Appendix A
CMS Response to Public Comments Received for CMS-10525

The Centers for Medicare and Medicaid Services (CMS) received comments related to PACE Quality Data Monitoring and Reporting (CMS-10525) from two PACE organizations (POs) and an industry advocate on behalf of their members. This is the reconciliation of the comments.

Frequency for Reporting PACE Quality Data with Root Cause Analysis (adverse events data)

Comment:
CMS received a comment from two POs and an industry advocate expressing their concerns regarding the proposed change to the frequency for reporting *PACE Quality Data with Root Cause Analysis (RCA)* from a quarterly basis to within three working days of identifying the incident. In light of the current requirements that POs initiate an RCA investigation within three working days, and discuss with CMS Account Managers (AMs) on a routine basis, modifying the frequency of reporting will not necessarily enhance POs efforts in identifying risk for harm and areas of quality improvement. Instead, it could potentially lead to unnecessary administrative burden and commenters requested that CMS reconsider the proposed change.

Response:
CMS thanks the commenters for expressing their concerns and the recommendation to reconsider changes to the reporting frequency. As discussed in the supporting statement, CMS has identified that reporting this data quarterly has resulted in missed opportunities for technical assistance and delays in implementing much needed quality improvement efforts that may jeopardize the health and safety of PACE participants. In order to successfully implement participant specific interventions and meaningful quality improvement initiatives, we believe that reporting this data in a more timely manner promotes collaboration, reduces risk and improves the health and safety of PACE participants. To account for this change, CMS has increased the estimated burden for reporting *PACE Quality Data with RCA* from 2 to 4 hours for each incident.

Comment:
CMS received a comment from a PO expressing their concerns around the proposed changes to the frequency for reporting *PACE Quality Data with RCA and RCA Data,* and how it will burden their current process for completing RCAs, which can include multiple meetings of upwards of ten individuals, especially for more serious events. As a result of the proposed changes and shortened timeframes, POs will struggle to effectively coordinate meetings and gather the information needed to appropriately respond and correct missteps.

Response:

CMS appreciates the concerns expressed by the commenter. As discussed above and in the supporting statement, CMS has identified that reporting this data on a quarterly basis has resulted in missed opportunities for technical assistance and delays in implementing much needed quality improvement efforts.

We further clarify that POs are required to report these incidents based on requirements outlined in the HPMS PACE Quality Monitoring User Guide. The data reported under the initial [3 day] entry process is standardized with drop-down menu selections to identify basic information. As such, we believe that the 3-day reporting timeframe is reasonable and will promote collaboration and optimize participant outcomes, especially when immediate action is warranted to prevent further harm. In addition, POs are able to modify their initial entry as needed.

Comment:
CMS received a comment from an industry advocate and a PO requesting that CMS provide further clarification on the specific details related to the *PACE Quality Data with RCA* incidents that POs would be required to report in HPMS and what system modifications, if any, would be made to HPMS to accommodate the proposed notification requirements.

Response:
CMS thanks the commenters for their question and clarifies that we are only proposing modifications to the frequency for reporting *PACE Quality Data with RCA incidents* and *RCA Data*. POs will continue to report these incidents based on the requirements as outlined in the HPMS PACE Quality Monitoring User Guide. In addition, the HPMS PACE Quality Monitoring Module currently allows users to enter PACE Quality data prior to the end of the quarter, therefore, changes to HPMS are not required.

Frequency for Reporting Root Cause Analyses Data

Comment:
CMS received a comment from a PO and an industry advocate suggesting that, in light of the current RCA reporting requirements and the concerns presented by CMS with respect to potential missed opportunities for technical assistance and delays in implementing quality improvement efforts, CMS require the RCA be completed and documented in HPMS within 45 days of identifying the incident.

Response:
CMS thanks the commenters for the suggestion and clarifies that the proposed timeframe for reporting RCA data in HPMS is within 45 days of identifying the incident. Please refer to the Supporting Statement and page 3 of the draft PACE Quality Monitoring and Reporting Guidance. If POs cannot meet the 45-day submission requirement, they have the ability to request an extension in HPMS as outlined in the HPMS PACE Quality Monitoring User Guide.

Comment:
CMS received a comment from a PO expressing their strong opposition to the proposed changes in the reporting timeframes. Requiring POs to submit this information in three and forty-five days, respectively, following an incident will result in a decrease in quality and limit the ability of CMS to effectively recognize opportunities to assist POs. Additionally, it will result in increased costs for all parties involved without any corresponding benefit.

Response:
CMS thanks the commenters for expressing their concerns. As discussed in the supporting statement, CMS has identified that reporting this data quarterly has resulted in missed opportunities for technical assistance and delays in implementing much needed quality improvement efforts that may jeopardize the health and safety of PACE participants. In order to successfully implement participant specific interventions and meaningful quality improvement initiatives, we believe that reporting this data in a more timely manner promotes collaboration, reduces risk and improves the health and safety of PACE participants.

The data reported under the initial [3 day] entry process is standardized with drop-down menu selections to identify basic information. As such, we believe that the 3-day reporting timeframe is reasonable and will promote collaboration and optimize participant outcomes, especially when immediate action is warranted to prevent further harm.

Burden Estimate

Comment:
CMS received a comment from two POs and an industry advocate expressing their view that the total estimated annual burden hours of 1194 hours per PO for submitting PACE Quality data with or without RCA underestimates the effort needed to comply with the PACE Quality Data and Monitoring requirements, due in large part to the lack of consideration of the hours that PACE organizations expend to collect data and conduct root cause analyses. Further, the estimated hours per data entry exceeds the suggested 2 hours, and is at a minimum, at least 4-5 hours to adhere to reporting requirements.

Response:
CMS appreciates concerns expressed by this commenter and we agree that the total estimated annual burden hours per PO should be increased from 2 to 4 hours for each incident. Accordingly, we revised the estimated total cost and the estimated annual burden hours from 1,194 to 1,296 hours per PO accordingly.

Comment:
CMS received a comment from a PO recommending that CMS take into account the exponential increase in burden this creates for PACE organizations with high patient volumes. While the CMS estimate is likely based on the average reports in HPMS, it does not account for the volumes experienced by large PACE organizations, nor has CMS put

the numbers in context of total participants served. Adding in a new HPMS reporting requirement at the initial report will only increase the paperwork burden to POs with no benefit to the beneficiaries served.

Response:
As discussed in the supporting statement, 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 in need of quality improvement and technical assistance. This applies to POs of all sizes. Additionally, CMS has identified that reporting this data quarterly has resulted in missed opportunities for technical assistance and delays in implementing much needed quality improvement efforts that may jeopardize the health and safety of PACE participants. In order to successfully implement participant specific interventions and meaningful quality improvement initiatives, we believe that reporting this data in a more timely manner promotes collaboration, reduces risk and improves the health and safety of PACE participants.

Lastly, the data reported under the initial [3 day] entry process is standardized with drop-down menu selections to identify basic information. As such, we believe that the 3-day reporting timeframe is reasonable and will promote collaboration and optimize participant outcomes, especially when immediate action is warranted to prevent further harm.

Comment:
CMS received a comment from an industry advocate pointing out that CMS utilized 131 POs to calculate the estimated burden, and there are now 134 POs in operation. The commenter requested that CMS revise the estimated burden based on 134 POs.

Response:
CMS has adjusted all burden estimates to reflect 134 POs.

Reporting Confirmed Incidents of Abuse

Comment:
CMS received a comment from a PO and an industry advocate pointing out that while all suspected and alleged incidences of abuse must be reported to appropriate state authorities, only abuse incidents confirmed by state authorities are required to be reported to CMS. They further note that a POs ability to determine if the incident meets the threshold for reporting is often hindered due to state authorities' unwillingness to provide the PACE organization with any specific details regarding the status and/or outcome of an investigation.

Response:
CMS thanks the commenter for expressing their concerns. We understand the challenges POs experience when trying to ascertain data from state authorities related to suspected or confirmed cases of elder abuse and will continue to take this

into consideration when reviewing PACE Quality Data. As POs await information from State authorities, it is our expectation that POs will assess and address any participant needs in the event there is a change in the participant's health status or their ability to live safely in the community.

PACE Quality Data Reporting Categories (Supporting Statement, Appendix A)

Comment:
CMS received a comment from a PO and an industry advocate recognizing CMS' efforts to update the terminology in the supporting statement and the PACE Quality Monitoring and Reporting Guidance, and to further clarify the types of PACE Quality Data. To provide further clarification to the list of distinct PACE Quality Data categories, the commenter points out that the 'denials of prospective enrollees' is not a separate and distinct incident type, rather a component of *'Enrollment Data,'* and therefore should not be reflected as a separate and distinct type of PACE Quality Data in Appendix A of the Supporting Statement.

Response:
CMS thanks the commenter for the recommendation. We agree that denials of prospective enrollees are part of enrollment data and not a distinct category of the PACE Quality Data without RCA, and have made the change to Appendix A.

PACE Quality Data Measures

Comment:
CMS received a comment from a PO and an industry advocate in support of quality measurement for PACE. In response to the removal of the PACE quality measures, e.g., falls, falls with injury and pressure ulcers from the PRA, the commenters request that CMS provide an update on these measures along with the status of the seven draft PACE quality measures posted for public comment by CMS on October 30, 2017 and November 15, 2017, which include: PACE Participants with an Advance Directive or Surrogate Decision Maker; PACE Participants with an Annual Review of Their Advance Directive or Surrogate Decision Maker; PACE Participants not in Nursing Homes; PACE Participants with Depression Receiving Treatment; Participant Influenza Immunization; PACE Staff Influenza Immunization; and Participant Emergency Department (ED) Utilization Without Hospitalization.

Response:
CMS thanks the commenter for their interest in PACE Quality measurement. As discussed in the Supporting Statement, to align with CMS' 16 strategic initiatives, including "Patients Over Paperwork" and reducing unnecessary burden, we are not implementing the falls, falls with injury and pressure ulcer measures. While not considered formal measurement, CMS currently collects data on these areas and expects PO to utilize this data to identify potential gaps in care and areas in need of quality improvement or specific participant intervention. If CMS decides to implement these measures in the future, we will incorporate them into a

separate PRA package.

Regarding the proposed PACE measure streams released by CMS for public comment, further steps in the measure development process are needed to ensure the validity and reliability of these measures. Additionally, we do not plan on imposing additional burden to POs for the reasons mentioned above.

RCA Data Fields

Comment:
CMS received a comment from a PO recommending that CMS be consistent with the data element categories across reporting domains in order to maintain the integrity of the data, and that HPMS include categories and actions appropriate to the service options and population. The commenter recommended that categories in need of consistent data elements or those that lack comprehensive options include location of care, contributing factors for falls, follow-up actions and grievances.

Response:
CMS appreciates the concerns expressed by this commenter and will evaluate the need to make changes accordingly in HPMS.

Miscellaneous—Erroneous Regulatory Citation in the Supporting Statement

Comment:
CMS received a comment from an industry advocate pointing out that an incorrect regulatory citation was referenced in Part A of the Supporting Statement. Specifically, CMS referenced 42 CFR § 460.140 as the basis, in part, for the collection of information. The correct citation is § 460.130(d).

Response:
CMS appreciates this being brought to our attention and have made the change accordingly in the Supporting Statement.