The Centers for Medicare and Medicaid Services’s (CMS) has received public comments regarding CMS’s plan to incorporate the Programs of All-Inclusive Care for the Elderly (PACE) Quality Data Entry in CMS’s Health Plan Monitoring System (HPMS). CMS published the plan in the Federal Register on June 13, 2016.

Two organizations provided comments: The National PACE Association (NPA) and Providence Health & Services. The NPA is a national organization, which provides support, advocates for improvements and development for their PACE organizations (POs) members. Providence Health & Services is a not-for-profit Catholic health care ministry that services 34 hospitals, 600 physician clinical, home health and hospice, senior services, supportive housing and other health and education services. Providence Health & Services also operates a PACE organization, called Providence ElderPlace PACE. Currently, Providence ElderPlace PACE operates 13 PACE centers in Oregon and 3 in Washington serving about 1,200 participants. CMS has reviewed and analyzed the nine comments received of which five were similar/common themed comments from the two organizations.

Below CMS provides detailed responses for “individualized” and “common themed” comments and whether we have revised requirements or burden estimates.

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| PRA Sections | Clarification/Response | Revision/ChangeN – NoChange | Crosswalk | Level ofApplicantBurden I = Increases burdenD – Decreases burdenN – NoChange |
| Supporting Statement Part A-General Comments |  |  |  |  |
| 1. Is the update to Level I and Level II requirements limited to the consolidation of these requirements under the single heading *of PACE Quality Data?*
 | The phrase*, PACE Quality Data*, will be used to refer to the current Level I and Level II requirements. These requirements were revised for minor corrections and clarifications. Historically, CMS referred to quality data as Level I & Level II events. Going forward CMS will replace Level I & Level II events with the general reference “PACE Quality Data”. | N |  | N |
| 1. Does CMS plan to replace existing Level I and Level II, now PACE Quality Data, elements on falls and pressure ulcer with the three quality measures adopted from the National Quality Forum (NQF)?
 | CMS anticipates replacing the existing Level I and Level II elements; falls, falls with injury and pressure ulcers, with NQF measures after the NQF measures have been tested and adopted for use in the PACE program.  | N |  | N |
| 1. Are additional updates to Level I and Level II, now PACE Quality Data, requirements planned?
 | As indicated above, CMS plans to make revisions based on the results of our quality measure testing. CMS continually assesses the appropriateness of measures and will continue to inform the public about any additional revisions or modifications to the PACE Quality Data going forward as appropriate.  | N |   | N |
| PRA Section | **Clarification/Response** | **Revision/Change** | **Crosswalk** | **Level of** **Data Entry** **Burden I = Increases burden****D – Decreases burden****N – No****Change** |
| Supporting Statement Part A-Publication/Tabulation Dates |  |  |  |  |
| 1. CMS indicates its plan to publish PACE quality Data benchmarks and overall quality and potentially publically report PACE Data. Commenter is requesting that CMS share its plans for release of all quality data and provide NPA, POs and other stakeholders’ ample opportunity to comment on these plans well in advance of making data publicly available?
 | CMS plans to work with stakeholders when developing its plan for releasing quality data and will share additional details and seek feedback from interested parties as appropriate. | N | N | N |
| 1. CMS references the potential to compare PO’s performance with of ‘other like services and programs”. One challenge in this regard is to appropriately adjust quality measures for key differences between populations’ served by PACE and other plans/providers. For example, comparisons between PACE participants’ and other managed care organization enrollees’ health outcomes and service utilization must account for differences in these populations’ characteristics (e.g., age, health and functional status, and social determinants of health).
 |  CMS’s analysis will include consideration of the comments and concerns we have received in response to this PRA request.  | N | N | N |
| 1. Commenters asked for clarification concerning “Additional Information Part 3 Quality Reporting”.
 |  “Additional Information Quality Reporting Part 3” discusses the transition from reporting Level II data in the DMAO portal to reporting the data in the HPMS PACE Quality Monitoring Module. CMS will transition the current practice of reporting Level II incidents via the “DMAO portal”, and has provided additional screen shots which display the current DMAO portal data entry form. The HPMS screen shots display the required reporting data elements (i.e. Quality Indicators and RCA).  | Adding 508 compliant screen shot of the DMAO Portal submission form for Level II data.  | During the transition POs will be provided a process that will reduce data collection duplication.  | N |
| PRA Section | **Clarification/Response** | **Revision/Change** | **Crosswalk** | **Level of** **Data Entry** **Burden I = Increases burden****D – Decreases burden****N – No****Change** |
| Data Collection & Reporting Burden |  |  |  |  |
| 1. Commenters requested clarification on how data entries and data elements are defined. How does each correspond to the number of data elements and entries in Exhibit #1 and rows 1-4?
 | Data elements are defined as a list of PACE quality indicators that are required to be reported to CMS. Data entries are defined as individual data items that describe the reported quality data indicator. For each PO, CMS estimates 80 data entries per each quality indicator/element. On average there are 8 of 10 quality indicator/elements that a PO submits regularly to CMS. CMS notes that every PO does not have participants that will meet all of the possible quality indicators. Each row (1-4) of Exhibit #1 corresponds with the associated logic, we calculated the estimated average of the possible reported elements, each data element type and the time it takes to enter an element.   | N | N | N |
| 1. Commenters suggested that CMS underestimated the level of effort needed/burden to comply with the updated PACE quality data requirements, Root Cause analysis work effort and impact of the minimal threshold criteria for Level II reporting and offered revised estimates.
 | CMS reevaluated and adjusted burden estimates based on the public comments regarding the requirements. CMS notes that one of the main focuses of this PRA package is entering what has been known as Level II and quality measures data into HPMS. Estimated burden for entering PACE quality into HPMS includes Root Cause Analysis (RCA).  | Exhibit # 1 and # 2- Revision(s)POs estimated annualizedburden hours: amount changed from 211,000 hours.Estimated annualizedburden cost for Quality Managers to enter PACE Quality and Measures Data: amount changed from $7,614,000.No change regarding RCA. | Exhibit # 1 and # 2- Crosswalk(s)POs estimated annualizedburden hours: changed to 275,000 hours.Estimated annualizedburden cost for Quality Managers to enter PACE Quality and Measures Data: changed to $9,918,000.No change regarding RCA. | INo change regarding RCA. |
| 1. Commenters noted that the estimates in Exhibit #1 and #2 were based one 100 POs; however, there currently are 120 POs.
 | CMS recognizes that the total number of POs may fluctuate during PRA preparation. CMS used 100 POs for purposes of calculating burden using a consistent number of POs. However, CMS has provided updated estimation for 120 POs.  | Review update estimations changed from 100 POs to 120. | 120 estimations include in all calculations | Increasing the number of POs from 100 to 120, resulted in an increase to the burden numbers, to reflect the current number of POs.  |
| 1. Commenters mentioned that the transition of PACE quality data entry and collection into HPMS seems to be a reasonable approach to ensure all interested parties have access to the same information that will reduce duplication of efforts and burden on POs.
 | CMS agrees and appreciates the comments. | N | N | N |
| 1. Commenters requested that CMS explain the inconsistency with the timeframes for reporting quarterly for PACE quality data and measures and its impact on the burden estimates.
 | CMS requested to collect quality data quarterly in the Supporting Statement A- “General Statement” the following, “By adopting NQF defined reliable data collection process for *these elements, certain existing Level I and Level II elements* will then officially meet quality measures collection standards. These measures will be used to improve quality of care for participants in PACE. PACE quality measures will be implemented via the existing HPMS. CMS will educate on data criteria, entry and will report *quarterly*.” CMS recognizes the correction needed in Statement A “Special Circumstances.” To provide clarity, the statement should read “POs *will be* required to report data elements and root cause analysis quarterly.” Previously, the requirement was to report a summary of the incident within 2 working days of the incident occurring and to report the RCA within 45 days. We are streamlining the data reporting process by requesting data be reported quarterly.  | Revision-“POs *are* required to report data elements and root cause analysis quarterly.  | “POs *will be* required to report data elements and root cause analysis quarterly. | N-No burden change  |
| Other Comments  |
| 1. Commenters requested that CMS publish the PACE quality measures specifications to facilitate their evaluation of the burden estimates and an implementation process.
 | PRA package 0938-1264 provides estimates for PACE quality measure data entry in HPMS. The specifications and burden estimates for the 3 quality measures will be provided in a separate PRA package. CMS will provide additional direction to POs as the quality measure implementation process moves forward.  | N | N | N |
| 1. Commenters offered suggestions concerning HPMS data entry spreadsheet, to make them more consistent to reduce the complexity and burden on the caregivers.
 | CMS appreciates the suggestions from the commenter and will consider these suggestions in future revisions.  | N | N | N |