I. Supporting Statement Part A
Health Plan Monitoring System Level I and Level II Data Entry
for the Program of all-Inclusive Care for the Elderly
CMS-10525, OCN 0938-New

Background

The Program of All-Inclusive Care for the Elderly (PACE) coordinates the care of 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. 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 is a program that provides comprehensive care. An interdisciplinary team of health professionals provides individuals with coordinated care. The overall quality of care is analyzed by information collected and reported to the Centers for Medicare & Medicaid Services (CMS) related to specific incidents that may cause potential or actual harm. CMS requires that these incidents be reported to CMS in one of two categories: Level I and level II, explained further below. CMS analyzes these reports to identify opportunities to improve the quality of care, safety and PACE sustainability and growth. We are requesting PRA approval for this collection.

Level I reporting requirements refer to those data elements used for monitoring that are regularly reported by POs via the CMS Health Plan Management System (HPMS) PACE monitoring module. (Please see Appendix A for the list of data elements.) POs have been collecting, submitting and reporting data to CMS and State administering agencies (SAA) since 1999.

Level II reporting requirements apply specifically to unusual incidents that result in serious adverse participant outcomes, or negative national or regional notoriety related to PACE. For example, Level II reportable incidents may include certain deaths, infectious disease outbreaks, pressure ulcers acquired while enrolled in the PACE program or traumatic injuries. (Please see Appendix A for the list of data elements.) POs have been collecting, submitting, and reporting Level II incident incidents to CMS and SAAs, via email.

HPMS has the capability to allow POs to enter Level I and Level II data electronically for purposes of identifying problematic trends and quality improvement opportunities. Currently, Level I data are entered into HPMS; however, Level II data are not.

Both Level I and Level II data are used to identify opportunities for quality of care improvement. When analyzing the Level I data, findings may or may not trigger a Quality Improvement (QI) process of analysis (e.g., Plan, Do, Study, Act known as PDSA). With respect to Level II reportable incidents, POs are required to complete an internal root cause investigation for unusual incidents that meet specific thresholds and report the investigation findings to CMS and the SAA within 30 days. Findings may indicate the need for a change in policies, procedures, systems, clinical practice or training.

In this PRA package, we are requesting that POs continue to collect and report Level I and Level II incidents to CMS and SAAs. Additionally, we want to require that POs enter Level I and Level II incidents in HPMS.

Reference Links for Level I and Level II:

1. CMS Manual System PACE 100-11, June 9th, 2011 Chapter 10, "Quality Assessment and Performance Improvement" Section 30.2 and 30.3
http://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/downloads/pace111c10.pdf

2. PACE Level II External Reporting Guidance, Pg. 3-7
https://dmao.lmi.org/dmaomailbox/Documents/PACE%20Level%20II%20Reporting%20Guidance%20March%202014%20Final%20Version.pdf

A. Justification

1. Need and Legal Basis
CMS requests a three-year clearance from the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 for POs to record and CMS to collect quality data (Level I and Level II) in the CMS HPMS for purposes related to monitoring, evaluating, and improving quality of care. Quality data is necessary for ensuring participant protection and creating quality improvement processes and programs.

CMS is focused on quality improvement and providing quality healthcare for Medicare beneficiaries. It is critical that POs have established benchmarks to compare and contrast care and quality outcomes against POs or other organizations with a similar, frail population. Level I and Level II data collection will enable POs and CMS to identify opportunities for measurement and evaluation of quality of care and improve health outcomes for PACE participants.

The legal basis is as follows:

- Statutory Section

  1894(b) (2) (A) of the Social Security Act requires a written plan to be developed by the PO of quality assurance and improvement, procedures for implementing such a plan.

- Regulations at 42 CFR Part 460

  §460.140(a) 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 a PO to meet external quality assessment and reporting requirements, as specified by CMS or State administering agency. 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.

- CMS Manual System PACE 100-11, June 9th, 2011 Chapter 10, "Quality Assessment and Performance Improvement" Section 30.2 and 30.3

- PACE Level II Reporting Guidance HPMS Memo, Issued October 1st, 2010

2. Information Users
The primary purpose of this action is to collect consistent data among all POs with the goal of using the data to analyze and identify overall quality improvement strategies for enhancing quality of care provided to PACE participants.

3. Use of Information Technology
The original data is collected at the PACE site and the data submissions for Level I incidents are uploaded in HPMS. POs are provided login identification codes and this code is considered their signature and is required by HPMS; Level II data entry capability is projected to be available September 2014. In the interim, POs send information via email to CMS and their SAA.

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 should not impact small businesses or other small entities.

6. Less Frequent Collection
Quality assurance and participant safeguards are at risk without the collection of quality data elements. PACE programs are required to submit data elements for Level I monitoring on a quarterly basis and to report Level II incidents within 48 hours of the incident occurring for the purposes of identifying risk for harm and areas for POs quality improvement. If these data is not submitted, CMS and POs cannot adequately assess their performance and participants are at increased risk for harm.

7. Special Circumstances
POs are required to provide a written summary of Level II incidents within 48 hours and root cause analysis within 30 days. The timely assessment and reporting of Level II allows POs to identify areas for improvement quickly, instead of waiting weeks or months following an incident to take corrective action. Level II data collection is not in connection with a statistical survey. This data collection does not require the use of statistical data classification reviewed and

approved by OMB.

8. Federal Register/Outside Consultation
The 60-day Federal Register notice published on May 23, 2014 (79 FR 29776). Comments were received. The comments and our response have been added to this PRA package.

9. Payments/Gifts to Respondents
Level I and II data collection do 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 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
Level I and II data collection does not include questions that are sensitive in nature.

12. Burden Estimates (Hours & Wages)
Exhibit 1 shows the estimated annualized burden hours for Level I and Level II HPMS data entry, which, for CY 2014, is 460 hours total burden hours, or 460 hours per organization and a total aggregate burden hours for 100 POs is 46,000.

Data Entry (DE) for each PO	Number of possible data entries/PO	Estimated Number of data elements per data entry	Hours per data entry	Total Burden Hours	Total Aggregate Burden Hours (for 100 POs)
Level I Monitoring Data Entry	30x	8x	0.25x	=60	6,000
Level II Monitoring Data Entry	40x	10x	1.0x	=400	40,000
Total	--	--	--	460 hours	46,000 hours

DE= Data Entry
Formula (#DE x # DE/element) x (# of hrs/DE) x100 POs

Additional Supportive Information
-Data Entry (DE) Frequency- Data entry could be monthly (Level I) or daily (Level II-within 48 hrs of the incident occurring) depending on the incident meeting either the Level I or Level II criteria.

Exhibit 2 shows the estimated annualized cost burden for Quality Managers to enter Level I and Level II data into HPMS for up to 18 different elements. We estimate this cost to be $16,560.00 for each PO and for 100 POs we estimate this cost to be 1,656,000.00.

Data Entry	Total Burden Hours	Hourly Wage Rate*	Total Burden Cost	Total Aggregate Burden Cost (for 100 POs)
Level I Monitoring Data Entry	60.0x	$36.00x	=$ 2,160.00	216,000
Level II Monitoring Data Entry	400.0x	$36.00x	=$14,400.00	1,440,000
Total	460	$36.00	=$16,560.00	=$1,656,000.00

*Based upon the wage average survey among PACE staff that currently holds the Clinical Quality *positions (total 10 PACE Quality personnel from different regions surveyed as of June, 2013).*

TBH=Total Burden Hours, HWR=Hourly Wage Rate, TBC=Total Burden Cost, TABC=Total Aggregate Burden Cost
Formula (TBH x HWR) = TBC
Formula TBC x 100 POs= TABC

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

14. Cost to Federal Government
In addition to the burden hours and costs described above, there are additional Federal government burden hours and costs associated with this data collection. For the cost estimates provided below, wages relates to one government employee who is/will frequently monitor and analyze HPMS Level I and Level II data.

Exhibit 3 shows the annualized cost burden to the Federal Government to analyze Level I and Level II HPMS data. We estimate that weekly reviews will require 8-10 hours by a nurse consultant.

Data Entry	Total Burden Hours	Hourly Wage Rate*	Total Burden Cost

Level I Monitoring Data Entry	60x	$42.66	$2,559.60
Level II Monitoring Data Entry	400x	$42.66	$17,064.00
Total			$19,623.00

Formula (TBH x HWR) = TBC

*Based upon from Federal Government GS 13 Step #1-Grade Chart http://www.opm.gov/policy-data-oversight/pay-leave/salaries-wages/

15. Changes to Burden

This is a new collection.

16. Publication/Tabulation Dates

Non-applicable (NA) - CMS does not plan to publish this data. However, aggregate data results will be computed for POs in HPMS to establish and evaluate quality initiatives, improvements, benchmarking and comparison among POs and other like services and programs.

17. Expiration Date

The collection described in this request employs data collection instruments that may be used for several years or longer.

18. Certification Statement

There are no exceptions to the certification statement.

B. Collections of Information Employing Statistical Methods

CMS does not intend to collect information employing statistical methods.

Appendix A

Level I Reporting Requirements/ Data Elements

- Grievances
- Appeals
- Enrollments
- Disenrollments
- Prospective Enrollees
- Readmissions
- Emergency (Unscheduled) Care
- Unusual Incidents
- Participants Death
- Reporting Requirements-All Reports

Level II Reporting Requirements/ Data Elements

- Abuse
- Adverse Drug Reactions
- Adverse Outcomes
- Burns
- Elopement
- Equipment-Related Occurrences
- Falls
- Fires/Other Disasters
- Food-borne Outbreaks
- Infectious Disease Outbreaks
- Media-Related Event
- Medication-Related Occurrences
- Motor Vehicle Accidents
- Pressure Ulcer
- Restraint Use
- Suicide and Suicide Attempts