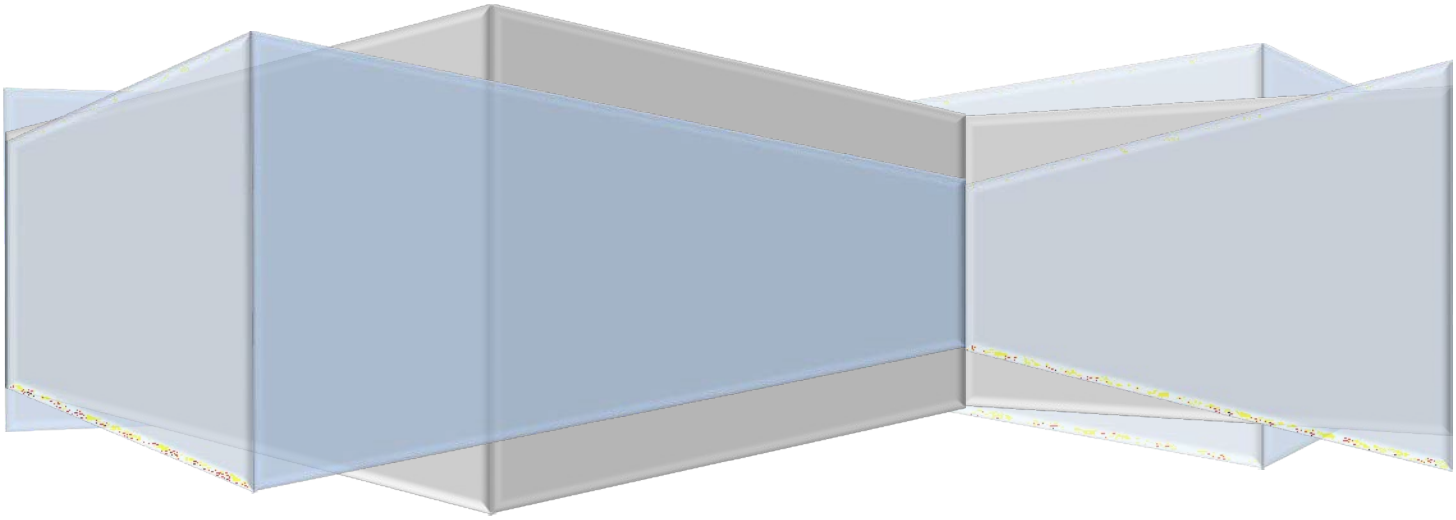
# Programs of All-Inclusive Care for the Elderly (PACE)

## Audit Protocol



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## Audit Purpose and Scope

1. **Purpose**: To evaluate PACE organizations' (POs') compliance with regulatory requirements in any or all of the following four areas related to the Programs of All-Inclusive Care for the Elderly (PACE). The Centers for Medicare and Medicaid Services (CMS) will perform its audit activities based on these instructions (unless otherwise noted).

   - Service Determination Requests, Appeals and Grievances (SDAG);
   - Provision of Services (care planning, participant assessments, interdisciplinary team (IDT) requirements, medical records, participant observations, etc.);
   - Personnel Records; and
   - Compliance and Quality Improvement

2. **Scope of Review**: CMS will review data and documentation collected prior to, during, and after the audit fieldwork, as well as conduct real-time observations of participants and equipment. CMS will conduct audits remotely, onsite or a combination of the two and the PO will grant CMS access to all relevant documentation or information related to the audit. CMS's remote review includes, but is not limited to, CMS accessing and obtaining information from the PO's electronic medical record system(s) as well as examination of case files uploaded by the PO.

   The initial data/document collection period for this protocol will be at least 6 months prior to, and including, the date of the audit engagement letter unless otherwise specified. CMS reserves the right to expand the data/document collection period to ensure sufficient universe size, evaluate participant impact or outcomes, and/or investigate quality of care concerns.

## Initial Documentation and Data Submissions

1. **Responding to Initial Documentation and Data Submissions:** The PO must submit accurate and timely documentation and universes in accordance with the instructions provided in this PACE audit protocol. See Appendix A for additional instructions on universe submissions.

   To fulfill audit related documentation requests, the PO is expected to upload any and all requested documentation to the Health Plan Management System (HPMS) and when applicable, use the designated file names as indicated in the Document Request Log (DRL) tab of HPMS. See the element sections for further information on documentation requirements.

2. **Initial Documentation and Data Submission Timeframes**: The following documentation and universes must be submitted in the timeframes indicated below.

   **2.1. Documentation due within 5 business days of the audit engagement letter:** POs must submit the following documentation in Microsoft Word (.docs), Microsoft Excel (.xlsx) or Portable Document File (PDF):

   - Completed PACE Supplemental Questions (Audit Engagement Letter, Attachment II)
   - Completed Pre-Audit Issue Summary (Audit Engagement Letter, Attachment III)

   **NOTE**: POs will be asked to provide a list of all issues of non-compliance disclosed to CMS prior to the date the audit engagement letter is issued, using the Pre-Audit Issue Summary template (Attachment III). This submission will include a description of each disclosed issue and the status of correction. The PO's Account Manager will review Attachment III to validate that disclosed issues were reported to CMS prior to receipt of the audit engagement letter. If issues were reported to someone in CMS other than the AM, the PO should indicate that in the attachment.

   Issues identified by CMS or the State administering agency (SAA) through ongoing monitoring or other account management and oversight activities during the audit year are not considered disclosed. POs should exclude PACE Quality data already reported to CMS, unless otherwise specified, and any data that is not relevant to the audit elements included in this document.

   **2.2. Documentation and universes due within 20 business days of the audit engagement letter**

   **2.2.1. Documentation:**
   - The PO's Quality Improvement (QI) plan(s) that were in use during the data collection period.
   - Participant Advisory Committee (PAC) minutes for the data collection period
   - Documentation that the PO implemented measures to prevent, detect, and correct noncompliance with PACE regulatory requirements, Part D regulatory requirements, and fraud, waste, and abuse.

   **2.2.2. Data Universes described in Appendix A:**
   - Table 1: Service Determination Requests (SDR)
   - Table 2: Appeal Requests (AR)
   - Table 3: Grievances (GR)
   - Table 4: List of Personnel (LOP)
   - Table 5: List of Participant Medical Records (LOPMR)

- Table 6: On-call (OC)
- Table 7: Contracted Entities and Providers (CEP)

# Audit Element Review

## I. Service Determination Requests, Appeals and Grievances (SDAG)

**1. Select Sample Cases:** CMS will initially select up to 40 targeted sample cases from the Service Determination (SDR), Appeal Requests (AR), and Grievances (GR) universes (Tables 1-3 of Appendix B). When selecting sample cases, CMS will attempt to ensure that the sample set is representative of various types of service determination requests, appeals and grievances. CMS will use all universes, documentation, and available information in order to target samples for review. The SDAG sample set will include:

- 10 denied service determination requests
- 10 approved service determination requests
- 5 denied appeals
- 5 approved appeals
- 10 grievances

CMS reserves the right to adjust the number of service determination requests, appeals or grievance samples if the number of entries in a given universe is less than the number of required samples. For example, if a PO does not have five approved appeals, CMS may select additional denied appeals or additional service determination requests to make up the total number of samples. Additionally, CMS may add samples in order to further investigate potential noncompliance or participant impact. CMS will provide sample selections to the PO no less than two business days before the SDAG review starts.

**2. Review Sample Case Documentation and Evaluate Universes:** CMS will review all sample case file documentation and evaluate SDR, AR, and GR universes to determine compliance with regulatory requirements including, but not limited to 42 CFR §§ 460.120, 460.121, 460.122 and 460.124. During the audit, the PO will need to submit the documentation listed in section 2 for each service determination request, appeal, and grievance sample selected. Documentation will be submitted through HPMS.

Each sample case file submitted to CMS must comprehensively address the applicable documentation requests below. The documentation for each sample case file must either be (1) combined into one file that is ordered according to the sequence in which the service determination request, appeal, or grievance was processed, or (2) zipped into a single file in which individual files within the zipped file are titled in accordance with their contents for easy identification (e.g., a document demonstrating IDT attendance for the review of a service determination request could be titled “IDT attendance during morning meeting on [date]”).

Additionally, each sample case file must include a cover sheet which includes all the requested documentation, whether the documentation is included in the case file, and if so, the page number where that documentation can be found. If any required documentation is unavailable, the PO must specify in the cover sheet that the required documentation does not exist. For example, if the PO does not have documentation that a participant received oral notification of a service determination request decision, the PO would indicate that documentation of oral notification was not available in the cover sheet. For any case file documentation in a language other than English, CMS will request the original documentation as well as a version translated into English.

**2.1 Service Determination Request Review:**

- All documentation related to the initial service determination request
- All documentation related to assessments conducted in response the service determination request and all IDT notes
- All documentation of the IDT's review of the service determination request
- For service determination requests with extensions, documentation identifying when the extension was initiated, why the extension was initiated, and all notification(s)
- Service determination request decision notification(s)
- All documentation related to the provision of approved services, including arranging or scheduling the delivery of services, timeframes for service delivery, and tracking and monitoring the provision of approved services
- Any other reports, system notes, or logs that document denial, partial denial, or approval of the request and participant notification

**2.2 Appeal Review:**

- All documentation related to the initial appeal request
- All documentation related to the underlying service determination request
- Documentation that the participant was given an opportunity to present evidence in-person as well as in writing
- All documentation related to expedited appeals and expedited appeals extensions (if applicable).
- All documentation provided to the third-party reviewers or committee related to the disputed service(s)
- All documentation related to the third-party reviewers or committee members, including their credentials
- All documentation related to the third-party reviewer or committee members appeal decision
- Appeal decision notification(s)
- Documentation that the PO continued to furnish the appealed service to Medicaid participants who requested to continue receiving disputed services under appeal until issuance of the final determination, if applicable
- All documentation related to the provision of approved services, including arranging or scheduling the delivery of services, timeframes for service delivery, and tracking and monitoring the provision of approved services
- Any other reports, system notes, or logs that document denial or approval of the request and participant notification
- Upon request from CMS, all materials provided by the PO explaining the PACE regulatory requirements

**2.3 Grievance Review:**

- All documentation related to the initial complaint, including each distinct issue identified by the participant and/or their representative
- All supplemental information submitted by the participant and/or their representative, including any written documentation
- Documentation of the distinct issues that required an investigation and the PO's investigations into each distinct issue
- All documentation related to the final resolution for each grievance issue, including the steps and actions taken by the PO to resolve each distinct issue
- All documentation related to resolution notification(s)
- All documentation related to quality of care issues and the PO's cooperation with Quality

Improvement Organizations (QIOs) (if applicable)

- Corrective action(s) taken by the PO in response to the grievance (if applicable)
- Any other system notes, progress notes, logs, or other data related to the complaint classified by the PO as a grievance
- Documentation of the grievance process information provided to the participant

**3. Apply Compliance Standard:** The criteria used to evaluate cases include, but are not limited to, the compliance standards in this section. CMS may review requirements not specifically addressed in these questions, including compliance standards noted in other elements if it is determined that there are other requirements not being met. In applying these standards, auditors may request written responses to questions and additional documentation to be submitted by the organization to demonstrate compliance with a particular requirement. Written responses to auditor questions must be submitted using the Request for Additional Information (RAI) template developed by CMS.

3.1. **Did the PO appropriately process service determination requests, appeals and grievances?**

- 3.1.1. Did the PO appropriately identify, classify, and process service determination requests, appeals, and grievances?
- 3.1.2. Did the PO appropriately process immediately approved service determination requests?
- 3.1.3. Did the full IDT review the service determination request, if applicable?
- 3.1.4. Did the PO ensure that the appeal was reviewed by an impartial and appropriately credentialed third-party reviewer or committee?
- 3.1.5. Did the PO distribute written or electronic materials to the third party reviewer or committee that meet the requirements in § 460.122(c)(5) necessary to understand the PACE benefit?
- 3.1.6. Did the PO conduct in-person assessments in response to a service determination request the IDT expected to deny or partially deny?
- 3.1.7. Did the in-person assessment evaluate whether the requested service was necessary to meet the participant's medical, physical, emotional, and social needs?
- 3.1.8. Did the IDT consider all relevant information when evaluating a service determination request, including, but not limited to: the findings and results of any reassessments, the participant's current medical, physical, emotional, and social needs, and current clinical practice guidelines and professional standards of care applicable to the particular service?
- 3.1.9. Did the PO automatically process as an appeal any service determination request that was not processed within the required timeframe?
- 3.1.10. Did the PO give all parties involved in an appeal a reasonable opportunity to present evidence in-person, as well as in writing?
- 3.1.11. Did the PO continue providing services to a Medicaid participant, during an appeal, if the participant requested to continue the services?
- 3.1.12. Did the PO conduct a thorough investigation of all distinct issues within the grievance when the cause of the issue is not already known?
- 3.1.13. Did the PO cooperate with the QIO in resolving participant complaints, when applicable?
- 3.1.14. Did the PO take corrective action(s) taken as a result of the grievance, when applicable?
- 3.1.15. Did the PO give the participant written information on the grievance process, upon enrollment and at least annually thereafter, that includes all of the required information specified in § 460.120(c)?

3.2. **Did the PO appropriately notify participants and/or their designated representatives of any decision relating to a service determination request, appeal or grievance?**

- 3.2.1. Did the PO provide oral and written notification of service determination request

denials and partial denials that included the specific reason for the denial, including why the service was not necessary to maintain or improve the participant's overall health status and considering the participant's medical, physical, emotional, and social needs, and the results of the reassessment(s), in understandable language?

3.2.2. Did the PO provide oral and written notification of service determination request denials and partial denials that included the participant or designated representative's right to appeal, including the right to an expedited appeal?

3.2.3. Did the PO inform Medicaid participants of their right to continue receiving disputed services during the appeals process and the conditions for continuing to receive disputed services?

3.2.4. Did the PO provide oral or written notification of service determination request approvals, including an explanation of the conditions of approval in understandable language and when the participant may expect to receive the approved service?

3.2.5. Did the PO provide appropriate written notification for favorable appeal decisions, including an explanation of the conditions of approval in understandable language?

3.2.6. Did the PO provide appropriate written notification for partially or fully adverse appeal decisions, including the specific reason(s) for the adverse decision, why the service would not improve or maintain the participant's overall health status, and a description of the participant's external appeal rights?

3.2.7. If a grievance was not related to quality of care, did the PO provide oral or written notification of the grievance resolution, based on the preference of the individual who submitted the grievance, except when the individual specifically requested not to receive notification?

3.2.8. If a grievance was not related to quality of care, did oral or written notification of the grievance resolution include a summary of all distinct issues, a summary of the pertinent findings or conclusions for each distinct issue that required investigation, and for grievances that required corrective action, the corrective action(s) taken or to be taken by the PACE organization, and when the participant may expect corrective action(s) to occur?

3.2.9. If a grievance was related to quality of care, did the PO provide written notification of the grievance resolution, except when the individual specifically requested not to receive notification?

3.2.10. If a grievance was related to quality of care, did written notification of the grievance resolution include a summary of all distinct issues, a summary of the pertinent findings or conclusions for each distinct issue that required investigation, and for grievances that required corrective action, the corrective action(s) taken or to be taken by the PACE organization, and when the participant may expect corrective action(s) to occur?

3.2.11. If a grievance was related to quality of care, did written notification of the grievance resolution inform Medicare participants or their representatives of the right to file a written complaint with the QIO with regard to Medicare covered services?

3.3. **Did the PO process service determination requests, appeals, and grievances within required timeframes and take appropriate extensions?**

3.3.1. For requests that were immediately approved by a member of the IDT, did the IDT member notify the participant or designated representative of the approval, at

the time the request was made?

3.3.2. For requests that were not immediately approved:

3.3.2.1 Did the PO ensure the service determination request was brought to the IDT as expeditiously as the participant's condition required, but no later than 3 calendar days from the time the request was made?

3.3.2.2 Did the PO notify the participant or designated representative of the IDT decision to approve, deny, or partially deny a service determination request no later than 3 calendar days after the date the IDT received the request?

3.3.2.3 Did the PO appropriately extend the timeframe for approving or denying a service determination request, if applicable?

3.3.2.4 If the IDT extended the service determination request processing timeframe, did the IDT provide notice of the extension to the participant or designated representative orally or in writing no later than 24 hours after the IDT decided to extend the timeframe?

3.3.2.5 If the IDT extended the service determination request processing timeframe, did the IDT notify the participant or designated representative of their decision no later than 8 days following the date the request was received by the IDT?

3.3.3. Did the PO notify all parties involved in the appeal of the standard appeal decision within 30 days of the appeal receipt date or, for expedited appeals, within 72 hours after the PO receives the appeal?

3.3.4. Did the PO appropriately extend the timeframe for responding to an expedited appeal, if applicable?

3.3.5. If the PO extended the appeals processing timeframe, did the PO provide notification to all parties involved in the appeal no later than 17 days after receipt of an expedited appeal for which an extension was taken?

3.3.6. Did the PO resolve the grievance as expeditiously as the case requires, but no later than 30 calendar days after the date the PACE organization receives the oral or written grievance?

3.3.7. Did the PO notify the individual who submitted the grievance of the grievance resolution as expeditiously as the case requires, but no later than 3 calendar days after the date the PACE organization resolved the grievance?

3.4. **Did the PO effectuate/provide approved services as expeditiously as the participant's condition required?**

3.4.2. Did the PO arrange and/or schedule the delivery of approved services within the required timeframe?

## II. Provision of Services

1. **Select Sample Cases:** This element will be tested using, at a minimum, medical record review and observations/inspections.

   Medical Record Review: CMS will initially select up to 25 targeted medical records from the List of Participant Medical Records (LOPMR) universe (Table 5 of Appendix B) that appear clinically significant. When selecting sample cases, CMS will attempt to ensure that the sample set is representative of various types of medical, functional, and social needs (e.g., hospitalizations, wound care, dialysis, social needs, home bound, skilled nursing care). CMS will use all universes, documentation, and available information in order to target participant samples for review. CMS will provide sample selections to the PO 1 hour prior to the start of the review of medical records.

   CMS may expand the scope of review, which includes, but is not limited to, adding medical records or reviewing relevant records beyond the universe collection periods, in order to appropriately investigate potential compliance issues discovered during the review of audit elements.

   Participant Observations: CMS will also conduct up to 5 participant observations during audit fieldwork in order to ensure participants are receiving appropriate care and services that were indicated to be necessary. Observations will also ensure care is being provided following CDC standard precautions. Observations may include but are not limited to:

   - Skilled care provided in participants' homes, including wound care and medication administration;
   - Skilled care provided at the center, or Alternative Care Setting, including wound care and medication administration; and
   - Dietary/meal services

   CMS will work with the PO prior to and during audit fieldwork to determine if participants are available for observations. If participants are available for observations, CMS may select participants and conduct observations. CMS will notify the PO of participant observation selections before conducting each observation. CMS may observe more participants if issues are noted that warrant additional observations.

   Emergency Equipment: CMS will conduct an inspection of specific emergency equipment and emergency medications in order to ensure the PO is properly equipped to handle an emergency situation.

   Vehicle Inspection: CMS will conduct an observation of at least one vehicle that the PO utilizes to transport participants in order to ensure that the PO is equipped to provide safe and appropriate transportation services.

   Participant/Caregiver/ Staff Interviews: CMS may conduct interviews with participants, caregivers, and/or staff to investigate potential concerns and/or determine compliance with regulatory requirements.

2. **Review Sample Case Documentation:** CMS will review participant medical records and conduct participant observations to determine compliance with regulatory requirements including but not limited to 42 CFR §§ 460.64, 460.70, 460.74, 460.76, 460.78, 460.84, 460.90, 460.92, 460.94, 460.96, 460.98, 460.100, 460.102, 460.104, 460.106, 460.112,

460.114, 460.120, 460.121, 460.122, 460.200, 460.210. CMS may also conduct interviews with participants, personnel, and caregivers as determined necessary. The PO must provide CMS auditors unrestricted access to these records and may be required to upload copies
and/or screenshots of the following documents during and/or after the audit.

**2.1 Medical Record Review:**

- All enrollment/disenrollment information
- Advanced directives, if applicable
- All participant assessments
- All participant care plans
    - All information related to the development, creation, evaluation, or revision of participant care plans, including care plan meeting minutes
- All information related to the provision of services, the delivery of participant care, the coordination of care between IDT members, the coordination of care between the IDT and other PACE employees, and the coordination of care between the IDT and contracted individuals and entities, including but not limited to:
    - IDT progress notes
    - All notes from other employees and contractors related to the provision services and participant care
    - IDT meeting minutes
    - Specialist records
    - Hospital discharge summaries
    - Summaries of other inpatient and long-term care services, including documentation of coordination of care with nursing facilities, assisted living facilities, and other sub-acute facilities
    - Medication records
    - Wound care records
    - Other treatment records
    - Laboratory results
    - Diagnostic testing results
    - Home care records
    - On-call records
    - Service determination request information
    - Appeals information
    - Grievance information
    - Incident reports, including information not contained within the medical record
    - All information related to coordination of participant care including communication between the PO and the participant, their designated representatives, their caregivers, hospitals, nursing facilities, assisted living facilities, other sub-acute facilities, specialists, other contractors, CMS, state and local agencies, any other individual who provides information pertinent to a participant's, care, health, or safety, etc.
- All information provided to the participant or designated representative regarding palliative care, comfort care, or end-of-life care

3. **Apply Compliance Standards:** The criteria used to evaluate cases include, but are not limited to, the compliance standards in this section. CMS may review requirements not specifically addressed in these questions, including compliance standards noted in other elements if it is determined that there are other requirements not being met. In applying these standards, auditors may request written responses to questions and additional documentation to be submitted by the

organization to demonstrate compliance with a particular requirement. Written responses to

auditor questions must be submitted using the Request for Additional Information (RAI) template developed by CMS.

**3.1. Did the PO furnish comprehensive services necessary to meet the needs of all participants?**

- 3.1.1. Did the PO furnish mandatory services at the PACE center?
- 3.1.2. Did the PO provide all Medicare covered services, Medicaid covered services, and other services determined necessary by the IDT?
- 3.1.3. Did the PO provide Medicare and Medicaid covered services without limitations or conditions relating to amount, duration, scope of services, deductibles, copayments, coinsurance, and other cost-sharing?
- 3.1.4. Did the PO provide immediate access to emergency services without prior authorization?
- 3.1.5. Did the PO furnish comprehensive medical, health, and social services that integrate acute and long-term care and in accordance with contracted services requirements, as applicable?
- 3.1.6. Did the PO ensure accessible and adequate services to meet the needs of its participants and, if necessary, increase the number of PACE centers, personnel, or other PACE services?

**3.2. Did the PO ensure that the IDT was appropriately involved in participant care?**

- 3.2.1. Did the PO establish an IDT composed of the required members at each PACE center?
- 3.2.2. Did the IDT conduct initial and periodic assessments, develop plans of care, and coordinate 24-hour care delivery?
- 3.2.3. Did the PO ensure that decisions by the IDT to provide or deny services were based on an evaluation of the participant that considers the participant's current medical, physical, emotional, and social needs?
- 3.2.4. Did the PO ensure that decisions by the IDT to provide or deny services were based on current clinical practice guidelines and professional standards of care applicable to the particular service?
- 3.2.5. Did the IDT remain alert to pertinent input from other team members, participants, caregivers, employees, contractors, specialists, and designated representatives?
- 3.2.6. Did the IDT order, approve, or authorize all necessary care, across all care settings?
- 3.2.7. Did the IDT communicate all necessary care and relevant instructions for care, across all care settings?
- 3.2.8. Did the IDT ensure care was implemented as it was ordered, approved, or authorized, across all care settings?
- 3.2.9. Did the IDT monitor and evaluate the participant’s condition to ensure that the care provided was effective and met the participant’s needs, across all care settings?
- 3.2.10. Did the IDT promptly modify care when it determined the participant's needs were not met in order to provide safe, appropriate, and effective care to the participant?
- 3.2.11. Did the IDT document all recommendations for care or services?
- 3.2.12. If the IDT did not approve or provide the recommended care or services, were the reasons for not approving or providing recommended care or services documented in accordance with medical records maintenance requirements?

3.2.13. Did the appropriate member(s) of the IDT review all recommendations from

hospitals, emergency departments, and urgent care providers and determine if the recommended services were necessary to meet the participant's medical, physical, social, or emotional needs as expeditiously as the participant's health condition requires, but no later than 48 hours from the time of the participant's discharge?

3.2.14. Did the appropriate member(s) of the IDT review all recommendations from other employees and contractors and determine if the recommended services were necessary to meet the participant's medical, physical, social, or emotional needs as expeditiously as the participant's health condition requires, but no later than 7 calendar days from the date the recommendation was made?

3.2.15. Did the IDT implement, coordinate, and monitor the plan of care whether the services were furnished by PACE employees or contractors, across all care settings?

3.2.16. Did the IDT evaluate and monitor the participant's medical, physical, emotional, and social needs, as well as the effectiveness of the plan of care, through the provision of services, informal observation, input from participants or caregivers, and communications among members of the IDT and other employees or contractors?

**3.3. Did the PO perform assessments as required?**

3.3.1. Did the IDT perform assessments as required (initial, semi-annual, or more frequently when necessary)?

3.3.2. Did the PO ensure the required IDT members performed assessments?

**3.4. Did the PO maintain a complete, accurate, and accessible medical record?**

3.4.1. Did the PO ensure the participant medical record was available to all personnel?

3.4.2. Did the PO maintain the required content in each participant medical record?

3.4.3. Did the PO safeguard records and data against loss, destruction, or inappropriate alteration, and ensure the medical records were appropriately authenticated and dated?

**3.5. Did the PO develop and document an appropriate care plan for the participants?**

3.5.1. Did the IDT develop and evaluate participant care plans within the required timeframes?

3.5.2. Did the PO ensure the full IDT was involved in creating and evaluating care plans?

3.5.3. Did the IDT consolidate initial, discipline-specific assessments into a

comprehensive care plan, including all necessary services?

3.5.4. If the IDT determined that certain services were not necessary for the care of the participant during the development of the initial plan of care, did the IDT document the reasoning behind the determination in the care plan?

3.5.5. Did each plan of care identify all of the participant's current medical, physical, emotional, and social needs, including all needs associated with chronic diseases, behavioral disorders, and psychiatric disorders that required treatment or routine monitoring, taking into consideration the most current assessment findings?

3.5.6. Did each plan of care address vision, hearing, dentition, skin integrity, mobility, physical functioning, including activities of daily living, pain management, nutrition, including access to meals that meet the participant's daily nutritional and special dietary needs, the participant's ability to live safely in the community, including the safety of their home environment, home care, center attendance, transportation, and communication, including any identified language barriers?

3.5.7. Did each plan of care identify each intervention needed to meet each medical, physical, emotional, and social need?

3.5.8. Did each plan of care identify how each intervention would be implemented, including a timeframe for implementation?

3.5.9. Did each plan of care identify a measurable goal for each intervention and how the goal for each intervention would be evaluated to determine whether the intervention should be continued, discontinued, or modified?

3.5.10. Did each plan of care identify the participant's preferences and goals of care?

3.5.11. Did the PO document participant and/or representative involvement in the development, review, and evaluation of care plans?

**3.6. Did the PO provide care and services necessary to meet the medical, physical, emotional, and social needs of each participant?**

3.6.1. Did the PO provide all necessary services, including all care planned, ordered, and IDT-approved services?

3.6.2. Did the PO document, track, and monitor the provision of all services to ensure services were provided as expeditiously as the participant's health condition required, considering the participant's medical, physical, emotional, and social needs?

3.6.3. Did the PO arrange and schedule the dispensing of medications as expeditiously as the participant's condition requires, but no later than 24 hours after a primary care provider ordered the medications?

3.6.4. Did the PO arrange or schedule the delivery of interdisciplinary team approved services, other than medications, as expeditiously as the participant's health condition required, but no later than 7 calendar days after the date the interdisciplinary team or member of the interdisciplinary team first approved the service, except for routine and preventative services as permitted in § 460.98(c)(3)?

**3.7. Did the PO protect and provide for the exercise of the participant's rights?**

3.7.1. Did the PO inform the participant in writing before implementing palliative care, comfort care, or end-of-life care services?

3.7.2. Did written notification inform the participant of how the PACE organization's palliative care, comfort care, or end-of-life care services differ from the care the participant is currently receiving and whether the services would be provided in addition to or in lieu of the care the participant is currently receiving?

3.7.3. Did written notification inform the participant of all services that are impacted and provide a detailed explanation of how the services will be impacted if the participant or

designated representative elects to initiate palliative care, comfort care, or end-of-life care?

3.7.4. Did written notification inform the participant of the right to revoke or withdraw their consent to receive palliative, comfort, or end-of-life care at any time and for any reason, either verbally or in writing?

3.7.5. Did the PO fully explain the palliative care, comfort care, or end-of- life treatment options before initiating palliative care, comfort care, or end-of- life care?

3.7.6. Did the PO obtain written consent before initiating palliative care, comfort care, or end-of-life care?

**3.8. Did the PO follow appropriate infection control standards when providing care?**

3.8.1. Did personnel wash/sanitize hands as appropriate?

3.8.2. Did personnel don and doff personal protective equipment as appropriate?

**3.9. Did the PO have emergency equipment immediately available (suction, oxygen, medications, etc.)?**

**3.10. Did the PO have a method of providing safe transportation to participants?**

3.10.1. Did the PO have a demonstrated method for securing participants (i.e., seat belts) and securing DME (e.g., wheelchairs, oxygen, walkers)?

3.10.2. Did the PO have a method for communicating between the vehicle and the PACE center?

3.10.3. Did the PO provide training to drivers on managing the special needs of the participants and handling emergency situations?

## III. Personnel Records

1. **Select Sample Cases:** CMS will initially select up to 10 targeted personnel records from the List of Personnel (LOP) universe (Table 4 of Appendix B). CMS will attempt to ensure that the sample set is representative of various types of employees, including part-time, full-time, and contracted staff. Additionally, CMS may add additional samples or case review in order to further investigate potential noncompliance or participant impact. CMS will provide sample selections to the PO two business days before the Personnel review starts.

2. **Review Sample Case Documentation:** CMS will review all sample case file documentation to determine compliance with regulatory requirements including, but not limited to 42 CFR § 460.64, 460.68, 460.71, 460.86, and 460.102. The PO must provide CMS auditors unrestricted access to these records and may be required to upload copies and/or screenshots of the following documents during and/or after the audit.

    - Documentation of any and all background checks conducted
    - Documentation of any and all OIG excluded provider checks conducted
    - Documentation that personnel have current and active licensure, if licensure is required for their position
    - Documentation that staff filling the social worker role on the IDT is a Master's-level social worker
    - Documentation that personnel were cleared for communicable diseases based on a physical examination and/or that a risk assessment was conducted to determine if a physical examination was required
    - Documentation that staff were determined to be free of active Tuberculosis
    - Documentation of completed competencies
    - Documentation of the date staff had direct participant contact
    - Documentation of the date staff began providing participant care independently

3. **Apply Compliance Standards:** The criteria used to evaluate cases include, but are not limited to, the compliance standards in this section. CMS may review requirements not specifically addressed in these questions, including compliance standards noted in other elements if it is determined that there are other requirements not being met. In applying these standards, auditors may request written responses to questions and additional documentation to be submitted by the organization to demonstrate compliance with a particular requirement. Written responses to auditor questions must be submitted using the Request for Additional Information (RAI) template developed by CMS.

    **3.1. Did the PO ensure all personnel were free of criminal convictions that would exclude them from employment, prior to their date of hire?**

    **3.2. Did the PO conduct an OIG exclusion check for all personnel prior to their date of hire?**

    **3.3. Did the PO ensure that personnel were appropriately legally authorized and/or appropriately credentialed, if applicable?**

    **3.4. Did the PO ensure that all personnel with direct participant contact were medically**

**cleared of communicable diseases before engaging in direct participant contact?**

3.4.1. If the PO conducted a physical examination, was the examination completed before personnel engaged in direct participant contact?

3.4.2. If the PO conducted a physical examination, was the examination performed by a licensed physician, nurse practitioner, or physician assistant acting **within the** scope of their authority to practice?

3.4.3. If the PO conducted a risk assessment, was the risk assessment completed before personnel engaged in direct participant contact?

3.4.4. If the PO conducted a risk assessment, did the risk assessment identify when a physical examination was required?

3.4.5. If the PO conducted a risk assessment, did the risk assessment assess whether the individual was exposed to or had any symptoms of COVID–19, Diphtheria, Influenza, Measles, Meningitis, Meningococcal Disease, Mumps, Pertussis, Pneumococcal Disease, Rubella, Streptococcal Infection, and Varicella Zoster Virus?

3.4.6. If the PO conducted a risk assessment, were the results of the risk assessment reviewed by a registered nurse, physician, nurse practitioner, or physician assistant?

3.4.7. If the PO conducted a risk assessment and the results of a risk assessment indicated a physical examination was required, was a physical examination completed as required, before personnel engaged in direct participant contact?

3.4.8. Did the PO determine that all personnel with direct participant contact were free of active Tuberculosis before engaging in direct participant contact?

**3.5. Did the PO ensure that personnel completed competencies before working independently?**

## IV. Compliance and Quality Improvement

1. **Compliance and Quality Improvement Review:** CMS will conduct an interview and review data/documentation with the PO's personnel responsible for the compliance oversight program and development and implementation of the quality improvement program.

2. **Review Documentation:** CMS will review relevant documentation and information related to the PO's compliance oversight and quality improvement programs to determine compliance with regulatory requirements including, but not limited to 42 CFR §§ 460.3, 460.60, 460.62, 460.63, 460.120, 460.122, 460.130, 460.132, 460.134, and 460.136. Upon request, the PO must
produce the following documents.

    - Documentation of the measures developed as part of the PO's compliance oversight program that prevent, detect, and correct noncompliance with regulatory requirements and fraud, waste, and abuse.
    - Documentation of investigations into any compliance issues (if applicable), and any results of those investigations.
    - Documentation of any corrective action taken in response to compliance issues (if applicable).
    - Documentation of compliance issues that were self-reported to CMS, the SAA, or both (if applicable).
    - Documentation that the PO's governing body reviews the quality improvement plan on at least an annual basis
    - Documentation that the PO collected, analyzed, and used data as a part of their Quality Improvement program to improve performance in the following areas:
        - Utilization of PACE services
        - Participant and caregiver satisfaction
        - Participant assessment data including physiological well-being, functional status, cognitive ability, social and behavioral functioning, and quality of life
        - The effectiveness and safety of personnel, including competency of clinical personnel, promptness of service delivery, and achievement of treatment goals
        - Nonclinical areas such as: grievances, appeals, transportation services, meals, and environmental issues
    - Specific actions taken in response to the detected quality issue(s), if applicable
    - Documentation that personnel were involved in the development and implementation of the Quality Improvement program
    - Documentation that the results of quality initiatives were communicated to personnel

3. **Apply Compliance Standards**: The criteria used to evaluate cases include, but are not limited to, the compliance standards in this section. CMS may review requirements not specifically addressed in these questions, including compliance standards noted in other elements if it is
determined that there are other requirements not being met. In applying these standards, auditors may request written responses to questions and additional documentation to be submitted by the organization to demonstrate compliance with a particular requirement. Written responses to auditor questions must be submitted using the Request for Additional Information (RAI) template developed by CMS.

    **3.1. Did the PO adopt and implement an effective compliance oversight program?**

3.1.1. Did the PO develop and implement measures to prevent, detect and correct non-compliance with regulatory requirements and fraud, waste, and abuse?
3.1.2. Did the PO establish and implement procedures and a system for promptly responding to compliance issues?
3.1.3. Did the PO investigate and correct compliance issues promptly?

**3.2. Did the PO develop and implement an effective, data-driven quality improvement program?**

3.2.1. Did the PO maintain, aggregate, and analyze information on grievance proceedings and use this information in the organization's internal quality improvement program?
3.2.2. Did the PO maintain, aggregate, and analyze information on appeals proceedings and use this information in the organization's internal quality improvement program?
3.2.3. Did the PO collect and analyze the minimum required data including: utilization of PACE services, participant and caregiver satisfaction, participant assessment data, the effectiveness and safety of personnel, and nonclinical areas, such as grievances, appeals, transportation services, meals, and environmental issues?
3.2.4. Did the PO use the minimum required data (utilization, participant and caregiver satisfaction, participant assessments, effectiveness and safety of personnel, and nonclinical data) to improve the delivery of PACE services?
3.2.5. Did the PO immediately correct any identified problem that directly or potentially threatens the health and safety of a PACE participant?

**3.3. Did the PO ensure that the appropriate personnel were involved in the development and implementation of Quality Improvement activities and did the PO appropriately disseminate information related to the Quality Improvement activities?**

3.3.1. Did the PO's governing body review the quality improvement plan on at least an annual basis?
3.3.2. Did the PO ensure the medical director was involved in the implementation and oversight of the quality improvement program?
3.3.3. Did the PO designate an individual to coordinate and oversee implementation of quality assessment and performance improvement activities?

# Analysis of Potential Non-Compliance

## I. Request for Additional Information (RAI)

If auditors require additional information to determine compliance with regulatory requirements, auditors may submit Requests for Additional Information (RAIs). RAIs are documents that may include questions, requests for documentation (evidence), or both. POs must provide a written response for each question in an RAI. The written response to each question must be entered directly into the RAI document and the completed document must be uploaded to HPMS in Microsoft Word (.docx) format (unless otherwise specified). POs must submit documentation to corroborate each RAI response or must indicate that documentation is not available to corroborate the response. All supporting documentation provided in response to an RAI, including documentation to corroborate RAI responses and documentation specifically requested by CMS, must be uploaded to HPMS. Documentation must be labeled in accordance with the RAI instructions. Each RAI response, including the written responses to RAI questions and all supporting documentation, is due within 24 hours of the original request unless otherwise noted. All documents associated with each RAI must be uploaded to HPMS in a single ZIP file, whenever possible.

## II. Root Cause Analysis (RCA)

Root Cause Analyses and/or Impact Analyses must be submitted by the PO when they are requested by the CMS audit team. Auditors request a Root Cause Analysis for each potential issue of noncompliance identified during the review. A Root Cause Analysis describes the nature of the issue and addresses why the noncompliance occurred. In order to adequately address why the noncompliance occurred and complete the Root Cause Analysis to the satisfaction of CMS, the PO must conduct a thorough investigation of the issue to determine all contributing factors, both individual and organizational, that led to the noncompliance. The factors that led to the noncompliance must be identified and explained in any Root Cause Analysis submitted to CMS. Root Cause Analyses that restate the circumstances of the noncompliance without analysis of why the noncompliance occurred will not be accepted. POs will have up to 2 business days to complete the requested Root Cause Analysis templates.

## III. Impact Analysis (IA)

When necessary, CMS will also request an Impact Analysis. For each Impact Analysis, CMS will identify the participants that must be reviewed by the organization. The PO must then identify which of those participants were subject to or impacted by the issues of noncompliance generally from the beginning of the data collection period through the audit exit conference. However, in some circumstances, CMS may modify the review scope as determined necessary. POs will have up to 10 business days to complete the requested Impact Analysis templates. CMS may validate the accuracy of the Impact Analysis submission(s). In the event an Impact Analysis cannot be produced, is incomplete, or is determined to be inaccurate, CMS will report that the scope of noncompliance cannot be determined and impacted an unknown number of participants within the PO.

## IV. Additional Records Review

The PO may be required to submit additional case files, documentation, data or provide access to participant medical records after CMS concludes audit fieldwork if CMS determines there is a need to validate the accuracy of information the PO submitted, such as the participant impact reported on an Impact Analysis, or to further investigate quality of care issues or follow-up on other potential noncompliance.

# Appendix

## Appendix A - Programs of All-Inclusive Care for the Elderly (PACE) Record Layouts

Unless otherwise specified by CMS, POs must ensure each universe in the Microsoft Excel (.xlsx) file format with a header row that corresponds to the record layouts shown in Appendix A, Tables 1-7 and the initial collection periods noted below. Excel documents must be placed into a zip file in order to be uploaded into HPMS. CMS may expand the data collection period to ensure sufficient universe size and/or evaluate participant impact or request data in alternatives formats such as Microsoft Text (.txt) files.

| Universe Record Layout | Universe Data Collection Start Date | Universe Data Collection End Date |
|---|---|---|
| Table 1<br>Table 2<br>Table 3<br>Table 4<br>Table 5<br>Table 7 | 6 months prior to the date of the audit engagement letter | Date of the audit engagement letter |
| Table 6 | 3 months prior to the date of the audit engagement letter | Date of the audit engagement letter |

Descriptions and clarifications of what must be included in each submission and data field are outlined in the individual universe record layouts below. Characters are required in all requested fields, unless otherwise specified, and data must be limited to the request specified in each record layout. Use a comma (,) with no spaces to separate multiple values within one field if there is more than one piece of information for a specific field (e.g., PCP, RN, MSW). Do not include any leading or trailing spaces and do not leave any fields blank. CMS will complete data entry tests on all of the universes to ensure there are no blank entries, no merged cells, and data is properly formatted.

Submissions that do not strictly adhere to the record layout specifications will be rejected. If CMS rejects a universe, resubmission of the universe may be requested before and/or after the entrance conference depending on when the data issue was identified.

### Table 1: Service Determination Requests (SDR) Record Layout

- Include all requests processed by the PO as service determination requests during the data collection period, including requests immediately approved by a member of the IDT.
- Submit cases based on the date the notification of the decision to approve or deny the request was first provided or should have been provided (the date the request was initiated may fall outside of the data collection period).

| Column ID | Field Name | Description | Example |
|---|---|---|---|
| A | Participant First Name | First name of the participant. | Jane |
| B | Participant Last Name | Last name of the participant. | Doe |

| Column ID | Field Name | Description | Example |
|---|---|---|---|
| C | Medicare Beneficiary Identifier | If the participant has Medicare, enter the Medicare Beneficiary Identifier. The MBI should only include uppercase alphabetic and numeric characters throughout the 11-digit identifier and is unique to each Medicare enrollee. This number must be submitted excluding hyphens or dashes.<br><br>Enter NA if the participant is not a Medicare beneficiary. | 6M52L458T10 |
| D | Participant ID | The identification number the PO uses to identify the participant. | 12345 |
| E | Person who Submitted the Service Determination Request | Indicate who submitted the request. Valid entries include: participant, designated representative, or caregiver. | Participant |
| F | Date Service Determination Request Made | Date the Service Determination Request was made by the participant, designated representative, or caregiver.<br><br>Submit in MM/DD/YYYY format (e.g., 01/01/2026). | 02/01/2026 |
| G | Date Service Determination Request Brought to the full IDT | Date the service determination request was brought to the full IDT.<br><br>Submit in MM/DD/YYYY format (e.g., 01/01/2026).<br><br>Enter NA if the service determination request was immediately approved by a member of the IDT, or if the service determination request was never brought to the full IDT. | 02/02/2026 |
| H | Extension | Enter Y if the PO took an extension when processing the service determination request.<br><br>Enter N if the PO did not take an extension. | Y |

| Column ID | Field Name | Description | Example |
|---|---|---|---|
| I | Extension Date | Enter the date the IDT made the decision to extend the service determination request notification timeframe.<br><br>Submit in MM/DD/YYYY format (e.g., 01/01/2026).<br><br>Enter NA if the service determination request was not extended. | 02/03/2026 |
| J | Extension Notification Date | Enter the date the IDT notified the participant and/or the designated representative, orally or in writing, of the IDT's decision to extend the service determination request timeframe.<br><br>Submit in MM/DD/YYYY format (e.g., 01/01/2026).<br><br>Enter NA if the service determination request was not extended or if the participant and/or designated representative was not notified of the extension in writing. | 02/03/2026 |
| K | Category of the Request | Provide the category or type of service delivery request. Examples include: Center Days, Eye Wear, Dental, Home Care, Medications, etc. | Home Care |
| L | Description of the Request | Provide a description of the service determination request. | The participant requested an increase in home care from 1x per day, 5 days per week to 2x per day, 5 days per week. |

| Column ID | Field Name | Description | Example |
|---|---|---|---|
| M | Date of the first assessment completed in response to the service determination request | Enter the date the first assessment was completed in response to the service determination request.<br><br>Submit in MM/DD/YYYY format (e.g., 01/01/2026).<br><br>Enter NA if no assessment was completed in response to the service determination request (e.g., do not include the date of the participant's latest semi-annual assessments if they were not done in response to the requested services). | 02/01/2026 |
| N | Date of the last assessment completed in response to the service determination request | Enter the date of the last assessment completed in response to the service determination request. The date of the first and last assessment will be the same if there was only one assessment completed in response to the service determination request.<br><br>Submit in MM/DD/YYYY format (e.g., 01/01/2026).<br><br>Enter NA if no assessment was completed in response to the service determination request (e.g., do not include the date of the participant's latest semi-annual assessments if they were not done in response to the requested services). | 02/03/2026 |
| O | How many assessments were completed in response to the service determination request? | Enter the total number of assessments completed in response to the service determination request.<br><br>Enter NA if no assessment(s) were completed in response to the service determination request (e.g., do not include the date of the participant's latest semi-annual assessments if they were not done in response to the requested services). | 3 |

| Column ID | Field Name | Description | Example |
|---|---|---|---|
| P | Assessment(s) In-person | Enter Y if all assessments that were completed were conducted in-person.<br><br>Enter N if any assessments that were completed were not conducted in-person.<br><br>Enter NA if no assessment was completed in response to the service determination request. | Y |
| Q | Request Disposition | Valid entries include: Approved, Denied, Partially Denied, or Withdrawn.<br><br>Enter Approved if the request was approved, in full, as requested.<br><br>Enter Denied if all of the requested services were denied.<br><br>Enter Partially Denied if the request was not fully approved as requested and/or the PO provided a modified or alternative service to the participant.<br><br>Enter Withdrawn if the participant and/or the designated representative requested to withdraw the service determination request prior to the organization rendering a decision. | Partially Denied |
| R | Immediate Approval | Enter Y if a member of the IDT was able to approve the service determination request in full at the time the request was made.<br><br>Enter N if a member of the IDT was not able to approve the service determination request in full at the time the request was made. | N |

| Column ID | Field Name | Description | Example |
|---|---|---|---|
| S | For Immediate Approvals, which IDT member approved the request? | For Immediate Approvals, which IDT member received and immediately approved the request? Valid entries include: PCP, RN, MSW, Home Care Coordinator, OT, PT, Dietitian, Recreational Therapist/Activities Coordinator, Personal Care Attendant, Transportation, Center Manager, Other.<br><br>Enter NA if the request was not immediately approved. | NA |
| T | Reason for Denial | If the request was denied or partially denied, please enter a brief explanation of why the request was denied.<br><br>Enter NA if the request was approved or withdrawn. | Participant needed assistance with chore services, which the IDT assessed could be completely with 4 additional hours of homecare per week. |
| U | Date of Oral Notification | Enter the date the PO provided oral notification, to the participant and/or the designated representative, of the decision (e.g., approve or deny the request).<br><br>Submit in MM/DD/YYYY format (e.g., 01/01/2026).<br><br>Enter NA if oral notification was not provided or not documented. | 02/03/2026 |
| V | Date of Written Notification | Enter the date the PO provided written notification, to the participant and/or designated representative, of the decision (e.g., approve or deny the request).<br><br>Submit in MM/DD/YYYY format (e.g., 01/01/2026).<br><br>Enter NA if written notification was not provided or not documented. | 02/03/2026 |

| Column ID | Field Name | Description | Example |
|---|---|---|---|
| W | Date Service Provided | Enter the date that the approved service was provided to the participant. Please enter a date for any request that was fully approved or partially approved (partially denied).<br><br>Submit in MM/DD/YYYY format (e.g., 01/01/2026).<br><br>Enter NA if the request was denied, withdrawn or if there was no documentation of the effectuation (provision) of the service. | 02/04/2026 |

### Table 2: Appeal Requests (AR) Record Layout

- Include all requests processed as standard or expedited appeals received by the PO during the data collection period.
- Exclude appeals from external reviewers (i.e., Medicaid appeals).
- Submit cases based on the date the notification of the decision was first provided or should have been provided (the date the request was initiated may fall outside of the data collection period).

| Column ID | Field Name | Description | Example |
|---|---|---|---|
| A | Participant First Name | First name of the participant. | John |
| B | Participant Last Name | Last name of the participant. | Smith |
| C | Medicare Beneficiary Identifier | If the participant has Medicare, enter the Medicare Beneficiary Identifier.<br><br>The MBI contains uppercase alphabetic and numeric characters throughout the 11-digit identifier and is unique to each Medicare enrollee. This number must be submitted excluding hyphens or dashes.<br><br>Enter NA if the participant is not a Medicare beneficiary. | 6M52L458T10 |
| D | Participant ID | The identification number the PO uses to identify the participant. | 12345 |
| E | Enrollment Type | Enter the participant's current enrollment type. Valid entries include: Medicare only, Medicaid only, Dual Eligible, and Private Pay. | Dual Eligible |
| F | Person who Submitted the Appeal | Indicate who submitted the appeal. Valid entries include: participant or designated representative. | Participant |
| G | Date Appeal Received | Date the appeal was received by the PO.<br><br>Submit in MM/DD/YYYY format (e.g., 01/01/2026). | 03/01/2026 |
| H | Time Appeal Received | Enter the time the expedited appeal was received by the PO.<br><br>Submit in HH:MM format (e.g., 23:54).<br><br>Enter NA for standard appeals (i.e., if the appeal was not expedited). | NA |

| Column ID | Field Name | Description | Example |
|---|---|---|---|
| I | Expedited | Enter Y if the appeal was processed as expedited.<br><br>Enter N if the appeal was not expedited (i.e., was processed as a standard appeal). | N |
| J | Extension | Enter Y if the PO took an extension when processing an expedited appeal.<br><br>Enter N if the PO did not take an extension on an expedited appeal.<br><br>Enter NA if the appeal was not expedited (i.e., was processed as a standard appeal). | NA |
| K | Category of the Appeal/ Appeal Type | Provide the category or type of appeal request. Valid entries include: Decreased Center Attendance, Denial of Enrollment, Dentures, Durable Medical Equipment, Glasses, Hearing Aid, Home Modification(s), Increased Center Attendance, Increased Home Care, Involuntary Disenrollment, Medical Procedure, Medical Supplies, Nursing Facility Placement - Long Term, Nursing Facility Placement – Respite, Nursing Facility Placement - Short Term, Specialist Consultation or Visit, Surgical Procedure, Transportation, or Other | Glasses |
| L | Description of the Appeal/ Specific Issue | Provide a description of the appeal. | The participant requested prescription bifocals. |
| M | Third-party reviewer or committee credentials | Enter the credentials of the third-party reviewer or committee that was involved in the review of this appeal. For a committee review, list all committee members' credentials. If the committee reviewing the appeal was another PO's full IDT, enter "Another PO's IDT".<br><br>Note: If the committee was another PO's IDT, but was not the full IDT, identify the credentials of all individuals that were involved as third-party reviewers.<br><br>Enter NA if the appeal was not reviewed by a third-party reviewer or committee. | Another PO's IDT |

| Column ID | Field Name | Description | Example |
|---|---|---|---|
| N | Request Disposition | Valid entries include: Approved, Denied, Partially Denied or Withdrawn.<br><br>Enter Approved if all of the requested services were approved as requested.<br><br>Enter Denied if all of the requested services were denied.<br><br>Enter Partially Denied if the request was not fully approved as requested and/or the PO provided a modified or alternative service to the participant.<br><br>Enter Withdrawn if the participant and/or designated representative requested to withdraw the appeal prior to a decision being rendered. | Approved |
| O | Reason for Denial | If the appeal was denied or partially denied, please enter a brief explanation of why the request was denied.<br><br>Enter NA if the appeal was approved or withdrawn. | Glasses were denied because the participant was assessed to have 20/20 vision. |
| P | Date of Written Notification | Enter the date the PO provided written notification to the participant or other representative (e.g. family or caregiver) of the third-party's decision to approve or deny the appeal.<br><br>Submit in MM/DD/YYYY format (e.g., 01/01/2026).<br><br>Enter NA if written notification was not provided or not documented. | 03/10/2026 |
| Q | Time of Written Notification | Enter the time the PO provided written notification to the participant or other representative (e.g. family or caregiver) of the third-party's decision to approve or deny the expedited appeal.<br><br>Submit in HH:MM format (e.g., 23:59).<br><br>Enter NA if the appeal was not expedited (i.e., was processed as a standard appeal) or if written notification was not provided. | NA |

| Column ID | Field Name | Description | Example |
|---|---|---|---|
| R | Date Service Provided | Enter the date that the approved service was provided to the participant. Please enter a date for any appeal that was fully approved or partially approved (partially denied).<br><br>Submit in MM/DD/YYYY format (e.g., 01/01/2026).<br><br>Enter NA if the appeal was not approved (i.e., denied) or if the service was not provided or if there was no documentation of the effectuation (provision) of the service. | 05/01/2026 |

### Table 3: Grievance (GR) Record Layout

- Include all complaints processed as grievances during the data collection period.
- Submit grievances based on the date the PO resolved or should have resolved the grievance (the date the complaint was initiated may fall outside of the data collection period).

| Column ID | Field Name | Description | Example |
|---|---|---|---|
| A | Participant First Name | First name of the participant. | Jane |
| B | Participant Last Name | Last name of the participant. | Doe |
| C | Medicare Beneficiary Identifier | If the participant has Medicare, enter the Medicare Beneficiary Identifier.<br><br>The MBI contains uppercase alphabetic and numeric characters throughout the 11-digit identifier and is unique to each Medicare enrollee. This number must be submitted excluding hyphens or dashes.<br><br>Enter NA if the participant is not a Medicare beneficiary. | 6M52L458T10 |
| D | Participant ID | The identification number the PO uses to identify the participant. | 123456 |
| E | Person who submitted the Grievance | Indicate who submitted the complaint. Valid entries include: participant, family member, designated representative, or caregiver. | Participant |
| F | Date Grievance Received | Date the grievance was received by the PO. Submit in MM/DD/YYYY format (e.g., 01/01/2026). | 04/01/2026 |
| G | Category of the Grievance/ Grievance Type | Provide the category or type of grievance. Valid entries include: Activities, Communication, Contracted Specialist, Contracted Facility (Hospital, SNF, etc.), Dietary, Disenrollment, Enrollment, Home Care, Marketing, Medical Care, Medication, PACE Services, Supplies, Transportation, or Other. | Contracted Specialist |
| H | Description of the Grievance/ Specific Issue | Provide a description of the grievance. If multiple issues were included in the complaint, please provide a brief description of each issue in the grievance. | The participant was dissatisfied with the time it took to arrange a cardiology appointment. |

| Column ID | Field Name | Description | Example |
|---|---|---|---|
| I | Quality of Care | Were any of the issues within the grievance related to quality of care concerns?<br><br>A quality of care concern means a concern that care provided did not meet a professionally recognized standard of health care.<br><br>Enter Y if any of the issues in the grievance related to quality of care concerns.<br><br>Enter N if none of the issues in the grievance related to quality of care concerns. | N |
| J | Investigation Required | Was an investigation of one or more issues within the grievance required?<br><br>Enter Y if any issues in the grievance required an investigation.<br><br>Enter N if no issues in the grievance required an investigation. | Y |
| K | Corrective Action Required | Was corrective action taken as a result of the grievance?<br><br>Enter Y if corrective action was required and taken.<br><br>Enter N if corrective action was required and not taken.<br><br>Enter NA if corrective action was not required. | N |
| L | QIO | Did the participant, family member, designated representative, or caregiver file a complaint with the QIO related to this grievance or any portion of this grievance?<br><br>Enter Y if a complaint was filed with the QIO related to this grievance.<br><br>Enter N if no complaints were filed with the QIO related to this grievance. | N |
| M | Date of Grievance Resolution | Date the PO resolved the grievance. Submit in MM/DD/YYYY format.<br><br>Enter NA if the grievance was not resolved. | 04/08/2026 |

| Column ID | Field Name | Description | Example |
|---|---|---|---|
| N | Notification Preference | Did the individual who submitted the grievance have a preference for how notification was provided? Valid entries include: oral, written, both, withhold, no preference. | oral |
| O | Date of Oral Notification | Enter the date the PO provided oral notification (if applicable) to the individual who submitted the grievance.<br><br>Submit in MM/DD/YYYY format (e.g., 01/01/2026).<br><br>Enter NA if oral notification was not provided or not documented. | 04/11/2026 |
| P | Date of Written Notification | Enter the date the PO provided written notification (if applicable) to the individual who submitted the grievance.<br><br>Submit in MM/DD/YYYY format (e.g., 01/01/2026).<br><br>Enter NA if written notification was not provided or not documented. | NA |

### Table 4: List of Personnel (LOP) Record Layout

- Include all personnel hired or employed during the data collection period (i.e., volunteer, part- time, full time, and contracted staff).
- Include only those contracted employees that provide care/services to participants in the participant's home, at the PACE center (or ACS) or when transporting participants. This includes all individuals who transported participants and all individuals who provided home care to participants.
- Exclude employees of institutional contracted providers such as nursing facilities and hospitals.
- Exclude all personnel terminated prior to the data collection period.

| Column ID | Field Name | Description | Example |
|---|---|---|---|
| A | First Name | First name of the employee or contracted individual. | John |
| B | Last Name | Last name of the employee or contracted individual. | Smith |
| C | Job Title | Provide the job title of the employee. Examples: Home Health Aide, Physical Therapist, etc. | Physical Therapist |
| D | Date of Hire | Date the employee or contracted individual was hired by the PO. Submit in MM/DD/YYYY format (e.g., 01/01/2026). | 12/01/2026 |
| E | Date of Termination | Date the employee was terminated or resigned from the PO. Submit in MM/DD/YYYY format (e.g., 01/01/2026).<br><br>Enter NA if the employee is still working for the PO. | NA |
| F | Type of Employment | Provide the type of employment for the employee. Valid entries include: Contract, Full-time, Part-time, Volunteer, or Other. | Full-time |
| G | Direct Participant Contact | Enter Y if the employee had direct participant contact during the data collection period. For audit purposes, an employee or contractor is considered to have had direct contact with a participant if the employee or contractor had the ability to transmit any type of infectious disease to the participant.<br><br>Enter N if the employee did not have direct participant contact during the data collection period. | Y |
| H | License | Enter Y if the employee requires a license in order to perform their duties with the PO.<br><br>Enter N if the employee does not require a | Y |

| Column ID | Field Name | Description | Example |
|---|---|---|---|
| | | license in order to perform their duties with the PO. | |
| I | IDT Member | Enter Y if the employee is a part of the PO's IDT. If a PO has multiple IDTs, the PO should enter Y if this individual is a member of any IDT.<br><br>Enter N if the employee is not a member of any of the PO's IDTs. | Y |
| J | IDT Role | Enter the discipline(s) the individual represents on the IDT. Valid entries include: PCP, RN, MSW, Home Care Coordinator, OT, PT, Dietitian, Recreational Therapist/Activities Coordinator, Personal Care Attendant, Transportation, Center Manager, Other.<br><br>Enter NA if the individual is not a part of an IDT. | PT |

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

- Include all participants enrolled in the PO at some point during the data collection period.
- Exclude all participants disenrolled prior to the start of the data collection period.
- POs may use any and all information available to them when populating these fields, including participant medical records, claims data, and any other participant-specific information the PO may maintain.

| Column ID | Field Name | Description | Example |
|---|---|---|---|
| A | Participant First Name | First name of the participant. | Juan |
| B | Participant Last Name | Last name of the participant. | Doe |
| C | Medicare Beneficiary Identifier | If the participant has Medicare, enter the Medicare Beneficiary Identifier.<br><br>The MBI contains uppercase alphabetic and numeric characters throughout the 11-digit identifier and is unique to each Medicare enrollee. This number must be submitted excluding hyphens or dashes.<br><br>Enter NA if the participant is not a Medicare beneficiary. | 6M52L458T10 |
| D | Participant ID | The identification number the PO uses to identify the participant. | 1234 |
| E | PACE Center | If the PO has more than one center, enter the name of the participant's assigned center.<br><br>If there is only one center, enter NA. | Center 1 |
| F | Date of Enrollment | Date the participant was enrolled in the PO. Submit in MM/DD/YYYY format (e.g., 01/01/2026). | 05/01/2018 |
| G | Date of Disenrollment | Date the participant disenrolled from the PO. Submit in MM/DD/YYYY format (e.g., 01/01/2026).<br><br>Enter NA if the participant is still enrolled. | NA |
| H | Reason for Disenrollment | Provide the reason for the disenrollment.<br><br>Enter NA if the participant is still enrolled. | Participant wanted to receive cardiac care from a non-contract provider. |
| I | Enrollment Type | Enter the participant's current enrollment type. Valid entries include: Medicare only, Medicaid only, Dual Eligible, Private Pay. | Dual Eligible |
| J | Participant's Preferred Language | Enter the participant's preferred language to receive communications from the PO. | Spanish |
| **Column ID** | **Field Name** | **Description** | **Example** |

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|---|---|---|---|
| K | Participant's Current Living Situation | Describe the participant's current living arrangement. Valid entries may include, but are not limited to: home with family member/ caregivers, home without family member/ caregiver, SNF/NF, ALF, etc. | Resides in home with a family member caregiver |
| L | Change in Living Situation | Identify whether the participant's living arrangement changed significantly during the data collection period. For example: the participant went from living in the community to living in a facility (ALF, NH, etc.), or vice versa; or if the participant went from living with family to living alone.<br><br>Enter Y if the participant's living arrangement changed significantly during the data collection period.<br><br>Enter N if the participant's living arrangement did not change significantly during the data collection period. | N |
| M | Number of Hospital Admissions/ Observations | Enter the number of hospital admissions and/or observations that occurred during the data collection period.<br><br>This includes:<br>• Admissions/observations from an emergency room<br>• Direct admissions | 2 |
| N | 30-Day Hospital Readmissions | Enter Y if the participant had an unplanned hospital readmission, for any cause, within 30 days of discharge from the previous admission, during the data collection period.<br><br>Enter N if the participant did not have an unplanned hospital readmission, for any cause, within 30 days of discharge from the previous admission during the data collection period. | Y |
| O | Number of Emergency Room Visits | Enter the number of emergency room visits that occurred during the data collection period. Include ER visits that resulted in a hospital admission or observation. | 3 |

| Column ID | Field Name | Description | Example |
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|---|---|---|---|
| P | Hospitalization / Emergency Room Reason | Was the participant diagnosed with hypoglycemia, hyperglycemia, internal bleeding, sepsis, medication overdose, or decreased oxygen saturation in the emergency room or on admission to the hospital?<br><br>Enter Y if the participant went to the ER or was admitted to the hospital (or observed at the hospital) with a primary or secondary diagnosis of hypoglycemia, hyperglycemia, internal bleeding, sepsis, medication overdose, or decreased oxygen saturation.<br><br>Enter N if the participant did not go to the ER or was not admitted to the hospital (or observed at the hospital with a primary or secondary diagnosis of hypoglycemia, hyperglycemia, internal bleeding, sepsis, medication overdose,<br>or decreased oxygen saturation). | Y |
| Q | Number of SNF/NF Admissions | Enter the number of skilled nursing facility/nursing facility admissions that occurred during the data collection period. This should include all SNF/NF admissions for any cause, including admission as a result of a request for services. | 1 |
| R | Specialist Consultations/ Visits | Was a consultation/visit with any of the following types of specialties approved by the IDT and/or ordered by a PCP during the data collection period?<br><br>• Cardiology<br>• Endocrinology<br>• Gastroenterology<br>• Infectious Disease<br>• Mental Health<br>• Oncology<br>• Ophthalmology<br>• Oral Maxillofacial Surgery<br>• Pulmonary Medicine<br>• Rheumatology<br>If Yes, enter **each** type of specialty. If No, enter N. | Cardiology, Oncology, Rheumatology |

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|---|---|---|---|
| S | Diagnoses | Did the participant have any of the following diagnoses/conditions during the data collection period?<br><br>• AIDS<br>• Anemia<br>• Auto-immune disorder (any type – specify the type in the response)<br>• Cancer (any type – specify the type in the response)<br>• Cellulitis<br>• Cerebrovascular Accident (CVA)<br>• Chronic Obstructing Pulmonary Disease (COPD)<br>• Congestive Heart Failure (CHF)<br>• Current Drug Abuse<br>• Dementia<br>• Diabetes Mellitus<br>• Hepatitis C<br>• Human immunodeficiency virus (HIV)<br>• Mental Illness (any type- specify the type in the response)<br>• Multiple Sclerosis<br>• Myasthenia Gravis<br>• Necrotizing Fasciitis<br>• Pneumonia<br>• Psychosis<br>• Sepsis<br><br>If Yes, enter each diagnosis and where applicable specify the type.<br><br>If No, enter N. | AIDS, Hepatitis C, Cancer - lung |

| Column ID | Field Name | Description | Example |
|---|---|---|---|
| T | CHF Exacerbation | Enter Y if the participant was diagnosed with a CHF exacerbation during the data collection period.<br><br>Enter N if the participant was not diagnosed with a CHF exacerbation or the participant did not have a diagnosis of CHF during the data collection period. | Y |
| U | COPD Exacerbation | Enter Y if the participant was diagnosed with a COPD exacerbation during the data collection period.<br><br>Enter N if the participant was not diagnosed with a COPD exacerbation or the participant did not have a diagnosis of COPD during the data collection period. | N |
| V | Received Home Care | Enter Skilled if the participant ever received either skilled home care or a combination of skilled and unskilled home care during the data collection period.<br><br>Enter Unskilled if the participant only received unskilled home care during the data collection period.<br><br>Enter NA if the participant did not receive home care during the data collection period. | Skilled |
| W | Assistance with Administering Medications | Enter Y if an employee/contracted employee administered medication to the participant in the participant's home and/or the PACE center at any time during the data collection period.<br><br>Enter N if an employee/contracted employee did not administer medication to the participant in the participant's home and/or the PACE center at any time during the data collection period. Prompting/medication reminders are not considered medication administration assistance. | Y |

| Column ID | Field Name | Description | Example |
|---|---|---|---|
| X | Current Center Attendance | Enter the number of days per month the participant is scheduled to attend the PACE center at the time the universe is completed. Enter 0 if the participant is not scheduled to attend the PACE center or had disenrolled (voluntarily, involuntarily or deceased) at the time the universe is completed. Do not include attendance at an Alternative Care Setting (ACS) in this field. | 2 |
| Y | Number of Falls with Injury | Enter the number of falls with injury the participant had that met the criteria for a root cause analysis per the PACE Quality Monitoring requirements during the data collection period. | 1 |
| Z | Number of Pressure Ulcers | Enter the number of pressure ulcers the participant had that met the criteria for a root cause analysis per the PACE Quality Monitoring requirements during the data collection period. | 1 |
| AA | Number of Confirmed Abuse Reports | Enter the number of confirmed abuse reports that met the criteria for a root cause analysis per the PACE Quality Monitoring requirements during the data collection period. | 0 |
| AB | Unexpected Death | Enter Y if the participant experienced an unexpected death that met the criteria for a root cause analysis per the PACE Quality Monitoring requirements during the data collection period.<br><br>Enter N if the participant did not experience an unexpected death that met the criteria for a root cause analysis per the PACE Quality Monitoring requirements during the data collection period. | N |
| AC | Functional Decline | Enter Y if the participant experienced a functional decline, as defined by the PO, during the data collection period.<br><br>Enter N if the participant did not experience a functional decline during the data collection period. | N |

| Column ID | Field Name | Description | Example |
|---|---|---|---|
| AD | Incontinence | Enter Y if the participant was routinely incontinent during the data collection period.<br><br>Enter N if the participant was not routinely incontinent or had acute/transient incontinence during the data collection period. | Y |
| AE | Indwelling Catheter | Enter Y if the participant had an indwelling catheter during the data collection period.<br><br>Enter N if the participant did not have an indwelling catheter during the data collection period. | N |
| AF | Restraints | Enter Y if physical or chemical restraints were used on the participant at any point during the data collection period,<br><br>Enter N if physical or chemical restraints were not used on the participant at any point during the data collection period. | N |
| AG | Dialysis | Enter Y if the participant received dialysis during the data collection period.<br><br>Enter N if the participant did not receive dialysis during the data collection period. | N |
| AH | Palliative Care, Comfort Care, or End-of-Life Services Initiated | Enter Y if palliative care, comfort care, or end-of-life care services were initiated during the data collection period.<br><br>Enter N if palliative care, comfort care, or end-of-life care services were not initiated during the data collection period. | Y |
| AI | Wound Care | Enter Y if the participant received regularly scheduled wound care during the audit review period. Do not include one time instances of wound care.<br><br>Enter N if the participant did not receive regularly scheduled wound care. | Y |

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|---|---|---|---|
| AJ | Type of Disenrollment | Valid entries include: Voluntary, Involuntary, and Deceased. Enter NA if the participant is still enrolled. | Voluntary |

### Table 6: On-Call (OC) Record Layout

- Include all after hour calls received by the PO during the data collection period.
- Exclude all calls received during normal business hours.

| Column ID | Field Name | Description | Example |
|---|---|---|---|
| A | Participant First Name | First name of the participant. | Jane |
| B | Participant Last Name | Last name of the participant. | Doe |
| C | Medicare Beneficiary Identifier | If the participant has Medicare, enter the Medicare Beneficiary Identifier.<br><br>The MBI contains uppercase alphabetic and numeric characters throughout the 11-digit identifier and is unique to each Medicare enrollee. This number must be submitted excluding hyphens or dashes.<br><br>Enter NA if the participant is not a Medicare beneficiary. | 6M52L458T10 |
| D | Participant ID | The identification number the PO uses to identify the participant. | 1234 |
| E | Caller Information | Identify who made the call (e.g., participant, daughter, spouse, caregiver). | Daughter |
| F | Date of Call | Date the call was received. Submit in MM/DD/YYYY format (e.g., 01/01/2026). | 02/01/2026 |
| G | Time of Call | Time the call was received. Submit in HH:MM format (e.g., 23:54). | 20:15 |
| H | Call Description/ Reason For Call | Provide a description of the reason for the call. | The participant called to report chest pain. Described the pain as persistent and radiating down left arm. |
| I | Response to Call | Provide a description of the response to the call as it relates to the participant (e.g., did the PO send someone to the participant's home, did the participant go to the hospital). | Called EMS for transport to hospital. |

### Table 7: Contracted Entities and Providers (CEP) Record Layout

- Include all entities contracted to provide services to PACE participants during the data collection period. This includes, but is not limited to:
  - All specialists, both medical and non-medical, including at a minimum all medical specialists listed under 460.70(a);
  - Home care providers, both skilled and non-skilled (name of home care companies, not individual employees);
  - Nursing facilities, short and long-term;
  - Hospitals and urgent care facilities
  - Other contracted residential facilities such as assisted living facilities, boarding homes, etc.
- Include all entities with pending contracts at the time the universe is completed.
- Include each distinct specialty or facility type (column B) for a given practice or facility (column A)

on a separate row.

- Do not include any entities whose contracts were terminated prior to the start of the data collection period.

| Column ID | Field Name | Description | Example |
|---|---|---|---|
| | Provider/ Practice/ Facility Name | Name of the provider, practice or facility.<br><br>For the purposes of this field, provider includes specialists, home care companies, hospitals, urgent care, and facility includes contracted nursing facilities and other contracted residential facilities. | Dr. Jane Smith, MD |
| | Specialty or Facility Types | Description of the specialty type or facility type associated with the provider/practice or facility name in column A.<br><br>If the PACE organization has a contract with one provider, practice, or facility to provide multiple types of specialist services or other services, enter each specialty or service in a new row.<br><br>For example, if the PACE organization is contracted with a hospital system to provide oncology, gastroenterology, and pulmonology, enter each of these specialties in a separate row with the same facility listed in column A. | Oncology |
| | Contract Status | Enter Active if a contract is in effect with the provider / facility at the time of the universe submission.<br><br>Enter Terminated if a contract was in effect for some portion of the data collection period but is terminated at the time of universe submission.<br><br>Enter Pending if the PO is currently attempting to establish a contract with the provider / facility but the contract is not in effect at the time of universe submission. | Active |
| | Contract Start Date | Enter the date the contract became effective.<br><br>Enter NA if the contract status is currently pending. | 11/01/2019 |
| | Contract Termination Date | Enter the date the contract was terminated.<br><br>Enter NA if the contract status is currently active or pending. | NA |

| Column ID | Field Name | Description | Example |
|---|---|---|---|
| F | Limitations / Restrictions | Enter Y if the contracted entity or provider implemented or imposed any blanket restrictions or limitations on services that impacted participants at any point during the data review period. Examples of limitations include: The provider placed a cap on the number of PACE participants they will accept, or the provider did not accept new PACE participants.<br><br>If there were no limitations or restrictions on the availability of services from contracted entities or providers, at any point during the data collection period, enter N.<br><br>Enter NA if the contract status is currently pending. | Y |
| | | | |

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According to the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it displays a valid OMB control number. The valid OMB control number for this information collection is 0938-1327. This information collection will allow CMS to conduct comprehensive reviews of PACE organizations to ensure compliance with regulatory requirements. The time required to complete this information collection is estimated at 780 per response, including the time to review instructions, search existing data resources, gather the data needed, to review and complete the information collection. This information collection is mandatory per CMS's authority under Section 1894 and 1934 of the Social Security Act and implementing regulations at 42 CFR § 460.190 and 460.194, which state that CMS, in conjunction with the State Administering Agency (SAA), audit PACE organizations (POs) annually for the first 3 contract years (during the trial period), and then on an ongoing basis following the trial period. Additionally, per § 460.200(a) PACE organizations are required to collect data, maintain records, and submit reports as required by CMS and the State administering agency. If you have comments concerning the accuracy of the time estimate(s) or suggestions for improving this form, please write to: CMS, 7500 Security Boulevard, Attn: PRA Reports Clearance Officer, Mail Stop C4-26-05, Baltimore, Maryland 21244-1850.