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Docket: CMS-2016-0140
(CMS–10630) The PACE Organization (PO) Monitoring and Audit Process in 42 CFR Part 460

Comment On: CMS-2016-0140-0001
(CMS-10630) The PACE Organization (PO) Monitoring and Audit Process in 42 CFR Part 460

Document: CMS-2016-0140-DRAFT-0002
CA

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General Comment

CMS-10630; OMB control number: 0938-New

CMS-10630 - Supporting statement includes the following:
"Historically, the PACE audit protocols have been included in the Medicare Advantage (MA) and Medicare Part D audit protocols PRA package (CMS 10191). However, in examining previous submissions, we do not believe that including it with the MA and Part D audit protocols allowed for an accurate representation of the burden. Due to PACE audits being substantially different from MA and Part D audits, we have separated the PACE audit protocols out from the MA and Part D protocols and created a new PRA package. We believe creating this will allow us to tailor the burden estimates more accurately for PACE organizations undergoing a CMS audit."

The above statement seems to imply that these protocols would be used in place of the MA and/or Part D audit protocols that are currently in place. However, after reviewing the protocols, it does not seem that either the IA templates or the universe templates that are in the PACE audit protocols would be appropriate to use for Part D.

Attached is a side by side comparison of the 2017 PACE and Part D CDAG universes for Appeals and Grievances. Although many data elements are common to both, there are data elements that are unique to PACE and CDAG. The PACE layouts seem to be specific to services whereas CDAG is specific to drug. The PACE Appeal layout has a data element for Date Service Provided but no drug information. The PACE Grievance "Category of the Grievance" examples are all service related. The CDAG "Category of the Grievance" examples are all pharmacy and drug related.

It does not appear that PACE Appeals and Grievances universes could replace the Part D CDAG Appeals and Grievances universes. For an audit of a PACE plan, it appears that the universes defined would be in

addition to the CDAG universes.

Can CMS please clarify in the final guidance whether the Part D CDAG universe and IA templates should be used for the Part D portion of a CMS program audit for a PACE program, or if only the PACE audit protocols should be used?

Attachments

2017 PACE vs CDAG side-by-side comparison

Overall the proposed rule changes appear reasonable, however, the implementation and maintenance required places a burden on PACE organizations. Specifically, the changes to the proposed audit process increases the tracking of data (falls, grievances, appeals) that is already submitted to CMS in other formats through the Health Plan Management System (HPMS). This data is then reviewed in detail by the Account Manager with the PACE organization on a quarterly basis. The proposed logs are submitting this data yet again for review by CMS during the audit process. With the detailed logs requested by CMS, it appears that a Surveyor could weight their sample with records that do not meet standards as opposed to a random sample that truly reflects the performance of the PACE organization. In many cases the log requires information already documented in the medical record, thus requiring a duplication or even triplication of efforts.

Overall costs for the proposed rule changes by CMS for Centra PACE, currently with three sites:

1. Proposed rule change to adopt oversight requirements based on the implementation of a risk assessment and internal audits: implementation **$8900** and the maintenance of **$12,000.**
2. Proposed changes to the audit process and data request: implementation **$1200**, annual maintenance **$72,775,** and audit preparation of logs **$10,800**.

These cost are not for direct participant care and do not reflect added value to the participants care.

Additionally, CMS interpretation of regulations, including 42 CFR § 460.104(d), appear to be an overstretching of the regulation's intent. The Compliance Standard application with statements like "appropriate" still leaves a great deal to the Surveyor's discretion. PACE organizations are being required to develop categories and timeframes without CMS guidance which a Surveyor may interpret differently.

See below detailed comments.

Proposed Rule Change Comments

1. Proposed rule change to adopt oversight requirements in new section 460.63, including the establishment and implementation of an effective system for monitoring and identification of risks. **Comment:** The expectation of this requirement is vague. Additional guidance on the types of documents and internal audits is needed. The CMS estimated cost of implementation **$8900** and the maintenance of **$12,000** is likely to be underestimated and certainly puts a burden on plans.
2. Audit Process and Data Request: CMS is proposing a change from the current document request of literally hundreds of documents to seven (7) logs representing a variety of services. On the surface this sounds very reasonable, because a number of these logs are already in place in most PACE organizations, and/or are completed at the audit. However, the amount of detail that will be required to implement and maintain these logs will be a burden to PACE organizations. To begin, each log will require approximately one (1) hour to establish based on the CMS fields (**7 hours/$350**). Each log is detailed below.

   Table 1 Service Delivery Request (SDR) Record Layout. Most PACE organizations currently keep a Service Delivery Request Log. In order to prevent duplication PACE organizations will need to adapt their current logs. The proposed log will need to be modified to assign each request a tracking number, and the modification removed prior to submission to CMS. However, an official request form must now be implemented, and additional documentation and quality checks will need to be done to maintain compliance.
   Approximate Time: Implementation: 5 hours/$250. Annual Time to Maintain Log and Associated Documentation per site (approximately 200 requests annually): 133 hours/$6,650.
   Column A: Participant First Name: Reasonable
   Column B: Participant Last Name: Reasonable
   Column C: Participant ID: Reasonable. PACE Organizations can use current MR#

Column D: Person who submitted request: Reasonable. This field can be a drop down box.
Column E: Date request received: **To meet CMS field description this needs to be designed in a customized field in Excel.**
Column F: Time request is received: 42 CFR § 460.104(d) states "The IDT must notify the participant or designated representative of its decision to approve or deny the request from the participant or designated representative as expeditiously as the participant's condition requires, but no later than 72 hours after the date the IDT receives the request for reassessment." **CMS is interpreting this regulation as 72 hours after the request is made NOT when the IDT receives the request.** A possible scenario is a Driver, who is not a member of the IDT receives the request on Friday afternoon at 3pm before a three day weekend, and does not return to the site until 5pm . When he returns to the site, he then completes the necessary form, and gives it his supervisor, who is a member of the IDT. The plan will be out of compliance because the request will not be taken to the IDT until Tuesday morning at 9:00 AM because Monday is a holiday.
Additionally the CMS description for time is in seconds. This type of documentation does not need second specific measurement.
Column G: Category of request. The types of categories appear to be left to the discretion of the PACE organization.
Column H: Description of request. Reasonable
Column I: Date(s) Assessments performed. Not all requests require an in person assessment, for example a social respite or request for a service that PACE does not provide (bill payment).
Will PACE organizations be cited as out of compliance if N/A is entered for these items? Additionally the data entry for this field is cumbersome.
Column J: Discipline performing assessment. See above Column I concern.
Additionally the data entry for this field is cumbersome, especially trying to line it up with Column I
Column K: Assessment made in person. **See concerns column I.**
Column L: Request Disposition. The compliance standard indicates a **disposition of approved, denied, partial denial.** However description only lists approval and denial.
Column M: Extension: Reasonable. However documentation must be in the chart to explain how this was in the interest of the participant.
Column N: Date of Decision. **This information is not required by CFR, and of uncertain value to the PACE organization or CMS. To meet CMS field description this needs to be designed in a customized field in Excel.**
Column O: Time of Decision. **This information is not required by CFR, and of uncertain value to the PACE organization or CMS. Additionally the CMS description for time is in seconds. This type of documentation does not need second specific measurement.**
Column P: Date of Oral Notification. **To meet CMS field description this needs to be designed in a customized field in Excel.**
Column Q: Time of Oral Notification**. See concerns voice on Column F. Additionally the CMS description for time is in seconds. This type of request does not need second specific measurement.**
Column R: Date of written notification: Reasonable, if CMS accepts that the written notification is given or mailed on the same day as it is dated. **To meet CMS field description this needs to be designed in a customized field in Excel.**
Column S: Time of written notification. **This is an unreasonable expectation, if the document is mailed to the participant. It is nearly impossible for a PACE Organization to determine the time a document is sent by mail. This type of record does not need second specific measurement.**
Column T: Date Service provided. **To meet CMS field description this needs to be designed in a customized field in Excel.**

Column U: Quality Analysis: **This a vague requirement. What is the expectation of CMS? Each request or a sample of requests will be reviewed as part of the Quality Improvement program? Or is this part of Table 6? Additionally the Description is for QAPI, but proposed rule change to replace all references in 42 CFR Part 460 to "quality improvement" in the PACE regulation.**

Table 2 Appeal Requests (AR) Record Layout. Most PACE organizations currently keep an Appeals log. In order to prevent duplication PACE organizations will need to adapt their current logs. The proposed log will need to be modified to assign each request a tracking number, and the modification removed prior to submission to CMS**. Submitting this detailed log is in addition to quarterly information submitted to CMS via HPMS, currently described as Level 1 data, and represents double reporting to CMS.**
Current Appeal forms will now need to be updated to address these requirements must now be implemented, and additional documentation and quality checks will need to be done to maintain compliance.
Approximate Time: Implementation: 2.5 hours/$125. Annual Time to Maintain Log and Documentation per site (approximately 5 requests annually): 2.5 hours/$125

Column A: Participant First Name: Reasonable
Column B: Participant Last Name: Reasonable
Column C: Participant ID: Reasonable. PACE Organizations can use current MR#
Column D: Person who submitted appeal: Reasonable. This field can be a drop down box.
Column E: Date appeal received: **To meet CMS field description this needs to be designed in a customized field in Excel.**
Column F: Time appeal received: **CMS description for time is in seconds. This type of appeal does not need second specific measurement.**
Column G: Expedited**:** Reasonable. This field can be a drop down box.
Column H: Extension: Reasonable. This field can be a drop down box.
Column I: Category of request. The types of categories appear to be left to the discretion of the PACE organization.
Column J: Description of request. Reasonable
Column K: Reviewer **This column is unnecessary. Currently CMS expects details of the impartial third party with credentials to be listed on the Appeals Form.**
Column L: Request Disposition. The compliance standard indicates a **disposition of approved, denied, partial denial.** However description only lists approval and denial
Column M: Date of Decision. **To meet CMS field description this needs to be designed in a customized field in Excel.**
Column N: Time of Decision. Reasonable.
Column O: Date of Oral Notification. **To meet CMS field description this needs to be designed in a customized field in Excel.**
Column P: Time of Oral Notification**. Time should not be required unless it is an expedited appeal. This type of appeal does not need second specific measurement.**
Column Q: Date of written notification: Reasonable, if CMS accepts that the written notification is given or mailed on the same day as it is dated. **To meet CMS field description this needs to be designed in a customized field in Excel.**
Column R: Time of written notification. **This is an unreasonable expectation, if the document is mailed to the participant. It is nearly impossible for a PACE Organization to determine the time a document is sent by mail. This type of documentation does not need second specific measurement.**
Column S: Date Service provided. **To meet CMS field description this needs to be designed in a customized field in Excel.**

Column T: Quality Analysis: **This a vague requirement. What is the expectation of CMS? Each request or a sample of requests will be reviewed as part of the Quality Improvement program? Or is this part of Table 6? Additionally the Description is for QAPI, but proposed rule change to replace all references in 42 CFR Part 460 to "quality improvement" in the PACE regulation.**

Table 3 Grievance Requests (GR) Record Layout. Most PACE organizations currently keep Grievance logs. In order to prevent duplication PACE organizations will need to adapt their current logs. The proposed log will need to be modified to assign each request a tracking number and list the name of the individual making the grievance. These modifications will need to be removed prior to submission to CMS**. Submitting this detailed log is in addition to quarterly information submitted to CMS via HPMS, currently described as Level 1 data, and represents double reporting to CMS.**
Current Appeal forms will now need to be updated to address these requirements must now be implemented, and additional documentation and quality checks will need to be done to maintain compliance.
Approximate Time: Implementation: 2.5 hours/$125. Annual Time to Maintain Log and Documentation per site (approximately 22 grievances annually): 33 hours/$1650
Column A: Participant First Name: Reasonable
Column B: Participant Last Name: Reasonable
Column C: Participant ID: Reasonable. PACE Organizations can use current MR#
Column D: Person who submitted Grievance: Reasonable. This field can be a drop down box.
Column E: Date Grievance received: **To meet CMS field description this needs to be designed in a customized field in Excel.**
Column F: Category of request. **The types of categories appear to be left to the discretion of the PACE organization, as opposed to the detailed list in HPMS.**
Column G: Description of grievance. Reasonable
Column H: Grievance Resolution. Reasonable. This field can be a drop down box.
Column I: Date of Decision. **To meet CMS field description this needs to be designed in a customized field in Excel. Additionally individual PACE Organizations will need to develop a timeframe for resolution, update policies, and educate staff.**
Column J: Date of Oral Notification. **To meet CMS field description this needs to be designed in a customized field in Excel.**
Column K: Date of Written Notification. **To meet CMS field description this needs to be designed in a customized field in Excel.** The detailed interpretation of the compliance standard is confusing. **The documentation showing resolution of notification to the Beneficiary (we call them Participants) and/or representative can be accomplished with a "decision letter" rather than a "resolution letter" with a date and time stamp. A time stamp is not necessary. Also they request documentation of an "oral notification" rather than "oral resolution" that is documented in the medical record. In the past PACE organizations have not been required to document grievances in the medical record. One wonders if these requirements were simply "cut and paste" from the Service Delivery Request details.**
Column L: Quality Analysis: **This a vague requirement. What is the expectation of CMS? Each request or a sample of requests will be reviewed as part of the Quality Improvement program? Or is this part of Table 6? Additionally the Description is for QAPI, but proposed rule change to replace all references in 42 CFR Part 460 to "quality improvement" in the PACE regulation.**

Table 4 List of Personnel (LOP) Record Layout

Approximate Time: Implementation: 3 hours/$150. Annual Time to Maintain Log and Association per site (approximately 47 staff members with a 10 new hires annually): 67 hours/ $3350
Column A: Employee First Name: Reasonable
Column B: Employee Last Name: Reasonable
Column C: Job Title: Reasonable
Column D: Job Description: Reasonable
Column E: Date of Hire: Reasonable: **To meet CMS field description this needs to be designed in a customized field in Excel.**
Column F: Date of Termination: Reasonable: **To meet CMS field description this needs to be designed in a customized field in Excel.**
Column G: Type of Employment: Reasonable. **In prior audits, PACE Organizations have been requested to provide Volunteer information. Should Volunteer be added as a valid field?**
Column H: Direct Participant Contact: **State Administrating Agencies (SAA) interpret this as all staff, and that all staff need medical clearance and immunizations. A better field would be Immunizations/Medical Clearance.**
Column I: License. Reasonable
Column J: Back Ground Check. **CMS needs to clarify the criteria needed for the back ground check. State Administrating Agencies (SAA) require a State Police Background check.**
Column K: Excluded Provider List. Reasonable.
Column L: Competency evaluations. **An additional column should be added for Emergency Training, and CMS needs to clarify the word "appropriate".**
Column M: OSHA Training: **Again CMS needs to clarify what OSHA training they are evaluating. OSHA training is a comprehensive phrase that could mean anything from personal protection to fork lift training.**

Table 5 Participant Medical Records (LOPMR)

Approximate Time: Completing the log for the audit 70 hours/$3500 (at one minute per column for 42 columns for a site with 100 participants; this would include the necessary record checks and other tracking systems.) Annual time to maintain systems to support data required for the log: 60 hours/$3000 (Tracking hospitalizations, ED visits, facility admissions, falls, and infections per participant.)

Column A: Participant First Name: Reasonable
Column B: Participant Last Name: Reasonable
Column C: Participant ID: Reasonable. PACE Organizations can use current MR#
Column D: Date of Enrollment: **To meet CMS field description this needs to be designed in a customized field in Excel.**
Column E: Date of Disenrollment: **To meet CMS field description this needs to be designed in a customized field in Excel.**
Column F: Reason for Disenrollment. **The reasons cited appear to be left to the discretion of the PACE organization.**
Column G: Number of Hospital Admissions/Observations. **Prior audits requested a yes/no response. Currently, our organization tracks hospitalizations in aggregate monthly while reviewing each one individually, additional tracking systems will need to be designed to facilitate a "rolling" 12 month period per participant.**
Column H: Most recent date of hospitalization. **To meet CMS field description this needs to be designed in a customized field in Excel. This field was not required in previous audits, and will need to be built into the tracking system described in Column G.**

Column I: Number of Emergency Room Visits. **Prior audits requested a yes/no response. Currently, our organization tracks ED Visits in aggregate monthly while reviewing each one individually, additional tracking systems will need to be designed to facilitate a "rolling" 12 month period per participant.**
Column J: Most recent date of hospitalization. **To meet CMS field description this needs to be designed in a customized field in Excel. This field was not required in previous audits, and will need to be built into the tracking system described in Column I.**
Column K: Number of SNF/NF admissions: **Prior audits requested a yes/no response. CMS needs to clarify the purpose of the admission. Currently our organization tracks admissions for medical reasons differently than an admission as the result of a request for services. The latter would be documented in Table 1.**
Column L: Currently in SNF/NF: Reasonable.
Column M: Received Home Care: Reasonable.
Column N: Currently Receiving Home Care: Reasonable
Column O: Current Center Attendance: **CMS provided responses requiring both the number of days each week and full or partial are cumbersome. CMS needs to clarify their definition of "partial".**
Column P: Transportation Services Provided. Reasonable
Column Q: Number of falls reported as a level 1 event. **Prior audits requested a yes/no response. Currently, our organization tracks falls in aggregate monthly while reviewing each one individually, additional tracking systems will need to be designed to facilitate a "rolling" 12 month period per participant. Again, this is duplicate information that is already required for HPMS.**
Column R: Number of falls reported as a level 2 event. **This is duplicate information that is our organization is required by our CMS Account Manager, which is reviewed in detail at the quarterly call. Additionally all level 2 are already reported to CMS per requirements.**
Column S: Currently recovering from a fall reported as a Level 1 or Level 2 event: **CMS needs to clarify their expectation of "recovering".**
Column T: Number of infections. **Currently, our organization tracks Infections meeting surveillance criteria in aggregate monthly while reviewing each one individually, additional tracking systems will need to be designed to facilitate a "rolling" 12 month period per participant. CMS will need to clarify "infection" i.e. meeting standardized/recognized (SHEA) surveillance criteria or anytime that a participant receives an antibiotic (which prior surveyors have requested during the infection prevention review.)**
Column U: List of infections. **Listing infections is cumbersome, especially with the comma requirement, and it will need to be built into the tracking system described in column T.**
Column V: Number of Pressure Ulcers **Currently, our organization tracks falls in aggregate monthly while reviewing each one individually, additional tracking systems will need to be designed to facilitate a "rolling" 12 month period per participant. Again, this is duplicate information because Stage 3 and 4 are required to be reported as Level 2 (see comments on column R.)**
Column W: Currently receiving treatment for pressure ulcer: Reasonable.
Column X: Incontinent: Reasonable
Column Y: Indwelling Catheter**:** Reasonable.
Column Z: Ambulation: **Needs clarification because some participants are unable to ambulate i.e. wheelchair/bed bound.**
Column AA: Significant weight loss: **CMS needs to clarify significant weight loss i.e. 5% in 30 days; 7.5% in 90 days, or 10% in 180 days. Also CMS needs to clarify if this is unplanned/unanticipated or planned/anticipate (end of life).**
Column AB: Mechanically altered diet Reasonable
Column AC: Parenteral or Enteral Feeding: Reasonable
Column AD: Dementia: Reasonable

Column AE: Psychoactive Medications: Reasonable
Column AF: Restraints Reasonable
Column AG: Assistance Administering Medications Reasonable
Column AH: Pain Management Reasonable
Column AI: Skilled Therapy: **Listing the types of therapy and purposed is cumbersome.**
Column AK: Functional decline: **CMS needs to clarify functional decline. Is this a decline that triggers an unscheduled IDT assessment?**
Column AL: Oxygen Use: **CMS needs to clarify oxygen use; does it include use during hospitalization or skilled care admission but discharged on room air.**
Column AM: Dialysis: Reasonable
Column AN: Impaired Vision: **Vague request. Our organization would prefer blind or wears glasses.**
Column AO: Impaired Hearing: **Vague request. Our organization would prefer wears hearing aide.**
Column AP: Quality Analysis: **This a vague requirement. What is the expectation of CMS? Each request or a sample of requests will be reviewed as part of the Quality Improvement program? Or is this part of Table 6? Additionally the Description is for QAPI, but proposed rule change to replace all references in 42 CFR Part 460 to "quality improvement" in the PACE regulation.**

Table 6 Quality Assessment Initiatives Records (QAIR)

Approximate Time: Implementation: minimal. Annual Time to Maintain Log per site (approximately 416 annually): 16 hours/$800.

Column A: Data Identifier: Reasonable
Column B: Quality Initiative Name: **CMS needs to qualify the definition of "initiative". Would this include teams that meet regularly to address specific outcomes i.e. falls, pressure ulcer, end of life, etc? Would it also include an action item that may occur during a Quality Meeting?**
Column C: Quality Initiative Goal: Reasonable
Column D: QAPI Plan. **Description is for QAPI, but proposed rule change to replace all references in 42 CFR Part 460 to "quality improvement" in the PACE regulation.**
Column E: Incident: Reasonable
Column F: Type of Data Collected: Reasonable
Column G: Start Date of Initiative: **To meet CMS field description this needs to be designed in a customized field in Excel.**
Column H: End Date of Quality Initiative: **To meet CMS field description this needs to be designed in a customized field in Excel.**
Column I: Root Cause Analysis: Reasonable
Column J: Corrective Action Required: Reasonable
Column K: Corrective Action Implemented: **This appears to be a redundant field. Would an organization ever identify action was required and not implemented?**
Column L: Date Corrective action implemented: **Would a separate data identifier be needed for each "corrective action" if multiple actions were taken for the same initiative**
Column M: Potential Participant Harm: Reasonable
Column N: Actual Harm: Reasonable
Column O: Quality Improvements: Reasonable
Column P: Quality Improvements Description: Reasonable
Column Q: Ongoing Review or monitoring: Reasonable
Column R: Frequency of review; reasonable

Table 7 On-Call Universe (OCU). PACE organizations track after hours calls in some format and document them in the Medical Record. **The purpose of this log in unclear. It does not contain a participant ID for tracing the call to the medical record. If the purpose of this log is to demonstrate that the PACE organization is providing 24 hour care/ 7 days a week, the detailed Medical Record review using the sample from Table 5 should be sufficient.**

Approximate Time: Implementation: 4 hours/$200. Annual Time to Maintain Log per site (approximately 416 annually): 173 hours/$8667. This does not include the time required to document the information in the medical record. Additional time and cost is incurred if a staff member does not have direct access to the log, and must record the information separately.

Column A: Participant First Name: Reasonable
Column B: Participant Last Name: Reasonable
Column C: Caller Information: Reasonable. This field can be a drop down box.
Column D: Date of Call: **To meet CMS field description this needs to be designed in a customized field in Excel.**
Column E: Time call received: **CMS description for time is in seconds. This type of information does not need second specific measurement.**
Column F: Description of grievance. Reasonable
Column G: Response to call. **This is duplicate documentation because this information is also in the Medical Record.**
Column H: PO Follow up. **Not only is this information available in the medical record. Because this column is only 100 characters, the purpose of this column is uncertain. It appears to be a repeat of information requested in Column G.**
Column I: Date of PO Follow up: **To meet CMS field description this needs to be designed in a customized field in Excel. Again the purpose of this column is uncertain.**

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VA

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General Comment

See attached file(s)

Attachments

Proposed Audit Changes

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2017 Draft Program Audit Protocols for PACE

Document Name, Section Title & Page Number	Description of Issue or Question	Suggested Revision/Comment
508_PACE_AuditProcess_Data Request, Audit Purpose and General Guidelines, PAGE 3 of 31	4. Pre-Audit Identified Issues of Non-Compliance: Within ***5 business days*** after receipt of the engagement letter, POs must provide a description of each issue as well as the remediation status (what was corrected and when) using the Pre-Audit Issue Summary template (Attachment III). The PO's Account Manager will review the summary for accuracy and completeness.	In order to allow sufficient time for a PO to ensure a QI review of the Attachment, recommend this to be 10 business days.
508_PACE_AuditProcess_Data Request, Audit Purpose and General Guidelines, PAGE 4 of 31	7. Informing PO of Results: POs will also receive a draft audit report which they may formally comment on and then a final report will be issued after consideration of a PO's comments on the draft.	Recommend to specify the actual number of days CMS will be issuing both the draft audit report and the final report so the PO knows what to expect. Additionally, agree with NPA's recommendations for CMS to specify a formal process of disputing the findings be provided to POs as part of the audit protocols that allows for a due process and an objective third-party review of the audit results.
508_PACE_AuditProcess_Data Request, Universe Preparation & Submission, PAGE 5 of 31	2.1. Documentation: Completed PACE questionnaire (PACEQ)	It does not appear this PACE questionnaire (PACE Q) was included as part of the draft documents for comments. In the draft documents issued for review there were two documents titled "508Attachment II-PACE_SupplementalQuestions", but both of those were the same document and *Supplemental Questions* only.
508_PACE_AuditProcess_Data Request, Audit Elements, Select Sample Cases	Under each of the 5 elements, the protocol indicates CMS will select a targeted sample of X-number of cases.	It is unclear how the PO will be notified of which sample cases CMS will be reviewing from the overall universe. The protocol simply states the number of each type that will be selected. Recommend including a description of the timing for notification to the PO, and expectation for turnaround times (for example, 3? 5? 10? days in advance of the CMS onsite visit, or how many days after the document submission will the targeted sample cases be selected).

Document Name, Section Title & Page Number	Description of Issue or Question	Suggested Revision/Comment
Supporting Statement A, Background, PAGE 1 of 11	CMS to develop an audit strategy to ensure we continue to obtain meaningful audit results. CMS' audit strategy reflected a move to a more targeted, data-driven and outcomes-based audit approach. We focused on high-risk areas that have the greatest potential for participant harm.	Based on the draft templates made available as part of the audit protocol, the process and information the PO will be required to provide are much more of an ***administrative*** process rather than an outcomes-based approach. A recommendation to obtain more meaningful audit results that are ***outcomes-based*** and focused on high-risk areas of greatest potential for participant harm would be for the audit elements to focus on specified quality metrics that would indicate the extent to which a PO is providing high-quality participant care and driving quality improvement.
Supporting Statement A, 12. Burden Estimate (Total Hours & Wages), PAGE 4 of 11 and 14. Cost to Federal Government PAGE 10 of 11	This is a total of approximately 180 hours for each PO. (for CMS) -The cost per audit is 220 hours x $99.67	Based on the work effort required of PO to document and compile all the templates, universes, and questionnaires that are a significant and detailed amount of information, the number of hours a PO is afforded should be equivalent to that of CMS.

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CA

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General Comment

Please see attached comment file.

Attachments

2016.9.29_H7501 Comments for 2017 Draft PACE Audit Protocols

CMS PROPOSED AUDIT PROCESS REVISIONS 2016

Proposed Rule: The PACE Organization (PO) Monitoring and Audit Process in Part 460 of 42 CFR CMS-10630, OMB 0938-TBD (New)

COMMENTS AND QUESTIONS:

1) **Audit Purpose and General Guidelines. Pre-Audit Identified Issues of Non-Compliance (pg. 3).** The CMS is proposing to have POs provide a list of all identified issues of non-compliance that occurred during the audit review period, which could include issues that were self-identified by the PO (that may or may not have been previously disclosed to CMS) or issues identified by the CMS during the course of the audit review period.

   Question: Will the CMS request the State Administering Agency (SAA) to include any issues of non-compliance that were identified during a technical advisory visit and/or state audit? Will the SAA have the opportunity to review the POs report of self-identified issues of non-compliance and disclose any additional areas of non-compliance to which the SAA is aware, but the PO may have omitted from its self-disclosure?

2) **Audit Purpose and General Guidelines. Pre-Audit Identified Issues of Non-Compliance (pg. 3).** The CMS proposes that issues reported as corrected prior to the audit review period will be assumed to be corrected. However, if during the audit the issue is found to not have been corrected, they "may" cite the applicable conditions in the audit report. Likewise, the CMS also writes that issues reported as uncorrected "may" be cited as conditions in the CMS audit report.

   Question: Can the CMS clarify why they "may" cite the PO in such situations? If a PO reports an issue has been corrected, but upon audit is found to be out of compliance, it would seem a citation would be indicated. Likewise, if an issue is reported and the PO states it has not taken action to correct it, it would seem a citation would be indicated. It is suggested that the CMS consider changing the word "may" to "will" in both sentences.

3) **Audit Purpose and General Guidelines. Pre-Audit Identified Issues of Non-Compliance (pg. 3).** The CMS states it will consider an issue corrected if the PO can demonstrate correction or remediation was implemented prior to the engagement letter being sent. Further, the CMS states that issues reported as corrected during the audit review period may be validated during the audit.

   Comment: It is recommended that the CMS validate implementation of all self-identified corrective actions during an audit, ensuring POs are held accountable and are following through on reported corrective action implementations. SAA staff is available to assist the CMS in the audit process and could be used to assist in these verifications. Overall, it has been documented that POs sometimes have the same findings audit to audit, indicating that corrective actions are not always followed through or implemented. This indicates the need for continued oversight of corrective action implementation, not less.

4) **Audit Purpose and General Guidelines. Calculation of Score (pgs. 3-4).** The proposed audit protocol discusses the calculation of an overall score based on the number of observations, corrective action required (CAR), or immediate corrective action required (ICAR) findings.

Question: How does the CMS intend to use these scores? Will the scores be published for public comparison between PACE organizations, or might scores from all POs within a state be published for state-to-state PACE comparison? Further, will the scores be used to determine whether a PACE organization will receive additional enforcement actions and/or sanctions?

5) **Responding to Universe and Documentation Requests (pg. 5).** The CMS writes that the PO has three attempts to provide requested audit documentation. If the PO cannot provide accurate and timely submissions after three attempts, the CMS will document this as an "observation" in the PO's program audit report.

   Comment: Although the PO may simply not be able to locate the requested documentation after three attempts, there is also the possibility that the PO did not complete a required activity or document appropriately and, as a result, does not have the requested information. In such cases, it would seem more appropriate to provide a corrective action finding, as opposed to an observation. The proposed protocol permits only an observation. It is recommended that the CMS include that a corrective action finding may be made in such cases, which would underscore the importance of maintaining accurate and accessible documentation.

6) **Audit Elements. SDAG. Select Sample Size (pg. 8).** In selecting sample service request, grievance, and appeal cases to review, CMS proposes selecting 30 cases that appear "significant."

   Question: Can the CMS provide more insight as to what is meant by "significant" in this situation? Specifically, what will set the precedent for "significant?"

7) Audit Elements. SDAG. (pg. 8).

   Question: If the CMS finds systemic issues during an audit of service request, grievance, and appeal cases and the issues had not been disclosed in the self-disclosure process, will the CMS then be prompted to audit additional records beyond the original sample size first selected?

8) Audit Elements. Clinical Appropriateness & Care Planning. Select Sample Cases (pg. 11). The proposed audit protocol states CMS will select 10 targeted medical records that appear clinically significant for audit purposes.

   Question: Can the CMS provide more insight as to what is meant by "clinically significant?" Specifically, what will be the precedent for "clinically significant?"

9) Audit Elements. Clinical Appropriateness & Care Planning. Review Sample Case Documentation (pg. 11). The proposed audit protocol states the CMS will, under bullet point 1, request all documentation related to participant assessments, including documentation that assessments were done in-person, when applicable.

   Question: Can the CMS provide examples of when a non-in-person assessment would be appropriate? According to CFR 460.104 initial assessments, periodic reassessments, and annual

reassessments all must be completed in-person.

10) **Audit Elements. Clinical Appropriateness & Care Planning. Apply Compliance Standard (pg. 12).** Compliance standard 3.5 asks whether the PO developed and documented an appropriate plan of care for participants. Subpart 3.5.4 asks whether an explanation of care plan changes was given to the participant, if appropriate. Subpart 3.5.5 asks whether the participant had a role in care plan decisions, if appropriate.

    Comment: Under CFR 460.106(e), POs are required to have "participant and caregiver involvement in plan of care." Specifically, the regulation states, "The team must develop, review, and reevaluate the plan of care in collaboration with the participant or caregiver, or both, to ensure that there is agreement with the plan of care and that the participant's concerns are addressed." Based on this regulation, it is suggested that the phrase "if appropriate" be removed from both 3.5.4 and 3.5.5. Instead, it is suggested that the questions are reworded to ask whether the participant or caregiver were provided an explanation of care plan changes (3.5.4) and whether the participant or caregiver had a "role in" care plan decisions (3.5.5), as one or the other must be involved. [NOTE: CMS may wish to include clarification that caregiver involvement/notification does not replace participant involvement/notification when the participant does not have any cognitive impairment.] Finally, it is suggested that the CMS further define the statement "had a role in care plan decisions," as "having a role" could mean simply that the participant or caregiver signed the care plan document, which would not constitute true participation as required by CFR.

11) **Audit Elements. Personnel Records. Apply Compliance Standard (pg. 14).**

    Comment: The Code of Federal Regulations sets forth that PACE organizations must follow accepted policies and standard procedures with respect to infection control, including at least the standard precautions developed by the Centers for Disease Control and Prevention (CFR 460.74). However, under subpart 3.5 of the proposed audit protocol, which asks whether the PO provided trainings and/or competencies for personnel, the auditor is directed to ensure the employee had a competency evaluation (3.5.1), OSHA training (3.5.2), ongoing trainings (3.5.3), and emergency training (3.5.4). There is no mention of the auditor ensuring that the employee was trained on infection control and/or standard precautions. It is recommended that a provision be added to ensure that training on infection control, including use of standard precautions, was provided.

12) **Audit Elements. Onsite Review. Apply Compliance Standard (p. 15).** Under the current audit protocol, Transportation Services is an independent element. The proposed audit protocol eliminates this element. Transportation, under the proposed protocol, is assessed under the "Onsite Review" element and includes only two components. Specifically, the auditor is asked (1) whether the PO has a method of communicating between the van and the PACE organization (3.1) and (2) whether the PO has a method of providing safe transportation to participants (3.2). Under compliance standard 3.2, subpart 3.2.1 specifies that the auditor assesses whether the PO has a demonstrated method for securing participants (i.e., seatbelts) and securing DME (e.g., wheelchairs, oxygen, walkers) while in the van.

    Question: Current audit protocol provides that van safety includes ensuring vans have appropriate emergency equipment. Will CMS continue to ensure during audit that such

emergency equipment is on the van (e.g., fire extinguisher, CPR equipment, etc.)? It is suggested the CMS consider adding a requirement that a first aid kit be on each van, as quick access to basic first aid provisions could contribute to ensuring infection control and participant well-being. Current audit protocol also specifies that an audit include ensuring the PO has documentation of preventive maintenance, repairs, and state inspections. Will the CMS continue to require such documentation? It is suggested that such documentation continue to be a part of the audit protocol, as proper maintenance and upkeep of vans used to transport participants is an important aspect of ensuring participant safety and well-being. The majority of PACE participants are transported via PACE vans and any van malfunction while participants are in route could be detrimental to their health and safety (due to extreme temperatures, medical conditions, etc.). Finally, it is suggested that the audit protocol include ensuring that staff tasked with transporting participants have a current CPR and basic first aid certification.

13) **Audit Elements. Onsite Review. Apply Compliance Standard (pgs. 15-16).** In the proposed audit process, infection control audit activities are reduced significantly. Specifically, infection control is reduced to auditors observing 3 to 5 participants and ensuring that staff working with these participants: (1) wash/sanitize hands as appropriate (3.5.1), (2) don/doff personal protective equipment as appropriate (3.5.2), and (3) follow aseptic technique, if applicable (3.5.3). In the current audit process, additional infection control checks are conducted during an audit. Some of these activities include observing personal care areas for cleanliness, ensuring water temperatures are appropriate, observing there is appropriate access to personal protective equipment, and interviews with staff to ensure awareness of the exposure control plan, reportable communicable diseases, standard/contact precautions, etc. Current audit protocol also includes observation of the handling and disposal of waste products (e.g., biohazard material), as well as the handling of laundry and equipment.

    Comment/Question: According to the "State Licensure Requirements for PACE Programs" document assembled by the National PACE Association, there are currently a minimum of 13 states that impose no licensing requirements upon PACE organizations (e.g., Adult Day Care Center licensure, PACE licensure, Home Care licensure). Therefore, in these states, the primary (or sole) audit of the PACE organization is conducted by the CMS, based upon the PACE regulations listed in the Code of Federal Regulations. If the CMS adopts the proposed audit protocol, the oversight of a POs infection control practices will be severely reduced, as was previously highlighted. In states requiring Adult Day Care Center (ADCC) Licensure, the CMS may assume that these additional areas of infection control are being monitored. However, in states such as Virginia, that do not require additional licensure (e.g., ADCC licensure), how will the CMS ensure these areas of infection control continue to be met by PACE centers?

14) **Audit Elements. Onsite Review. Apply Compliance Standard (pgs. 15-16).** The proposed audit protocol omits the physical environment element, whereas the current audit protocol has such an element. Under the current physical environment element, the CMS ensures the PO has a current Life Safety Code and/or fire inspection, maintains a safe and sanitary environment, stores medications and chemicals in a locked/secure fashion, as well as separate from food, has appropriate narcotic medication accrual and disposal procedures, that maintenance has been conducted on medical equipment, appropriate cleaning and temperature logs have been maintained, that oxygen and other items are stored appropriately, and that annual emergency and disaster plan testing has occurred. In addition, it is under the element of physical environment that the CMS currently ensures the center is appropriately staffed and is secure,

with a process for participant arrivals/departures, visitor registration, and procedures to prevent elopement. Other safety issues, such as the availability of a ramp, handrails, and other assistive devices have also traditionally been included in the assessment of physical environment.

Comment/Question: According to the "State Licensure Requirements for PACE Programs" document assembled by the National PACE Association, there are currently a minimum of 13 states that impose no licensing requirements upon PACE organizations (e.g., Adult Day Care Center licensure, PACE licensure, Home Care licensure). Therefore, in these states, the primary (or sole) audit of the PACE organization is conducted by the CMS, based upon the PACE regulations listed in the Code of Federal Regulations. If the CMS adopts the proposed audit protocol, the physical environment section of the CMS audit will be eliminated. In states requiring Adult Day Care Center (ADCC) Licensure, the CMS may assume that physical environment components, previously examined under audit by the CMS, will continue to be monitored under the audit processes of state agencies overseeing ADCC licensure. However, in states such as Virginia, that do not require additional licensure (e.g., ADCC licensure), how will the CMS ensure these components of a PACE organization's physical environment continue to be maintained?

15) **Audit Elements. Onsite Review. Apply Compliance Standard (p. 16).** The proposed audit protocol omits the dietary services element, whereas the current audit protocol has such an element. Under the current dietary services element, the CMS ensures the PO complies with dietary regulations set forth in the Code of Federal Regulations. These regulations require that the PO provides appropriate meal selections, including special diets, and that the PO stores and prepares food in a manner consistent with infection control measures. It is under this element the CMS ensures the PO has a process for maintaining emergency food and nutritional supplement supplies in the event of an emergency. It is also under this element the CMS ensures all food is prepared and stored at appropriate temperatures and in an appropriate manner. In section 3.8 of the "Onsight Review" element of the proposed audit protocol, the auditor follows 3-5 participants to determine whether (1) the PO identified one of the selected participants as requiring a special diet (pureed, etc.) and (2) if identified as requiring a special diet, whether the PO provided the diet ordered in the plan of care. This is the extent of dietary service observation under the proposed audit protocol.

Comment/Question: According to the "State Licensure Requirements for PACE Programs" document assembled by the National PACE Association, there are currently a minimum of 13 states that impose no licensing requirements upon PACE organizations (e.g., Adult Day Care Center licensure, PACE licensure, Home Care licensure). Therefore, in these states, the primary (or sole) audit of the PACE organization is conducted by the CMS, based upon the PACE regulations listed in the Code of Federal Regulations. If the CMS adopts the proposed audit protocol, the oversight of a PO's dietary services will be effectively eliminated, as was previously highlighted. With the elimination of dietary services oversight, how will the CMS ensure that dietary service compliance is maintained by PACE centers? Will the CMS request to see documentation of a current kitchen inspection provided by the state and, if so, how will the CMS handle those POs without an inspection, as some have food prepared at a kitchen offsite and delivered to the PO? In such cases will POs need to provide kitchen inspection certification of the contracted organization that prepares the food? Further, how will the CMS ensure food is maintained at appropriate temperatures during transportation and storage at the PO, thus

meeting all infection control requirements?

16) **Audit Elements. Onsite Review. Apply Compliance Standard (pg. 16).** Under subpart 3.6, auditors are instructed to document whether the PO has emergency equipment available (suction, oxygen, medications, etc.).

    Question: Is the auditor expected to simply provide a "yes" or "no" answer to this question, or will the auditor be instructed to inspect the items for expiration dates, appropriate maintenance, functioning, etc.? If an item is expired, or does not function, would this result in a "no," response, even though the item was present?

17) **General comments:**
    - **a.** CMS is to be applauded for attempting to review the audit process for PACE programs. many of the Practices are dated
    - **b.** CMS does not in any of its revisions appear to incorporate person centered practices. It is acknowledged that PACE is very oriented to the individual. However, nowhere is mentioned in the revisions any guidance on how to assure person centeredness is documented and practiced.
    - **c.** A review of SAA practices varies widely in its role and scope of activities. CMS needs to explore this as a strong resource to support CMS's new guidance by offering added guidance to SAA.
    - d. As the PACE Innovations Act moves forward demonstrating PACEs ability to serve individuals with disabilities these Audit recommendations need to explore how audits would change. Special caution will be needed to not universally apply concepts but to allow natural variations between disabilities and aging.

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VA

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General Comment

See attached file(s)

Attachments

Part 460 of 42 CFR CMS-10630, OMB 0938-TBD (New)

October 4, 2016

Comments

Re: Agency Information Collection Activities: Proposed Collection; Comment Request - CMS-2016-0141 and revised Program of All-inclusive care for the Elderly (PACE) Audit Protocols.

Introduction

The New York State Department of Health ("the Department") submits the following comments regarding the Centers for Medicare and Medicaid Services (CMS) proposal to revise the audit/survey protocol for PACE Organizations (POs) through its Notice of Proposed Rule Making (NPRM) of August 5, 2016 - CMS-2016-0141 Medicare and Medicaid Programs and revisions to the audit protocols as outlined in the August 11, 2016 PACE Audit Updates ("the Updates").

At this time, the Department feels that there is insufficient detail available on the actual audit protocol revisions to offer a comprehensive response to the proposed changes. Therefore, the following comments reflect our position on general principles regarding the NPRM and the Updates and supporting materials currently posted on the CMS Website. We reserve the right to make additional comments as more details become available. The following comments by the Department are divided between the NPRM, which has a comment deadline of October 4th and the audit protocol set for a January 2017 implementation date.

- ***Paperwork Reduction Act (PRA) NPRM***

In general, the Department is supportive of the concept that the PACE data collection and audit protocols should stand alone as opposed to the historical process that included POs under the heading of Medicare Advantage (MA) and Medicare Part D.

The distinct treatment of PACE is justified based on the following:

- PACE is distinct from MA and Part D in that it bears responsibility as both a provider and a plan. The metrics for assessing a PACE program cannot be based solely on its performance as an insurance product. The utilization of services is determined almost exclusively by the Interdisciplinary Team (IDT) decision-making which if functioning properly is independent of the management of the insurance aspects of the model. In addition, the participants have extensive appeal rights that may involve a third party adjudication of care/services to be provided and are outside of any formulary or plan benefit restrictions.

- PACE services a defined population needing a Nursing Home Level of Care (NHLOC), with the main goal of keeping these individuals out of an institutional setting. In general, this cohort is more likely to need a more intensive level of care and services and are more likely to suffer a chronic and steady decline in health status.

- As part of its core mission of keeping individuals out of institutions, the PACE program may provide care/services that are above and beyond its defined benefit package. This flexibility is fundamental to the PACE model, but diverges significantly from a defined insurance package of benefits.

- Unlike a traditional insurance model, the limited population enrolled in a PACE program is statistically less likely to correspond with a bell curve distribution of relatively healthy and unhealthy individuals as found in most managed care models, thus incorporating a different risk profile.

- As noted above, the number of lives covered in a PACE program will likely be smaller than a traditional MA plan, and the number of slots available is limited by factors such as the size of the center and the availability of transportation. It is unlikely that a PACE program can achieve the same economies of scale as a typical MA or Part D plan.

- The PACE program also involves an investment in capital and physical plant that is not found in a typical MA or Part D plan.

Fundamentally, the unique structure of the PACE requires metrics and audit protocols specifically designed for PACE. Given the recent growth in PACE nationally, we are probably at the point where there is a high level of confidence in using PACE specific metrics and analytics, and the Department supports a move in this direction. Therefore, we support CMS in its goal of implementing a PACE-targeted information gathering system.

- ***PACE Audit Updates***

In general, the Department supports revisions to the PACE audit protocol that are data-driven and outcomes-based, with a focus on high-risk areas that have the greatest potential for impacting participants as outlined in the Updates. Likewise, the Department supports initiatives on the part of CMS that include measures to achieve greater operational flexibility, eliminating redundant provisions and outdated information, and codifying already existing practices.

The Department is grateful to CMS for providing an outline of proposed changes to the PACE Audit Protocol to take effect January 2017, including stakeholder informational sessions. We anticipate that these revisions will also support the aims found in the separate comprehensive overhaul of the PACE regulations found in the NPRM CMS-4168-P.

The Department is offering its comments based on the preliminary information currently available. In general, we are supportive of the goals:

- To make PACE audits more outcomes-based;
- To improve access and enhance the participant's experience;
- To schedule audits based on PO performance on critical measures instead of using a regular cycle of audits;
- To reduce the administrative burden on PACE organizations;

- To promote closer coordination between the state and CMS; and
- To drive improvements in the quality of care for participants.

The Department also supports proposed enhancements that include:

- An annual report of Common Conditions that would summarize statistical and audit findings across PACE plans;
- Data driven audits with more pre-audit statistical analysis;
- Reduction in pre-audit document submissions;
- Frequency of audits driven by individual PO track record;
- A greater role for POs to self-report and correct issues;
- Improved internal worksheets and tools for CMS auditors; and
- The development of a Program Audit Consistency Tool (PACT) to compare audit findings across CMS regions to ensure audit consistency on a national basis.

To these goals, we add the following:

The State Administering Agency (SAA) must maintain its authority to enforce measures it deems critical to the health and safety of the participants and maintaining program. In particular state oversight to ensure that participants are protected from any abuse, mistreatment or neglect and that the PO is not engaged in fraud, waste or misappropriation of Medicaid funds is critical. The SAA also maintains a vital interest in enforcing standards regarding the financial viability of the plan under state insurance regulations.

Nationally, we are witnessing the transition of Medicaid-based safety net health insurance programs from fee-for-service to managed care and value based payment (VBP). New York is at the leading edge of this transition and therefore has an interest in ensuring that our PACE plans operate in a manner that aligns with the state's overall goals in developing an integrated Medicaid managed care and VBP environment.

Audit Period: We support a one year audit period with a pre-audit analysis that would include issues disclosed and self-identified by the plans; the scoring and classification of participants' conditions and risk factors; and an analysis of the potential impact of these factors on quality of care and plan performance. The SAA must maintain the authority to review enrollments to ensure that participants are meeting necessary eligibility criteria, including the chronic need for home and community based services and the NHLOC.

New Populations: Under the PACE Innovation Act, New York is seeking to expand the PACE model to additional populations that currently fall under the supervision of other state agencies. As states seek to incorporate additional populations into PACE, it remains critical that the SAAs retain their authority in safeguarding care and services for these individuals.

L1 and L2 Reporting: We support the revised scoring and classification of conditions by the combining of enhanced clinical reporting, with uniform **Level 1 and Level 2 reporting** (currently L1 and L2 have different reporting criteria), Corrective Action Reports (CARs) and Immediate Corrective Action Reports (ICAR).

Collection of P&Ps: We support the streamlined collection of policies and procedures (P&Ps), as long as the SAA retains authority to collect and review P&Ps based on its own priorities. Specifically, a review of contracts/provider networks and enrollment/disenrollment P&Ps are areas of importance to this Department, but are not included in the standard list in this proposal. Likewise for environmental and emergency preparedness.

Sample Size: Regarding the audit sampling, the sample sizes being proposed appear adequate, however, for states that may have larger than average programs, CMS needs to consider a provision or formula for adapting the sample sizes.

Pre-Audit Data: Regarding the pre-audit identification of issues, CMS is limiting data submissions only to those five areas (i.e. Service Delivery, Appeals and Grievances (SDAG), Clinical Appropriateness and Care Planning, Personnel Records, Onsite Review, Quality Assessment) identified as elements of the survey. It must be clear that the SAA retains the right to expand data collection and reporting requirements beyond these five elements. For example, there are many critical aspects of the PO operations not contained in these five areas that can involve issues of abuse, mistreatment and neglect where the SAA has a duty to enforce its standards. It is also unclear as to the correlation between these five areas and the Star Ratings system and to what degree the Star Ratings are part of this process.

Coordinated Findings: This Department welcomes the opportunity to work more closely with CMS, however, it must be clear that where CMS or the SAA is enforcing a higher standard that the higher standard prevails. In other words, the PO cannot use the rationale that "this was OK with CMS so the state has no right to cite us." Likewise, it needs to be made clear that because prior audits did not find a deficiency in a particular area that this does not preclude either agency from enforcing a higher standard as justified by current regulation or code.

- ***Posting to HPMS***

As noted above, the Department supports a closer cooperation and coordination with CMS in the audit process, with the mutual goal of ensuring that our PACE programs are meeting the highest standards of service and care for dual eligibles, Medicaid-only, and private pay participants. We welcome the option to post our findings on HPMS and we believe that some standard format such as Excel™ or Word™ will work best. However, we have several concerns in this regard that are best addressed by ensuring that the SAA posting is optional, and does not determine whether the state can institute its own enforcement.

There also has to be some mechanism to reconcile findings where there may be a difference of opinion between the SAA and CMS. As an example, we need to be sure that there is not a circumstance in which one party posts a "clean" survey, while the other party posts some negative finding(s). One tried and true strategy is to always defer to the more rigorous standard or to rely upon the finding that is most aligned with the interests/rights of the participant(s).

CMS also needs to consider the potential for conflicting information between the HPMS posting and the Star Ratings system. As an example, CMS needs to ensure that there will not be plans that score high in the Star Ratings but have negative findings in their HPMS report.

Finally there needs to be a clear understanding between CMS, the SAA and the POs that posting on HPMS is optional on the part of the SAA and does not impact the SAA's authority in terms of issuing its own findings.

Conclusion

Flexibility is a central theme of the comprehensive overhaul of the PACE regulations found in the NPRM CMS-4168-P. CMS needs to ensure that the revisions to the data gathering and audit protocol support achieving that flexibility. New York is embarked upon a comprehensive re-structuring of our Medicaid system based upon the aims of managed care and VBP. The Department views the expansion of the PACE program in line with the goals of the federal PACE Innovation Act a potentially important piece of this restructuring. In fact, we have a model program in place right now that expands the PACE model to the developmentally/intellectually disabled populations. The Department looks forward to working with CMS in developing new protocols to meet the needs of an expanded and more innovative PACE model.

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NY

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General Comment

See attached file(s)

Attachments

Audit Comments File

Comments for PACE Organization and Monitoring Process 2017 Audit Protocols

from

Michigan Department of Health and Human Services

Audit Purpose and General Guidelines

MDHHS would like clarification on the calculation of score referenced on page 3 of the Audit Process Document. There is confusion with the scoring point system relating to Observation, Corrective Action Required, and Immediate Corrective Action Required.

Onsite Review

MDHHS has a variety of concerns with the onsite review process. Overall, there appears to be a substantial decrease in the review items during the onsite review. The transportation review of the van seems to be lacking several important areas such as fire extinguisher, no smoking signs and review of maintenance records. Also, there doesn't appear to be a detailed environmental review of the PACE center. There is no review of the kitchen/dining area, clinic, or therapy areas noted in the guidelines.

MDHHS noted there is no review of the PACE provider contracts. This is an area of concern due to the importance of appropriate verbiage necessary within the PACE contracts. Some other areas noted missing from the guidelines include the lack of staff or participant interviews, no governing body review, no shower/bath observation, and no IDT team observation.

Audit Process and Data Request

MDHHS has concerns with the amount of data requested for the Medical Records information. Specifically, the PACE provider is being requested to include all participants enrolled in the PACE organization at some point during the audit period. This seems overly burdensome for the PACE provider to complete this for all participants, which in some cases, may be several hundred.

Summary

MDHHS has concerns with the substantial decrease in oversight of the PACE providers in comparison to the current audit system used by CMS. The lack of a comprehensive onsite evaluation and the potential for increasing the length of time between audits seems to provide a recipe for issues arising in the future. If the PACE providers do not have appropriate oversight through the audit process, there may be unintended consequences to the PACE participants.

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MI

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General Comment

See attached file(s)

Attachments

MDHHS comments for CMS Audit process

Cal PACE
Community Leaders for California's Seniors

AltaMed PACE
Los Angeles

Brandman Centers for Senior Care
Los Angeles

CalOptima PACE
Garden Grove

Center for Elders Independence
Oakland

Fresno PACE
Fresno

InnovAge Greater California PACE
San Bernardino

On Lok Lifeways
San Francisco

Redwood Coast PACE
Eureka

San Diego PACE
San Ysidro

St. Paul's PACE
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October 3, 2016

Centers for Medicare and Medicaid Services
Office of Strategic Operations and Regulatory Affairs
Division of Regulations Development
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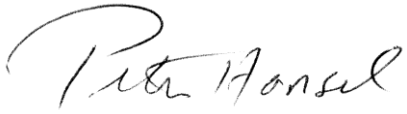
RE: CMS-10630 (OMB control number: 0938-1000): The PACE Organization (PO) Monitoring and Audit Process

CalPACE, the California Association of PACE Organizations, appreciates the opportunity to comment on the Center for Medicare and Medicaid Services' (CMS) information collection request published in the *Federal Regis*ter on August 5, 2016 relating to the *PACE Organization monitoring and audit process*.

CalPACE represents 11 PACE organizations that provide services in California, all of whom are also members of the National PACE Association.

CalPACE and its members support the comments and recommendations of the National PACE Association on the proposed information request.

Sincerely,



Peter Hansel
CEO
phansel@calpace.org

PUBLIC SUBMISSION

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(CMS–10630) The PACE Organization (PO) Monitoring and Audit Process in 42 CFR Part 460

Comment On: CMS-2016-0140-0001
(CMS-10630) The PACE Organization (PO) Monitoring and Audit Process in 42 CFR Part 460

Document: CMS-2016-0140-DRAFT-0012
CA

Submitter Information

Name: Peter Hansel
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Sacramento, CA, 95814
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General Comment

CalPACE, the California Association of PACE Organizations, appreciates the opportunity to comment on the Center for Medicare and Medicaid Services' (CMS) information collection request published in the Federal Register on August 5, 2016 relating to the PACE Organization monitoring and audit process.

CalPACE represents 11 PACE organizations that provide services in California, all of whom are also members of the National PACE Association.

CalPACE and its members support the comments and recommendations of the National PACE Association on the proposed information request.

Peter Hansel
CEO

Attachments

Comments on CMS proposed PACE monitoring and audit process -- 10-3-16

October 4, 2016

Centers for Medicare and Medicaid Services
Office of Strategic Operations and Regulatory Affairs
ATTN: CMS-10630/OMB Control #: 0938-New
Division of Regulations Development
7500 Security Boulevard, Room C4-26-05
Baltimore, MD 21244-1850
Submitted via: http://www.regulations.gov

Re: CMS-10630 (OMB control number: 0938-New): The PACE Organization (PO) Monitoring and Audit Process

The National PACE Association (NPA) appreciates the opportunity to comment on the Centers for Medicare and Medicaid Services' (CMS) information collection request published in the *Federal Register (FR)* on August 5, 2016 relating to the *PACE Organization monitoring and audit process*.

NPA is a national organization representing 118 operating PACE organizations (POs), and entities pursuing PACE development and supportive of PACE. POs serve among the most vulnerable of Medicare and Medicaid populations—frail, older adults who are State certified as requiring nursing home level of care. We share CMS' goal of engaging in oversight that focuses on mitigating high-risk areas that have the greatest potential for participant harm and hope our comments below, developed with considerable input from NPA's members, will contribute positively to this objective.

We appreciate CMS' recognition in formulating the proposed process that PACE audits are substantially different from Medicare Advantage (MA) and Part D audits. While it is reasonable to focus on the operational effectiveness of a MA plan, in considering our comments, NPA recommends that CMS take into account the provider-based nature of the PACE program, as distinct from insurer-based MA health plans. As currently proposed, NPA views the *PACE Organization monitoring and audit process* as an administrative oversight process that assesses whether or not federal requirements are followed rather than the extent to which a PO delivers high-quality participant care. *We recommend that CMS place more emphasis on the results of participant care, through quality measures, observations of participants and staff, and the review of the medical records.*

NPA Comments on PACE Audit Process and Data Request

NPA appreciates the aim of the proposed changes in CMS' monitoring and audit process to focus on the most significant requirements, increase administrative efficiency, and promote consistency. We share these goals and offer the following comments in support of achieving them.

Administrative

- NPA recognizes that CMS reduced the number of elements for which POs' compliance is evaluated from 29 to 5 – focusing on the most prevalent areas of noncompliance. We also support that POs are no longer required to submit policy and procedure documentation as part of the proposed audit review process.
- However, we are concerned that the proposed audit process will require POs to submit a significant volume of detailed quality and compliance information. We question the necessity of much of this information in driving quality improvement for PACE participants.
- Specifically, with regard to the Service Delivery Requests, Appeals and Grievances (SDAG) universe, we question the value of the inclusion of a number of items listed under *Field Name* as these data elements are highly specific and are not outcomes-oriented. The categories include:
    - Time Service Delivery Request Received
    - Time of Decision
    - Time of Oral Notification
    - Time of Written Notification
    - Time Appeal Received
    - Please note that we have offered specific comments regarding Appendix A – PACE Record Layouts in Exhibit 1.
- In *Pre-Audit Identified Issues of Non-Compliance*, it is our view that the *Pre-Audit Issue Summary template (Attachment III)* includes details that are not needed for CMS to achieve its objectives. For example, the *Pre-Audit Issue Summary template* requires POs to include the name of the individual (first and last) to whom a pre-audit issue was reported. It is unclear to whom CMS is suggesting the issue was reported (i.e., CMS or PO staff) and what value this information provides to the audit process. Collection and reporting of this information increases the data collection burden on POs and exceeds the apparent value of the information provided.
- In addition, the remedial actions required to be reported include operational actions, as well as actions taken to address any participants who were negatively impacted. We understand the importance of reporting on operational actions to

remediate an issue identified pre-audit; however, submitting all actions taken to address individual participants is onerous and incongruent with CMS' intent. This is particularly concerning given the time estimated for a PO to assemble and review the information to be submitted prior to the audit.

Consistency

- While CMS does provide minimum "compliance standards", NPA remains concerned that the lack of interpretive guidance may result in a degree of subjectivity that continues to cause regional inconsistency in the audit process findings.
- As proposed, POs will be required to provide universe and documentation submissions within 30 calendar days of the engagement letter date. Rather than submit a universe of data during the pre-audit process, we recommend that POs submit a pre-determined sample of *Personnel Records* and medical records (*Clinical Appropriateness & Care Planning*) in advance of the audit and that auditors utilize the proposed methodology in the *Audit Process and Data Request* document for *SDAG*, *Onsite Review*, and *Quality Assessment*, and develop a sampling methodology for *On-Call Universe* during the onsite review. *We request details regarding how sample cases will be selected.*

Transition and Implementation

- Given the complexity and scope of the audit requirements, the fact that some POs have audits scheduled for early 2017, and that some of the audit procedures may be modified by the pending PACE regulation, the January 1, 2017 effective date should be delayed to January 1, 2018. Such a delay allows CMS to align its PACE audit requirements and POs to update and/or modify internal data systems and personnel requirements to comply with the new audit requirements. At a minimum, we request that POs not be penalized if unable to submit the full universe in the first 18 months the new audit requirements are implemented. This consideration will take into account that a limited number of required data elements may not be available and others may be accessible only through manual chart review for audit review periods in 2016, and would provide POs time to modify data collection and reporting systems in 2017.
- It appears that the CMS' intent is to incentivize a PO to effectively monitor its care delivery and other processes to make improvements, as needed. In *Pre-Audit Identified Issues of Non-Compliance*, CMS states "Issues that are reported as uncorrected may be cited as conditions in the CMS audit report. Issues reported as corrected <u>after the date of the audit start notice</u> will be treated as uncorrected issues". If a PO is actively working on an issue that it has self-identified and ongoing efforts are evident, the PO should not be automatically cited by CMS

due to its inability to fully resolve the issue prior to the audit review period. This policy creates a disincentive for a PO to report self-identified issues and actively work to identify issues.

- Throughout the *Pre-Audit Identified Issues of Non-Compliance* section, CMS uses temporal references to describe how the resolution status of an issue will be addressed. For example, CMS states "Issues that are reported as corrected prior to the audit review will be assumed to be corrected". Our understanding is that the audit review period is defined as "one year preceding the date of the audit engagement letter". Based on this assumption, a PO would not report such an issue on the *Pre-Audit Issue Summary template* as it would not be within the scope of the audit. We seek clarity regarding the terms *audit start notice* and *audit review period*.
- Referring to *Informing PO of Results,* there is no stated expectation regarding the maximum period of time in which a PO should receive the draft or final audit report. *Given the inclusion of civil money penalties and other enforcement actions in the proposed PACE regulation, CMS auditors should be required to provide the draft/final audit report within a limited and specified timeframe (e.g., within 30 days of the exit conference). Additionally, we recommend that a formal process of disputing the findings be provided to POs that allows for due process and an objective third party review of the audit results*.

NPA Comments on' Burden Estimates in Support Statement A

In general, NPA believes CMS' estimate of 180 hours is an underestimation of the effort needed for a PO to comply with the updated requirements and complete the audit process.

- With regard to the *pre-audit* phase, 40 hours significantly underestimates the time that will be required of PO staff time to retrieve and report data to the degree of detail CMS is requesting. Relative to the current audit process, less information in the form of policies and procedures is required of POs, but the volume and detail of data included in the *Pre-Audit Issue Summary* and the audit *Universes* are extensive. For example, the proposed *Universes* will require PO staff to collect minute details; time/date; and attribution of information exchange between personnel. This ongoing time commitment will be significantly greater than what is currently required of POs. *It is recommended that this time estimate be increased to a minimum of 80 hours to align with the time estimated that CMS audit staff will require to complete the necessary work prior to the audit.*
- CMS estimates 40 hours will be required of PO staff for actual administration of the audit. In 2014 and 2015, on average, administration of the audit required 28

hours. *Please provide rationale for the projected increase in time that PACE organizations staff would need to be available to CMS auditors while they are on-site. Also, provide clarify whether the entire audit will be done on-site.*

- CMS estimates that 20 hours will be required for PO staff to review and respond to the draft audit report. Based on POs' current experience and the additional requirement for PO staff to complete impact analyses for any deficiencies identified during the audit, which may involve medical record reviews and other time consuming activities, we believe 20 hours underestimates the amount of time that will be required to sufficiently review the draft audit report and provide feedback. *It is recommended that this time estimate be increased to a minimum of 40 hours.*
- While 80 hours seems to be a reasonable estimate of the time required to develop and submit a corrective action plan (CAP) addressing the deficiencies identified by the audit; it does not include the time required of PO staff for implementation of corrective actions and ongoing monitoring of the CAP. These activities include staff education, policy development and/or modification, and monitoring to ensure the issues have been resolved effectively. *We request that the time estimate by modified to account for these ongoing activities.*

At a minimum, a PO should be afforded the same amount of time as CMS estimates its auditors will expend on each audit – approximately 220 hours. It is not reasonable to expect that the investment of time by POs throughout the audit process will be less than the time invested by the CMS auditors.

Referring to the burden estimates associated with costs to POs, it appears that the *Total Cost* of $790,560 or $10,980 per PO does not account for the development/upfront costs associated with modifying and/or creating the information technology (IT) infrastructure required to report and validate the data CMS plans to collect under the new audit process. The underlying assumption that all POs maintain a seamless, integrated electronic health record (EHR) system is flawed. Currently, some of the most sophisticated PO EHR systems only collect 50 to 65 percent of the data proposed, requiring the creation of electronic systems to capture the remaining information. As an example, one PO estimates this additional investment alone will cost $42,500 [500 hours @ 85/hr.].

Both the FR notice and *Supporting Statement Part A* state that CMS will engage in 72 audits per year and *Supporting Statement Part A* infers that the 2017 Audit Protocol becomes effective on January 1, 2017. We would appreciate an explanation of how CMS arrived at its estimate of 72 audits in 2017 and confirmation that this figure is based on current requirements of §460.190 and §460.192. Further, we would like to confirm our

understanding that the number of audits will reduce by approximately 50 percent if CMS implements the changes to PACE monitoring requirements described in the proposed rule published in FR on August 17, 2016.

Thank you for taking the time to consider our feedback, concerns, and recommendations. Please direct any questions to Del M. Conyers, vice president of PACE QI & Compliance at delc@npaonline.org.

Sincerely,

Shawn M. Bloom
President & CEO

Enclosure: Exhibit 1

Exhibit 1 – Comments on Appendix A – PACE Record Layouts

Table 1: Service Delivery Request (SDR) Record Layout

To comply with this data requirement, PACE organizations (POs) will have to adapt and/or create a Service Delivery Request Log.

- **Column F:** Time request is received: 42 CFR § 460.104(d) states "The IDT must notify the participant or designated representative of its decision to approve or deny the request from the participant or designated representative as expeditiously as the participant's condition requires, but no later than 72 hours after the date the IDT receives the request for reassessment." ***In some CMS regions, auditors are interpreting this regulation as 72 hours after the request is made NOT when the IDT receives the request***. A possible scenario is a Driver, who is not a member of the IDT receives the request on Friday afternoon at 3 p.m. before a three-day weekend, and does not return to the site until 5p.m. When he returns to the site, he then completes the necessary form, and gives it his supervisor, who is a member of the IDT. The plan will be out of compliance because the request will not be taken to the IDT until Tuesday morning at 9 a.m. because Monday is a holiday. ***Additionally, the CMS description for time is in seconds. This type of documentation does not need second-specific measurement.***
- **Column I:** Date(s) Assessments performed. Not all requests require an in-person assessment, for example, a social respite or request for a service that PACE does not provide (i.e., bill payment). ***Will PACE organizations be cited as out of compliance if N/A is entered for these items? Additionally, the data entry for this field is cumbersome.***
- **Column J:** Discipline performing assessment. ***See above Column I concern. Additionally, the data entry for this field is cumbersome.***
- **Column K:** Assessment made in person. ***See concerns in Column I.***
- **Column L:** Request Disposition. ***The compliance standard indicates a disposition of approved, denied, partial denial. However, description only lists approval and denial.***
- **Column N:** Date of Decision. ***This information is not required by CFR, and of uncertain value to the PACE organization or CMS.***
- **Column O:** Time of Decision. ***This information is not required by CFR, and of uncertain value to the PACE organization or CMS. Additionally, the CMS description for time is in seconds. This type of documentation does not need second-specific measurement.***
- **Column Q:** Time of Oral Notification***. See concerns voice on Column F. Additionally the CMS description for time is in seconds. This type of request does not need second-specific measurement.***
- **Column S:** Time of written notification. ***This is an unreasonable expectation, if the document is mailed to the participant. It is nearly impossible for a PACE Organization to determine the time a document is sent by mail. This type of record does not need second-specific measurement.***
- Column U: Quality Analysis: ***This a vague requirement. What is the expectation of CMS? Will each request or a sample of requests be reviewed as part of the Quality Improvement program? Or is this part of Table 6?***

Table 2: Appeal Requests (AR) Record Layout

Most POs maintain an Appeals log. Submitting this detailed log is in addition to quarterly information submitted to CMS via HPMS, currently described as Level 1 data, and represents duplicate reporting to CMS. To comply with this data requirement, PACE organizations will be required to modify current appeals log to address these requirements and additional documentation and quality checks will need to be done to maintain compliance.

- **Column F:** Time appeal received: ***CMS description for time is in seconds. This type of appeal does not need second-specific measurement.***
- **Column K:** Reviewer ***This column is unnecessary. Currently, CMS expects details of the impartial third party with credentials to be listed on the Appeals Form.***
- **Column L**: Request Disposition. ***The compliance standard indicates a disposition of approved, denied, partial denial. However, description only lists approval and denial.***
- **Column P:** Time of Oral Notification***. Time should not be required unless it is an expedited appeal. This type of appeal does not need second-specific measurement.***
- **Column R:** Time of written notification. ***This is an unreasonable expectation, if the document is mailed to the participant. It is nearly impossible for a PACE Organization to determine the time a document is sent by mail. This type of documentation does not need second specific measurement.***
- Column T: Quality Analysis: ***This a vague requirement. What is the expectation of CMS? Will each request or a sample of requests be reviewed as part of the Quality Improvement program? Or is this part of Table 6?***

Table 3: Grievance Requests (GR) Record Layout

Most PACE organizations currently keep Grievance logs. Submitting this detailed log is in addition to quarterly information submitted to CMS via HPMS, currently described as Level 1 data, and represents duplicate reporting to CMS. To comply with this data requirement, PACE organizations (POs) will be required to modify current appeals log to address these requirements and additional documentation and quality checks will need to be done to maintain compliance.

- **Column I:** Date of Decision. ***To meet CMS field description this needs to be designed in a customized field in Excel. Additionally, individual PACE organizations will need to develop a timeframe for resolution, update policies, and educate staff.***
- **Column K:** Date of Written Notification. ***To meet CMS field description this needs to be designed in a customized field in Excel. The detailed interpretation of the compliance standard is confusing. The documentation showing resolution of notification to the Beneficiary ("Participant") and/or representative can be accomplished with a "decision letter" rather than a "resolution letter" with a date and time stamp. A time stamp is not necessary. Also, CMS requests documentation of an "oral notification" rather than "oral resolution" that is documented in the medical record. In the past PACE organizations have not been required to document grievances in the medical record.***
- **Column L:** Quality Analysis: ***This a vague requirement. What is the expectation of CMS? Will each request or a sample of requests be reviewed as part of the Quality Improvement program? Or is this part of Table 6?***

Table 4: List of Personnel (LOP) Record Layout

- **Column J**: Background Check. ***Please specify the criteria needed to satisfy the background check.***
- **Column M:** OSHA Training: ***Please specify the criteria needed to satisfy completion of OSHA training.***
- **Column L:** Competency Evaluations: ***Please clarify when these evaluations should occur (e.g., upon hire, annual, or both).***

Table 5: List of Participant Medical Records (LOPMR) Record Layout

- **Column G:** Number of Hospital Admissions/Observations. ***Prior audits requested a yes/no response. Currently, some POs track hospitalizations in aggregate monthly. To comply with this standard, additional tracking systems will need to be designed to facilitate a "rolling" 12-month period per participant.***

- **Column H:** Most recent date of hospitalization. ***To meet CMS field description this needs to be designed in a customized field in Excel. This field was not required in previous version of CMS Audit Guidance, and will need to be built into the tracking system described in Column G.***
- **Column I:** Number of Emergency Room Visits. ***Prior audits requested a yes/no response. Currently, some POs track ER visits in aggregate monthly. To comply with this standard, additional tracking systems will need to be designed to facilitate a "rolling" 12-month period per participant.***
- **Column J:** Most recent date of hospitalization. ***To meet CMS field description this needs to be designed in a customized field in Excel. This field was not required in previous audits, and will need to be built into the tracking system described in Column I.***
- **Column K:** Number of SNF/NF admissions: ***Prior audits requested a yes/no response. CMS needs to clarify the purpose of the admission. Currently, some POs track admissions for medical reasons differently than an admission as the result of a request for services. The latter would be documented in Table 1.***
- **Column O:** Current Center Attendance: ***The requirement for POs to provide both the number of days each week a participant attends the center and whether the attendance is full or partial is cumbersome. We request that CMS clarify the definition of "partial".***
- **Column Q:** Number of falls reported as a level 1 event. ***Prior audits requested a yes/no response. Currently, some POs track falls visits in aggregate monthly. To comply with this standard, additional tracking systems will need to be designed to facilitate a "rolling" 12-month period per participant. Again, this is duplicate information that is already required for HPMS.***
- ***Column R: Number of falls reported as a level 2 event. This requirement duplicates information that POs are required to submit CMS Central Office and/or the CMS Regional Account Manager, which is reviewed in detail at the quarterly call.***
- **Column S:** Currently recovering from a fall reported as a Level 1 or Level 2 event: ***We request that CMS clarify the definition of "recovering".***
- **Column T:** Number of infections. ***Currently, most POs track infections meeting surveillance criteria in aggregate monthly. To comply with this standard, additional tracking systems will need to be designed to facilitate a "rolling" 12-month period per participant. We request that CMS define "infection" (i.e. meeting standardized/recognized (SHEA) surveillance criteria; anytime that a participant receives an antibiotic).***
- **Column U:** List of infections. ***Listing infections is cumbersome, especially with the comma requirement, and it will need to be built into the tracking system described in column T.***
- **Column V:** Number of Pressure Ulcers. ***Currently, most POs track pressure in aggregate monthly. To comply with this standard, additional tracking systems will need to be designed to facilitate a "rolling" 12-month period per participant. Again, this is a duplicate of effort as information Stage 3 and 4 are required to be reported as Level 2 (see comments on column R.)***
- **Column Z:** Ambulation: ***The currently description does account for participants who are unable to ambulate (i.e., wheelchair or bed bound).***
- **Column AA:** Significant weight loss: ***We request that CMS clarify the definition of "significant weight loss" (i.e. 5% in 30 days; 7.5% in 90 days, or 10% in 180 days). Also, we recommend that CMS consider cases when weight loss is planned/anticipated.***
- **Column AI:** Skilled Therapy: ***Listing the types of therapy and purpose may be burdensome.***
- **Column AK:** Functional decline: ***We request that CMS clarify the definition of "functional decline" (e.g., a decline that triggers an unscheduled IDT assessment).***
- **Column AL:** Oxygen Use: ***We request that CMS clarify "oxygen use" (e.g., use during hospitalization or skilled care admission but discharged on room air).***
- **Column AN:** Impaired Vision: ***We request that CMS clarify "impaired vision".***
- **Column AO:** Impaired Hearing: ***We request that CMS clarify "impaired hearing".***

- **Column AP:** Quality Analysis: ***This a vague requirement. What is the expectation of CMS? Will each request or a sample of requests be reviewed as part of the Quality Improvement program? Or is this part of Table 6?***

Table 6: Quality Assessment Initiatives Records (QAIR)

- **Column B:** Quality Initiative Name: ***We request that CMS clarify the definition of "initiative". (e.g., IDTs that meet regularly to address specific outcomes, such as falls, pressure ulcer, end of life; an action item that may occur during a Quality Meeting)***
- **Column L:** Date Corrective action implemented: ***Would a separate data identifier be needed for each "corrective action" if multiple actions were taken for the same initiative?***

Table 7: On-Call Universe (OCU)

Currently, there is a variation in how POs track after hours calls. CMS' intent for the request is unclear. If the purpose of this log is to demonstrate that the PACE organization is providing 24-hour care/ 7 days a week, the detailed Medical Record review using the sample from Table 5 should be sufficient.

- **Column G:** Response to Call. ***Providing this information is a duplication of effort as it included in the Medical Record.***
- **Column H:** PO Follow-up. ***Providing this information is a duplication of effort as it included in the Medical Record.***

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Comment On: CMS-2016-0140-0001
(CMS-10630) The PACE Organization (PO) Monitoring and Audit Process in 42 CFR Part 460

Document: CMS-2016-0140-DRAFT-0013
VA

Submitter Information

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Alexandria, VA, 22314
Email: delc@npaonline.org
Organization: National PACE Association

General Comment

See attached file(s)

Attachments

NPA Draft Comment Letter to CMS on Changes to PACE Audit Process_2016-10-04

NORTHLAND PACE
Senior Care Services
Program of All-Inclusive Care for the Elderly

October 4, 2016

Centers for Medicare and Medicaid Services
Office of Strategic Operations and Regulatory Affairs
Division of Regulations Development
7500 Security Boulevard, Room C4-26-05
Baltimore, MD 21244-1850
Submitted via: http://www.regulations.gov

Re: CMS-10630 (OMB control number: 0938-1000): The PACE Organization (PO) Monitoring and Audit Process

Thank you for the opportunity to comment on the Centers for Medicare and Medicaid Services' (CMS) information collection request published in the *Federal Register (FR)* on August 5, 2016 relating to the *PACE Organization monitoring and audit process*.

The Northland PACE Program serves the frail elderly by providing services to enable the elderly to remain living in their homes instead of placement in a nursing facility.

The National PACE Association (NPA) represents about 120 PACE Programs and has offered comments on behalf of the members of the Association. Due to the significant changes proposed in the monitoring and audit process, I feel it is very important to share our comments and concerns as well.

1. The proposed update has an effective date of January 1, 2017. Due to the necessary updates in our EMR and data collection systems, it will be extremely time consuming to populate the proposed templates with the required universe of data. Some of the template data currently is not captured and will be unavailable for pre-audit data submission. We agree with the NPA comment to not be penalized for incomplete data submission during the initial year of implementation.

2. PACE Programs will need additional time to gather and submit the pre-audit data with the proposed update than with previous surveys. The proposed audit process requires a significant amount of quality and compliance information.

3. CMS estimates each PACE Program to spend approximately 180 hours for administrative and systematic work in undergoing a CMS PACEE audit as listed below:
    - 40 hours Pre-audit: assemble and review information for completeness
    - 40 hours Onsite audit review: actual implementation of the audit
    - 20 hours Post-audit: to review and respond to draft report
    - 80 hours Corrective action and audit close-out activities

We agree with the NPA estimation that a minimum of 220 hours is a more reasonable expectation to expend on the audit which is the amount of time estimated for the CMS auditor's process.

4. In the Pre-Audit Identified Issues of Non-Compliance, the Pre-Audit Issue summary template (Attachment III) requests the name of the individual to whom a pre-audit issue was reported. We strongly feel the name should not be included in the template. This template also requires remedial action including operational as well as actions taken to address individual participants who were negatively impacted. Given the potential implications, this could be an onerous process. The information could be provided to describe the process taken for the group of participants rather than for each individual person.

5. For the SDAG universe, our processes do not capture the "Time" for the template field titles. Capturing accurate time data is questionable as is the purpose to collect such detail.
   - Time Service Delivery Request Received
   - Time of Decision
   - Time of Oral Notification
   - Time of Written Notification
   - Time Appeal Received

6. Another request for consideration relates to the different templates proposed for the audit process. The PACE Programs will be required to manage multiple templates to collect data for the audit process as well as for the HPMS Level I Reporting, specifically the Appeals and Grievance templates. It would lessen the burden if these templates included the information in the HPMS Level I Reporting Templates.

Again, thank you for the opportunity to comment on the PACE Organization (PO) Monitoring and Audit Process.

Sincerely,

Marlys Harrison

Marlys Harrison
Compliance Manager
Northland PACE Program
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Comment On: CMS-2016-0140-0001
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Document: CMS-2016-0140-DRAFT-0014
ND

Submitter Information

Name: Marlys Harrison
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Bismarck, ND, 58501
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General Comment

See attached file(s)

Attachments

N PACE Response to CMS Proposed Audit Process

October 4, 2016

Centers for Medicare and Medicaid Services
Office of Strategic Operations and Regulatory Affairs
ATTN: CMS-10630/OMB Control #: 0938-New
Division of Regulations Development
7500 Security Boulevard, Room C4-26-05
Baltimore, MD 21244-1850
Submitted via: http://www.regulations.gov

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NPA Comments on PACE Audit Process and Data Request

NPA appreciates the aim of the proposed changes in CMS' monitoring and audit process to focus on the most significant requirements, increase administrative efficiency, and promote consistency. We share these goals and offer the following comments in support of achieving them.

Administrative

- NPA recognizes that CMS reduced the number of elements for which POs' compliance is evaluated from 29 to 5 – focusing on the most prevalent areas of noncompliance. We also support that POs are no longer required to submit policy and procedure documentation as part of the proposed audit review process.
- However, we are concerned that the proposed audit process will require POs to submit a significant volume of detailed quality and compliance information. We question the necessity of much of this information in driving quality improvement for PACE participants.
- Specifically, with regard to the Service Delivery Requests, Appeals and Grievances (SDAG) universe, we question the value of the inclusion of a number of items listed under *Field Name* as these data elements are highly specific and are not outcomes-oriented. The categories include:
    - Time Service Delivery Request Received
    - Time of Decision
    - Time of Oral Notification
    - Time of Written Notification
    - Time Appeal Received
    - Please note that we have offered specific comments regarding Appendix A – PACE Record Layouts in Exhibit 1.
- In *Pre-Audit Identified Issues of Non-Compliance*, it is our view that the *Pre-Audit Issue Summary template (Attachment III)* includes details that are not needed for CMS to achieve its objectives. For example, the *Pre-Audit Issue Summary template* requires POs to include the name of the individual (first and last) to whom a pre-audit issue was reported. It is unclear to whom CMS is suggesting the issue was reported (i.e., CMS or PO staff) and what value this information provides to the audit process. Collection and reporting of this information increases the data collection burden on POs and exceeds the apparent value of the information provided.
- In addition, the remedial actions required to be reported include operational actions, as well as actions taken to address any participants who were negatively impacted. We understand the importance of reporting on operational actions to

remediate an issue identified pre-audit; however, submitting all actions taken to address individual participants is onerous and incongruent with CMS' intent. This is particularly concerning given the time estimated for a PO to assemble and review the information to be submitted prior to the audit.

Consistency

- While CMS does provide minimum "compliance standards", NPA remains concerned that the lack of interpretive guidance may result in a degree of subjectivity that continues to cause regional inconsistency in the audit process findings.
- As proposed, POs will be required to provide universe and documentation submissions within 30 calendar days of the engagement letter date. Rather than submit a universe of data during the pre-audit process, we recommend that POs submit a pre-determined sample of *Personnel Records* and medical records (*Clinical Appropriateness & Care Planning*) in advance of the audit and that auditors utilize the proposed methodology in the *Audit Process and Data Request* document for *SDAG*, *Onsite Review*, and *Quality Assessment*, and develop a sampling methodology for *On-Call Universe* during the onsite review. *We request details regarding how sample cases will be selected.*

Transition and Implementation

- Given the complexity and scope of the audit requirements, the fact that some POs have audits scheduled for early 2017, and that some of the audit procedures may be modified by the pending PACE regulation, the January 1, 2017 effective date should be delayed to January 1, 2018. Such a delay allows CMS to align its PACE audit requirements and POs to update and/or modify internal data systems and personnel requirements to comply with the new audit requirements. At a minimum, we request that POs not be penalized if unable to submit the full universe in the first 18 months the new audit requirements are implemented. This consideration will take into account that a limited number of required data elements may not be available and others may be accessible only through manual chart review for audit review periods in 2016, and would provide POs time to modify data collection and reporting systems in 2017.
- It appears that the CMS' intent is to incentivize a PO to effectively monitor its care delivery and other processes to make improvements, as needed. In *Pre-Audit Identified Issues of Non-Compliance*, CMS states "Issues that are reported as uncorrected may be cited as conditions in the CMS audit report. Issues reported as corrected <u>after the date of the audit start notice</u> will be treated as uncorrected issues". If a PO is actively working on an issue that it has self-identified and ongoing efforts are evident, the PO should not be automatically cited by CMS

due to its inability to fully resolve the issue prior to the audit review period. This policy creates a disincentive for a PO to report self-identified issues and actively work to identify issues.

- Throughout the *Pre-Audit Identified Issues of Non-Compliance* section, CMS uses temporal references to describe how the resolution status of an issue will be addressed. For example, CMS states "Issues that are reported as corrected prior to the audit review will be assumed to be corrected". Our understanding is that the audit review period is defined as "one year preceding the date of the audit engagement letter". Based on this assumption, a PO would not report such an issue on the *Pre-Audit Issue Summary template* as it would not be within the scope of the audit. We seek clarity regarding the terms *audit start notice* and *audit review period*.
- Referring to *Informing PO of Results,* there is no stated expectation regarding the maximum period of time in which a PO should receive the draft or final audit report. *Given the inclusion of civil money penalties and other enforcement actions in the proposed PACE regulation, CMS auditors should be required to provide the draft/final audit report within a limited and specified timeframe (e.g., within 30 days of the exit conference). Additionally, we recommend that a formal process of disputing the findings be provided to POs that allows for due process and an objective third party review of the audit results*.

NPA Comments on' Burden Estimates in Support Statement A

In general, NPA believes CMS' estimate of 180 hours is an underestimation of the effort needed for a PO to comply with the updated requirements and complete the audit process.

- With regard to the *pre-audit* phase, 40 hours significantly underestimates the time that will be required of PO staff time to retrieve and report data to the degree of detail CMS is requesting. Relative to the current audit process, less information in the form of policies and procedures is required of POs, but the volume and detail of data included in the *Pre-Audit Issue Summary* and the audit *Universes* are extensive. For example, the proposed *Universes* will require PO staff to collect minute details; time/date; and attribution of information exchange between personnel. This ongoing time commitment will be significantly greater than what is currently required of POs. *It is recommended that this time estimate be increased to a minimum of 80 hours to align with the time estimated that CMS audit staff will require to complete the necessary work prior to the audit.*
- CMS estimates 40 hours will be required of PO staff for actual administration of the audit. In 2014 and 2015, on average, administration of the audit required 28

hours. *Please provide rationale for the projected increase in time that PACE organizations staff would need to be available to CMS auditors while they are on-site. Also, provide clarify whether the entire audit will be done on-site.*

- CMS estimates that 20 hours will be required for PO staff to review and respond to the draft audit report. Based on POs' current experience and the additional requirement for PO staff to complete impact analyses for any deficiencies identified during the audit, which may involve medical record reviews and other time consuming activities, we believe 20 hours underestimates the amount of time that will be required to sufficiently review the draft audit report and provide feedback. *It is recommended that this time estimate be increased to a minimum of 40 hours.*
- While 80 hours seems to be a reasonable estimate of the time required to develop and submit a corrective action plan (CAP) addressing the deficiencies identified by the audit; it does not include the time required of PO staff for implementation of corrective actions and ongoing monitoring of the CAP. These activities include staff education, policy development and/or modification, and monitoring to ensure the issues have been resolved effectively. *We request that the time estimate by modified to account for these ongoing activities.*

At a minimum, a PO should be afforded the same amount of time as CMS estimates its auditors will expend on each audit – approximately 220 hours. It is not reasonable to expect that the investment of time by POs throughout the audit process will be less than the time invested by the CMS auditors.

Referring to the burden estimates associated with costs to POs, it appears that the *Total Cost* of $790,560 or $10,980 per PO does not account for the development/upfront costs associated with modifying and/or creating the information technology (IT) infrastructure required to report and validate the data CMS plans to collect under the new audit process. The underlying assumption that all POs maintain a seamless, integrated electronic health record (EHR) system is flawed. Currently, some of the most sophisticated PO EHR systems only collect 50 to 65 percent of the data proposed, requiring the creation of electronic systems to capture the remaining information. As an example, one PO estimates this additional investment alone will cost $42,500 [500 hours @ 85/hr.].

Both the FR notice and *Supporting Statement Part A* state that CMS will engage in 72 audits per year and *Supporting Statement Part A* infers that the 2017 Audit Protocol becomes effective on January 1, 2017. We would appreciate an explanation of how CMS arrived at its estimate of 72 audits in 2017 and confirmation that this figure is based on current requirements of §460.190 and §460.192. Further, we would like to confirm our

understanding that the number of audits will reduce by approximately 50 percent if CMS implements the changes to PACE monitoring requirements described in the proposed rule published in FR on August 17, 2016.

Thank you for taking the time to consider our feedback, concerns, and recommendations. Please direct any questions to Del M. Conyers, vice president of PACE QI & Compliance at delc@npaonline.org.

Sincerely,

Shawn M. Bloom
President & CEO

Enclosure: Exhibit 1

Exhibit 1 – Comments on Appendix A – PACE Record Layouts

Table 1: Service Delivery Request (SDR) Record Layout

To comply with this data requirement, PACE organizations (POs) will have to adapt and/or create a Service Delivery Request Log.

- **Column F:** Time request is received: 42 CFR § 460.104(d) states "The IDT must notify the participant or designated representative of its decision to approve or deny the request from the participant or designated representative as expeditiously as the participant's condition requires, but no later than 72 hours after the date the IDT receives the request for reassessment." ***In some CMS regions, auditors are interpreting this regulation as 72 hours after the request is made NOT when the IDT receives the request***. A possible scenario is a Driver, who is not a member of the IDT receives the request on Friday afternoon at 3 p.m. before a three-day weekend, and does not return to the site until 5p.m. When he returns to the site, he then completes the necessary form, and gives it his supervisor, who is a member of the IDT. The plan will be out of compliance because the request will not be taken to the IDT until Tuesday morning at 9 a.m. because Monday is a holiday. ***Additionally, the CMS description for time is in seconds. This type of documentation does not need second-specific measurement.***
- **Column I:** Date(s) Assessments performed. Not all requests require an in-person assessment, for example, a social respite or request for a service that PACE does not provide (i.e., bill payment). ***Will PACE organizations be cited as out of compliance if N/A is entered for these items? Additionally, the data entry for this field is cumbersome.***
- **Column J:** Discipline performing assessment. ***See above Column I concern. Additionally, the data entry for this field is cumbersome.***
- **Column K:** Assessment made in person. ***See concerns in Column I.***
- **Column L:** Request Disposition. ***The compliance standard indicates a disposition of approved, denied, partial denial. However, description only lists approval and denial.***
- **Column N:** Date of Decision. ***This information is not required by CFR, and of uncertain value to the PACE organization or CMS.***
- **Column O:** Time of Decision. ***This information is not required by CFR, and of uncertain value to the PACE organization or CMS. Additionally, the CMS description for time is in seconds. This type of documentation does not need second-specific measurement.***
- **Column Q:** Time of Oral Notification***. See concerns voice on Column F. Additionally the CMS description for time is in seconds. This type of request does not need second-specific measurement.***
- **Column S:** Time of written notification. ***This is an unreasonable expectation, if the document is mailed to the participant. It is nearly impossible for a PACE Organization to determine the time a document is sent by mail. This type of record does not need second-specific measurement.***
- Column U: Quality Analysis: ***This a vague requirement. What is the expectation of CMS? Will each request or a sample of requests be reviewed as part of the Quality Improvement program? Or is this part of Table 6?***

Table 2: Appeal Requests (AR) Record Layout

Most POs maintain an Appeals log. Submitting this detailed log is in addition to quarterly information submitted to CMS via HPMS, currently described as Level 1 data, and represents duplicate reporting to CMS. To comply with this data requirement, PACE organizations will be required to modify current appeals log to address these requirements and additional documentation and quality checks will need to be done to maintain compliance.

- **Column F:** Time appeal received: ***CMS description for time is in seconds. This type of appeal does not need second-specific measurement.***
- **Column K:** Reviewer ***This column is unnecessary. Currently, CMS expects details of the impartial third party with credentials to be listed on the Appeals Form.***
- **Column L**: Request Disposition. ***The compliance standard indicates a disposition of approved, denied, partial denial. However, description only lists approval and denial.***
- **Column P:** Time of Oral Notification***. Time should not be required unless it is an expedited appeal. This type of appeal does not need second-specific measurement.***
- **Column R:** Time of written notification. ***This is an unreasonable expectation, if the document is mailed to the participant. It is nearly impossible for a PACE Organization to determine the time a document is sent by mail. This type of documentation does not need second specific measurement.***
- Column T: Quality Analysis: ***This a vague requirement. What is the expectation of CMS? Will each request or a sample of requests be reviewed as part of the Quality Improvement program? Or is this part of Table 6?***

Table 3: Grievance Requests (GR) Record Layout

Most PACE organizations currently keep Grievance logs. Submitting this detailed log is in addition to quarterly information submitted to CMS via HPMS, currently described as Level 1 data, and represents duplicate reporting to CMS. To comply with this data requirement, PACE organizations (POs) will be required to modify current appeals log to address these requirements and additional documentation and quality checks will need to be done to maintain compliance.

- **Column I:** Date of Decision. ***To meet CMS field description this needs to be designed in a customized field in Excel. Additionally, individual PACE organizations will need to develop a timeframe for resolution, update policies, and educate staff.***
- **Column K:** Date of Written Notification. ***To meet CMS field description this needs to be designed in a customized field in Excel. The detailed interpretation of the compliance standard is confusing. The documentation showing resolution of notification to the Beneficiary ("Participant") and/or representative can be accomplished with a "decision letter" rather than a "resolution letter" with a date and time stamp. A time stamp is not necessary. Also, CMS requests documentation of an "oral notification" rather than "oral resolution" that is documented in the medical record. In the past PACE organizations have not been required to document grievances in the medical record.***
- **Column L:** Quality Analysis: ***This a vague requirement. What is the expectation of CMS? Will each request or a sample of requests be reviewed as part of the Quality Improvement program? Or is this part of Table 6?***

Table 4: List of Personnel (LOP) Record Layout

- **Column J**: Background Check. ***Please specify the criteria needed to satisfy the background check.***
- **Column M:** OSHA Training: ***Please specify the criteria needed to satisfy completion of OSHA training.***
- **Column L:** Competency Evaluations: ***Please clarify when these evaluations should occur (e.g., upon hire, annual, or both).***

Table 5: List of Participant Medical Records (LOPMR) Record Layout

- **Column G:** Number of Hospital Admissions/Observations. ***Prior audits requested a yes/no response. Currently, some POs track hospitalizations in aggregate monthly. To comply with this standard, additional tracking systems will need to be designed to facilitate a "rolling" 12-month period per participant.***

- **Column H:** Most recent date of hospitalization. ***To meet CMS field description this needs to be designed in a customized field in Excel. This field was not required in previous version of CMS Audit Guidance, and will need to be built into the tracking system described in Column G.***
- **Column I:** Number of Emergency Room Visits. ***Prior audits requested a yes/no response. Currently, some POs track ER visits in aggregate monthly. To comply with this standard, additional tracking systems will need to be designed to facilitate a "rolling" 12-month period per participant.***
- **Column J:** Most recent date of hospitalization. ***To meet CMS field description this needs to be designed in a customized field in Excel. This field was not required in previous audits, and will need to be built into the tracking system described in Column I.***
- **Column K:** Number of SNF/NF admissions: ***Prior audits requested a yes/no response. CMS needs to clarify the purpose of the admission. Currently, some POs track admissions for medical reasons differently than an admission as the result of a request for services. The latter would be documented in Table 1.***
- **Column O:** Current Center Attendance: ***The requirement for POs to provide both the number of days each week a participant attends the center and whether the attendance is full or partial is cumbersome. We request that CMS clarify the definition of "partial".***
- **Column Q:** Number of falls reported as a level 1 event. ***Prior audits requested a yes/no response. Currently, some POs track falls visits in aggregate monthly. To comply with this standard, additional tracking systems will need to be designed to facilitate a "rolling" 12-month period per participant. Again, this is duplicate information that is already required for HPMS.***
- ***Column R: Number of falls reported as a level 2 event. This requirement duplicates information that POs are required to submit CMS Central Office and/or the CMS Regional Account Manager, which is reviewed in detail at the quarterly call.***
- **Column S:** Currently recovering from a fall reported as a Level 1 or Level 2 event: ***We request that CMS clarify the definition of "recovering".***
- **Column T:** Number of infections. ***Currently, most POs track infections meeting surveillance criteria in aggregate monthly. To comply with this standard, additional tracking systems will need to be designed to facilitate a "rolling" 12-month period per participant. We request that CMS define "infection" (i.e. meeting standardized/recognized (SHEA) surveillance criteria; anytime that a participant receives an antibiotic).***
- **Column U:** List of infections. ***Listing infections is cumbersome, especially with the comma requirement, and it will need to be built into the tracking system described in column T.***
- **Column V:** Number of Pressure Ulcers. ***Currently, most POs track pressure in aggregate monthly. To comply with this standard, additional tracking systems will need to be designed to facilitate a "rolling" 12-month period per participant. Again, this is a duplicate of effort as information Stage 3 and 4 are required to be reported as Level 2 (see comments on column R.)***
- **Column Z:** Ambulation: ***The currently description does account for participants who are unable to ambulate (i.e., wheelchair or bed bound).***
- **Column AA:** Significant weight loss: ***We request that CMS clarify the definition of "significant weight loss" (i.e. 5% in 30 days; 7.5% in 90 days, or 10% in 180 days). Also, we recommend that CMS consider cases when weight loss is planned/anticipated.***
- **Column AI:** Skilled Therapy: ***Listing the types of therapy and purpose may be burdensome.***
- **Column AK:** Functional decline: ***We request that CMS clarify the definition of "functional decline" (e.g., a decline that triggers an unscheduled IDT assessment).***
- **Column AL:** Oxygen Use: ***We request that CMS clarify "oxygen use" (e.g., use during hospitalization or skilled care admission but discharged on room air).***
- **Column AN:** Impaired Vision: ***We request that CMS clarify "impaired vision".***
- **Column AO:** Impaired Hearing: ***We request that CMS clarify "impaired hearing".***

- **Column AP:** Quality Analysis: ***This a vague requirement. What is the expectation of CMS? Will each request or a sample of requests be reviewed as part of the Quality Improvement program? Or is this part of Table 6?***

Table 6: Quality Assessment Initiatives Records (QAIR)

- **Column B:** Quality Initiative Name: ***We request that CMS clarify the definition of "initiative". (e.g., IDTs that meet regularly to address specific outcomes, such as falls, pressure ulcer, end of life; an action item that may occur during a Quality Meeting)***
- **Column L:** Date Corrective action implemented: ***Would a separate data identifier be needed for each "corrective action" if multiple actions were taken for the same initiative?***

Table 7: On-Call Universe (OCU)

Currently, there is a variation in how POs track after hours calls. CMS' intent for the request is unclear. If the purpose of this log is to demonstrate that the PACE organization is providing 24-hour care/ 7 days a week, the detailed Medical Record review using the sample from Table 5 should be sufficient.

- **Column G:** Response to Call. ***Providing this information is a duplication of effort as it included in the Medical Record.***
- **Column H:** PO Follow-up. ***Providing this information is a duplication of effort as it included in the Medical Record.***

On Lok Senior Health Services

1333 Bush Street, San Francisco, CA 94109-5611
p: 415-292-8888 f: 415 292 8745 www.onlok.org

October 3, 2016

Centers for Medicare and Medicaid Services
Department of Health & Human Services
Attention: CMS-1654-P
Mail Stop C4-26-05
7500 Security Boulevard
Baltimore, MD 21244-1850
Submitted via: www.regulations.gov

Re: CMS-10630 (OBM control number: 0938-1000): The PACE Organization (PO) Monitoring and Audit Process

On Lok Senior Health Services (On Lok) appreciates the opportunity to comment on the Centers for Medicare and Medicaid Services' (CMS) information collection request published in the Federal Register (FR) on August 5, 2016 relating to the *PACE organization monitoring and audit process*.

On Lok Senior Health Services was created in San Francisco over 40 years ago to assist frail older adults remain in their own homes with community services. Through a series of federal demonstration projects, On Lok created the national prototype for Program of All-Inclusive Care for the Elderly (PACE). Today, On Lok's PACE Program, On Lok Lifeways, serves almost 1,500 PACE participants, the vast majority of whom are dually eligible for Medicare and Medicaid. On Lok Lifeways participants are 82 years of age on average, with 46% over the age of 85. Our average participant has 21 medical diagnoses and 61% have a diagnosis of Alzheimer's disease or related dementia.

We endorse the comments made by the National PACE Association (copy attached) regarding CMS' proposal related to the PACE organization monitoring and audit process. In particular, we would like to underscore the following points:

- **Data Collection and Reporting Burden:** We believe the CMS' estimates for the pre-audit phase significantly underestimate the PACE organization's staff time to retrieve and prepare the detailed information that CMS is proposing. Specifically, On Lok's electronic health record (EHR) is not currently programmed to capture and retrieve the information requested on the "Participant Medical Records (LOPMR) Record Layout." As a result, some of the requested information would need to be pulled together manually. Since On Lok Lifeways serves almost 1,500 participants, this is a significant commitment of staff time that we do not believe is reflected in the CMS estimate. Furthermore, reprogramming On Lok EHR to automate the retrieval process will require an investment of resources and take time to implement.

- **PACE Audit Process and Data Request:** We strongly agree with NPA's questioning of the value of the detailed information requested for the SDAG universe for service delivery requests (e.g., time service delivery request received, time of decision, etc.). Additionally, we believe that tracking and collecting the date for approved service delivery requests is an administrative burden without benefit to the beneficiary.

  We are very concerned with the significant expansion in scope of the participant population and elements "Participant Medical Records (LOPMR) Record Layout" request. Currently, the participant medical record information requested by CMS for a PACE audit is limited to the participants served at the respective PACE centers that are being audited. Generally, CMS requests participant medical records data on the three On Lok Lifeways PACE centers included in the audit out of a total of seven PACE centers. As we understand, the proposed LOPMR request would require medical records information for the entire On Lok Lifeways participant population of almost 1,500 participants which more than doubles the participant records required for the data request. In addition, the number of data elements has been expanded significantly from about 20 to 40. For the reasons cited above, we suggest that CMS reconsider this proposal to request data for a sample of PACE participants rather than all PACE participants and extend the implementation timeframe to allow PACE organizations time to implement automated data collection systems.

Thank you for your consideration of our comments.

Sincerely,

Eileen Kunz
Chief of Government Affairs and Compliance

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(CMS–10630) The PACE Organization (PO) Monitoring and Audit Process in 42 CFR Part 460

Comment On: CMS-2016-0140-0001
(CMS-10630) The PACE Organization (PO) Monitoring and Audit Process in 42 CFR Part 460

Document: CMS-2016-0140-DRAFT-0015
CA

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General Comment

On Lok Senior Health Services submits the attached comment letter related to the Centers for Medicare and Medicaid
Services' (CMS) information collection request published in the Federal Register (FR) on August 5, 2016, CMS - 10630,
PACE Organization Monitoring and Audit Process. We appreciate the opportunity to comment on the proposed CMS process.
Thank you for your consideration of our comments.

Attachments

On Lok Comment Letter to CMS-10630 - PACE Monitoring and Audit Process_2016.10.03

NPA Comment Letter to CMS on Changes to PACE Audit Process_2016-10-04

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NJ

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General Comment

In reviewing the proposed changes in the audit process, we agree with self auditing, but we cannot agree with the
amount of data being requested during the 12 month audit period. The cost associated with the resources necessary
to accomplish this are unrealistic, given the need to dedicate PACE resources to our participants. This will put
a significant financial burden on PACE organizations.

Further clarification is needed for Appendix A- Table 4 (LOP) and 5 (LOPMR).
LOP- the need to review every single record for every person hired is extraordinary and a sample size should
be sufficient for CMS to ensure personnel records meet requirements.
LOPMR lacks clarity. Is your request for the entire census of enrolled participants during the audit period, or those
newly enrolled during the audit period?
We believe CMS has severely underestimated the cost associated with collecting this level of detailed data on every
participant and personnel record.

In addition, no other healthcare entities regulated by CMS are required to provide this level of detail for 100 percent of their
census or their employees.
We suggest that CMS considers providing a definition of their high risk parameters and require submission of data on a
sample size of participants that meet the definition.

1. Will the audits be conducted at the Parent Level or Contract Level? For organizations with multiple PACE contracts, the data collection complexity and reporting is further increased.

2. If the PACE organization has more than one site, will CMS conduct the onsite audit at all of the sites or some? If CMS will not conduct audits at all PACE sites, what is the selection criteria that CMS will use to determine which sites are to be visited?

3. Consideration for varying sizes of PACE organizations. Time and effort to provide complete responses for larger multi-site PACE organizations will be very different from time and effort required by smaller, one-site PACE organizations. Until automation of data gathering is fully achieved, the level of detail required by the proposed new audit process will offset any economies of scale in larger PACE organizations. We request that CMS consider larger PACE organizations will incur greater expenses preparing for audits using the proposed audit protocols.

4. The draft audit templates require specific information related to grievances, appeals and incidents utilizing drop down categories. Many of these categories are similar to, but not the same as, the choices when submitting the same data to HPMS.
    a. For example, the HPMS grievance categories for source are: Caregiver, Contracted provider, Family, Participant. The proposed Audit Data request template categories for source are: Participant, Caregiver, Other.

   The capture of the same data in a slightly different way will yield no identifiable value to either quality or regulatory oversight but will simply add an additional burden to the PACE organization staff responsible for collecting and analyzing the data. We recommend that CMS use HPMS language and terminology wherever possible within the PACE protocols for consistency and clarity.

5. Our organization anticipates that the first one to two years of audit preparation readiness will be the most costly as we develop the infrastructure required to readily produce the data and utilize it effectively for monitoring. We suggest the cost estimates in addition to being graduated for PACE size, be further enhanced for the first 1-2 years' investment which will be required by all PACE organizations.

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MA

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General Comment

Fallon Health supports the recommendations on the 2017 draft PACE audit protocol to be submitted by the National PACE Association (NPA) and would like to add the attached comments/questions regarding the 2017 draft protocols.

Attachments

Comments on 2017 draft PACE audit protocol - Fallon Health H2219

VIRGINIA SAA COMMENTS – CMS PROPOSED AUDIT PROCESS REVISIONS 2016

Proposed Rule: The PACE Organization (PO) Monitoring and Audit Process in Part 460 of 42 CFR CMS-10630, OMB 0938-TBD (New)

SAA COMMENTS AND QUESTIONS:

1) **Audit Purpose and General Guidelines. Pre-Audit Identified Issues of Non-Compliance (pg. 3).** The CMS is proposing to have POs provide a list of all identified issues of non-compliance that occurred during the audit review period, which could include issues that were self-identified by the PO (that may or may not have been previously disclosed to CMS) or issues identified by the CMS during the course of the audit review period.

   Question: Will the CMS request the State Administering Agency (SAA) to include any issues of non-compliance that were identified during a technical advisory visit and/or state audit? Will the SAA have the opportunity to review the POs report of self-identified issues of non-compliance and disclose any additional areas of non-compliance to which the SAA is aware, but the PO may have omitted from its self-disclosure?

2) **Audit Purpose and General Guidelines. Pre-Audit Identified Issues of Non-Compliance (pg. 3).** The CMS proposes that issues reported as corrected prior to the audit review period will be assumed to be corrected. However, if during the audit the issue is found to not have been corrected, they "may" cite the applicable conditions in the audit report. Likewise, the CMS also writes that issues reported as uncorrected "may" be cited as conditions in the CMS audit report.

   Question: Can the CMS clarify why they "may" cite the PO in such situations? If a PO reports an issue has been corrected, but upon audit is found to be out of compliance, it would seem a citation would be indicated. Likewise, if an issue is reported and the PO states it has not taken action to correct it, it would seem a citation would be indicated. It is suggested that the CMS consider changing the word "may" to "will" in both sentences.

3) **Audit Purpose and General Guidelines. Pre-Audit Identified Issues of Non-Compliance (pg. 3).** The CMS states it will consider an issue corrected if the PO can demonstrate correction or remediation was implemented prior to the engagement letter being sent. Further, the CMS states that issues reported as corrected during the audit review period may be validated during the audit.

   Comment: It is recommended that the CMS validate implementation of all self-identified corrective actions during an audit, ensuring POs are held accountable and are following through on reported corrective action implementations. SAA staff is available to assist the CMS in the audit process and could be used to assist in these verifications. Overall, it has been documented that POs sometimes have the same findings audit to audit, indicating that corrective actions are not always followed through or implemented. This indicates the need for continued oversight of corrective action implementation, not less.

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15) **Audit Elements. Onsite Review. Apply Compliance Standard (p. 16).** The proposed audit protocol omits the dietary services element, whereas the current audit protocol has such an element. Under the current dietary services element, the CMS ensures the PO complies with dietary regulations set forth in the Code of Federal Regulations. These regulations require that the PO provides appropriate meal selections, including special diets, and that the PO stores and prepares food in a manner consistent with infection control measures. It is under this element the CMS ensures the PO has a process for maintaining emergency food and nutritional supplement supplies in the event of an emergency. It is also under this element the CMS ensures all food is prepared and stored at appropriate temperatures and in an appropriate manner. In section 3.8 of the "Onsight Review" element of the proposed audit protocol, the auditor follows 3-5 participants to determine whether (1) the PO identified one of the selected participants as requiring a special diet (pureed, etc.) and (2) if identified as requiring a special diet, whether the PO provided the diet ordered in the plan of care. This is the extent of dietary service observation under the proposed audit protocol.

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Document: CMS-2016-0140-DRAFT-0007
VA

Submitter Information

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Organization: Virginia Department of Medical Assistance Services

General Comment

See attached file(s) to review the Virginia Department of Medical Assistance Services comments on the proposed PACE Organization Monitoring and Audit Process in 42 CFR Part 460.

Attachments

Audit_Process_Proposed_Changes_VA_SAA_COMMENTS

CMS PROPOSED AUDIT PROCESS REVISIONS 2016

Proposed Rule: The PACE Organization (PO) Monitoring and Audit Process in Part 460 of 42 CFR CMS-10630, OMB 0938-TBD (New)

COMMENTS AND QUESTIONS:

1) **Audit Purpose and General Guidelines. Pre-Audit Identified Issues of Non-Compliance (pg. 3).** The CMS is proposing to have POs provide a list of all identified issues of non-compliance that occurred during the audit review period, which could include issues that were self-identified by the PO (that may or may not have been previously disclosed to CMS) or issues identified by the CMS during the course of the audit review period.

   Question: Will the CMS request the State Administering Agency (SAA) to include any issues of non-compliance that were identified during a technical advisory visit and/or state audit? Will the SAA have the opportunity to review the POs report of self-identified issues of non-compliance and disclose any additional areas of non-compliance to which the SAA is aware, but the PO may have omitted from its self-disclosure?

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VA

Submitter Information

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Richmond, VA, 23230
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General Comment

See attached file(s) for my comments on the proposed rule.

Attachments

Audit_Process_Proposed_Changes_VA_Personal_COMMENTS