 134 POs) to POs.

Also, we increased the burden estimate for the cost incurred by the Federal Government as it was significantly underestimated in the current PRA and did not take into account the total number of POs submitting PACE Quality Data to CMS annually. Therefore, to account for 134 POs submitting PACE Quality Data to CMS annually, we increased the estimated burden hours to CMS from 435 hrs to 18,224 hrs, which reflects an increase of 17,789 hrs (18,224 hrs – 435 hrs). Likewise, we increased the cost estimate to CMS from $19,205 to $896,439, which reflects an increase of $877,234 ($896,439 – $19,205).

Lastly, we removed the PACE quality measures, which include Falls, Falls with Injury and Pressure Ulcer Prevalence, and the estimated burden included in the current PRA package. To align with CMS' 16 strategic initiatives, including "Patients Over Paperwork" and reducing unnecessary burden, we are not implementing these measures at this time, which is a cost savings of $972,000 and a reduction in 27,000 annual burden hours. CMS currently collects data on these measures as part of the PACE Quality Data reporting efforts. If CMS decides to implement these measures in the future, we will incorporate them into a separate PRA package.

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 (revised version), 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 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