



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

Audit Protocol

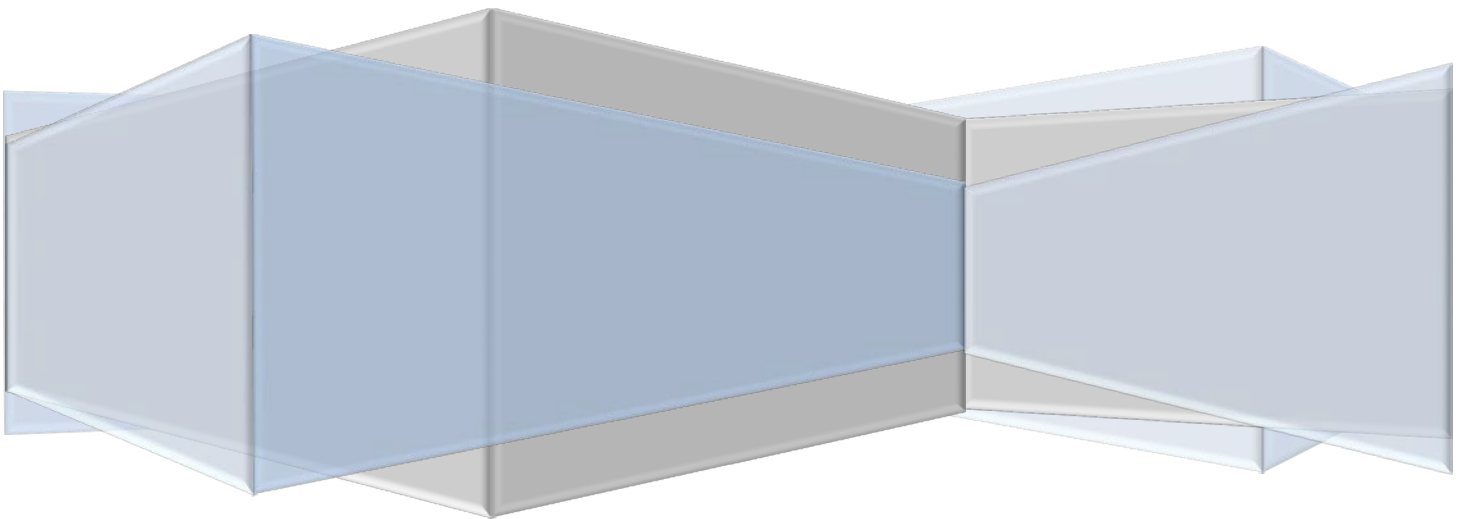


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Audit Purpose and Scope

1. **Purpose**: To evaluate PACE organizations' (POs') compliance with regulatory requirements in 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' remote review includes, but is not limited to, CMS accessing and obtaining information from the PO's electronic medical records 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 noncompliance 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 demonstrating the measures developed as part of the PO's compliance oversight program to prevent, detect, and correct noncompliance with regulatory requirements and fraud, waste, and abuse

2.2.2. Monitoring Reports:

- For 30 participants selected by CMS at the time the engagement letter is issued: Reports that detail the PO's monitoring and tracking of all services across all care settings that were ordered, approved, or care planned during the data collection period. At a minimum, reports should be arranged in

alphabetical order by participant last name and include:

- Participant first and last name (provided by CMS)
- Medicare Beneficiary Identifier (MBI) (if applicable)
- Participant ID
- Date the service was ordered, approved, or care planned
- Description of the service ordered, approved or care planned
- Date the service was provided

2.2.3. 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. 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 two business days before the SDAG 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: identifying the request, processing the request, notifying participants of the IDT decision, and providing any approved services. 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 should comprehensively address the applicable documentation requests below with documentation that is either (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]”). For any required documentation that is unavailable, the PO must include a note in the case file that states the required documentation does not exist. For example, if the PO does not have documentation to support what was communicated to a participant during oral notification of a denied service determination request, then the PO would include a page in the case file that states the PO does not have a record of the oral notification conversation.

2.1. For service determination requests:

Documentation of the initial request

- Documentation of the initial request (received in writing, orally, etc.), including all system notes, progress notes, logs, written communication from the participant, designated representative, and/or caregiver, and any other data, such as the date the

request was made and who made the request, related to the receipt of the service determination request

Documentation of reassessments conducted in response to the service determination request

- All assessments conducted in response to the service determination request and all IDT notes and discussions regarding the assessments, including:
 - Documentation of the date(s) of the assessment(s)
 - Documentation of which IDT member(s) were selected by the IDT to perform the assessment(s) and which IDT member(s) performed the assessment(s)
 - Documentation showing that the assessment(s) was/were conducted in-person, if applicable
 - Documentation of the contents of the assessment(s), such as the evaluation of the participant's medical, physical, emotional, and social needs

Documentation of full IDT involvement in the service determination request review (not applicable to immediate approvals by IDT member)

- Documentation of the IDT's review of the service determination request, including:
 - Documentation of all IDT members involved in the review of the service determination request
 - Documentation identifying the date(s) the request was reviewed by the IDT
 - Documentation that the IDT considered all relevant information when evaluating the service determination request
 - Documentation of the IDT's decision to approve, deny, or partially deny the request

Documentation for service determination requests with extended processing timeframes

- If the extension was requested by the participant, the participant's designated representative, or the participant's caregiver, documentation of their request for an extension
- If the extension was taken because the IDT needed additional information, provide documentation of the circumstances that led to the extension and how the extension was in the participant's best interest
- Documentation demonstrating when the IDT extended the review/notification timeframe
- A copy of the written notice of extension provided to the participant, the participant's designated representative, or caregiver

Documentation of service determination request notifications based on request disposition

- Denied and partially denied service determination requests:
 - Documentation of the oral and written notification provided to the participant or designated representative, including the specific reason for the denial and the participant's appeal rights
- Approved service determination requests:
 - Documentation of oral and/or written notification provided to the participant or designated representative, including an explanation of the conditions of the approval and when the participant may expect to receive the approved service(s)

- Any other reports, system notes, or logs that document denial or approval of the request and participant notification

Documentation of the provision of services

- For all approved and partially denied service determination requests, documentation showing that all approved services were provided as expeditiously as the participant's health condition requires, considering the participant's medical, physical, emotional, and social needs (e.g., an annotation in the participant's medical record, assessments, progress notes)

2.2. For appeals:

- Documentation of the initial appeal request (received in writing, orally, etc.), including any system notes, progress notes, logs, or other data related to the appeal request
- All case notes, progress notes and assessments related to the appeal, including the underlying service determination request denial
- Documentation that the participant was given an opportunity to present evidence in-person as well as in writing
- Documentation indicating why an appeal was expedited (if applicable)
- Documentation indicating why an expedited appeal was extended, including the participant's request for an extension or documentation the PO justified the extension to the SAA (if applicable)
- Documentation identifying the third-party reviewers and their credentials
- Documentation of the third-party reviewer decision
- **Note:** Upon request by CMS, POs may be asked for the documentation provided to the third-party reviewer or committee reviewer that explained the PACE benefit structure, including services that must be provided and how determinations must be consistent with relevant laws and regulations. This information does not need to be routinely included in appeal case files.

Documentation of appeal notifications based on the appeal disposition

- Partially and fully adverse appeal decisions:
 - Documentation of the written notification provided to all parties involved in the appeal, including the specific reason(s) for the denial, and their external appeal rights available through Medicare and/or Medicaid
- Favorable appeal decisions:
 - Documentation of written notification of the decision, including explanation of the conditions of approval in understandable language
 - If oral notification was provided, documentation of the oral notification
- Any other reports, system notes, or logs that document denial or approval of the request and participant notification

Documentation of the provision of services

- Documentation showing that all approved services were provided as expeditiously as the participant's health condition required (e.g., an annotation in the participant's medical record, assessments, progress notes)
- 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

2.3. For grievances:

- Documentation of the initial complaint including system notes, progress notes, logs, or other data related to the complaint classified by the PO as a grievance
- Documentation detailing each issue in the grievance
- Documentation of all supplemental information submitted by the participant and/or their caregiver
- Documentation showing the steps the PO took to resolve each issue identified in the grievance, such as documentation of communication with other individuals and organizations internal and external to the PO that the PO contacted in order to resolve the grievance
- Documentation describing the final resolution for each grievance issue
- Documentation showing resolution notification of each issue identified in the grievance to the participant and/or their representative
 - If written notification was provided, a copy of the written resolution letter and documentation of the date/time the letter was mailed
 - If oral notification was provided, a copy of progress notes and/or other documentation of the notification including the date the notification was provided
- Documentation to demonstrate that any necessary follow-up actions identified by the PO when processing the grievance were followed up as appropriate.

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.

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 full IDT review the service determination request, if applicable?
- 3.1.3. Did the PO ensure that the appeal was reviewed by an impartial and appropriately credentialed third-party reviewer or committee?
- 3.1.4. 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?
- 3.1.5. Did the PO conduct in-person assessments in response to a service determination request the IDT expected to deny or partially deny?
- 3.1.6. Did the in-person assessment evaluate whether the requested service was necessary to meet the participant's medical, physical, emotional, and social needs?
- 3.1.7. 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?
- 3.1.8. Did the PO automatically process as an appeal any service determination request that was not processed within the required timeframe?
- 3.1.9. Did the PO give all parties involved in an appeal a reasonable opportunity to

- present evidence in-person, as well as in writing?
- 3.1.10. Did the PO continue providing services to a Medicaid participant, during an appeal, if the participant requested to continue the services?
 - 3.1.11. Did the PO properly identify and address all issues in a grievance?

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. Did the PO notify the participant of the grievance resolution(s)?

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

- 3.3.1. Did the PO notify the participant or designated representative of the approval, at the time the request was made for a service that could be immediately approved by a member of the IDT?
- 3.3.2. 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?
- 3.3.3. 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?
- 3.3.4. Did the PO appropriately extend the timeframe for approving or denying a service determination request, if applicable?
- 3.3.5. If the IDT extended the service determination request processing timeframe, did the IDT provide notice of the extension to the participant or designated representative in writing no later than 24 hours after the IDT decided to extend

- the timeframe?
- 3.3.6. If the IDT extended the service determination request processing timeframe, did the IDT notify the participant or designated representative no later than 8 days following the date the request was received by the IDT?
 - 3.3.7. 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?
 - 3.3.8. Did the PO appropriately extend the timeframe for responding to an expedited appeal, if applicable?
 - 3.3.9. 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?

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

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 30 targeted medical records 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 identify the participants selected for observation on the first day of the week of the participant observations review. 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 if services are being provided appropriately.

2. **Review Sample Case Documentation:** CMS will review participant medical records and conduct participant observations to determine compliance with regulatory requirements including: provision of required services, coordination and management of participant care, completion of required assessments, and the development and review of participant care plans. 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.

Medical Record Review:

- All documentation related to participant assessments:
 - Initial comprehensive assessments
 - Semi-annual and unscheduled assessments
 - Documentation that assessments were completed as required
 - IDT progress notes, evaluations, or other documentation related to initial, semiannual, and unscheduled assessments
 - Documentation related to assessment outcomes, changes in care plans, participant outcomes, etc.
- All documentation related to participant care plans:
 - Documentation showing when and how the care plan was developed/re-evaluated including documentation of IDT members involved in the development and re-evaluation
 - Changes made to the care plan at any point
 - IDT recommendations and notes related to the care plan
 - Assessments that were used in constructing or revising the care plan
 - Documentation that the participant and/or caregiver was appropriately involved in the development and revision of the care plan
 - Documentation showing that services and care indicated in a participant's care plan were provided appropriately
 - Documentation that initial care plans include the rationale for not providing services identified in initial assessments (if the IDT determined the services are not necessary)
- All documentation related to service delivery and emergency care:
 - Documentation that the PO is providing all necessary services and care as determined by the IDT
 - Documentation that the PO is tracking and monitoring the provision of services across all care settings
 - Documentation that the PO provided services as expeditiously as the participant's health condition requires, taking into account the participant's medical, physical, emotional, and social needs
 - Documentation that the PO provides Medicare and Medicaid covered services, as appropriate and necessary
 - Documentation that the PO provides comprehensive PACE services to meet participants' medical, physical, emotional, and social needs
 - Documentation that an on-call provider is available to participants 24 hours a day
 - Documentation the PO provides immediate access to emergency care
 - Documentation of emergency care, including documentation that the participant was held harmless
 - Documentation relating to the use of restraints, if applicable
- Documentation that the PO provided Medicare and Medicaid benefits without any limitations or conditions related to amount, duration, scope of services, deductibles, copayments, coinsurance, or other cost-sharing
- Documentation relating to the IDT including:
 - Documentation that the IDT consists of all required members
 - Documentation showing appropriate members were involved in assessments and care planning as required

- Documentation of all IDT communications
- Documentation of recommendations or requests for care or services by IDT members, participants, caregivers, PO employees, contractors, specialists, and designated representatives
- In the case of recommended services that were not approved and/or not provided by the IDT, the documented reason(s) the service(s) were not approved and/or provided
- Documentation of communications from the participant, their designated representative, a family member, a caregiver, or any other individual who provides information pertinent to a participant's health or safety or both, including access to original written communication
- Documentation of communications from an advocacy or governmental agency such as Adult Protective Services, including access to original written communication
- All other documentation related to participant experience and care at the PO
- Documentation related to visits or consults with specialists
- Documentation from outside provider including hospital records, SNF/NF records, respite care
- Documentation related to medication administration and orders
- Any documentation relating to the participants dietary needs
- Any documentation relating to participant attendance at the PACE center
- Documentation that treatment options were explained in a culturally competent manner

Participant observations:

- A private area (can be the clinic) to view a willing participant receiving care
- Home visit(s) to view a willing participant receiving care
- Visit(s) to an outside facility (such as a SNF), if applicable

Equipment:

- Emergency equipment available at the center
- At least one vehicle used to transport participants

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.

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 document all recommendations for care or services?
- 3.2.7. 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?
- 3.2.8. Did the IDT implement, coordinate, and monitor the plan of care whether the services were furnished by PACE employees or contractors?
- 3.2.9. Did the PO continuously monitor the participant's health and psychosocial status, as well as the effectiveness of the plan of care, through the provision of services, informal observation, input from participants or representatives, and communications among members of the IDT and other providers?

3.3. Did the PO perform assessments as required?

- 3.3.1. Did the PO 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 reevaluate the participant care plans as required?
- 3.5.2. Did the PO ensure that the appropriate IDT members were 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, did the IDT document the reasoning behind the determination in the care plan?
- 3.5.5. Did the IDT identify how each intervention in the participant's initial plan of care would be implemented and evaluated to determine progress in reaching specified goals and desired outcomes?
- 3.5.6. 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?

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

- 3.7.1. Did personnel wash/sanitize hands as appropriate?
- 3.7.2. Did personnel don and doff personal protective equipment as appropriate?

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

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

- 3.9.1. Did the PO have a demonstrated method for securing participants (i.e., seat belts) and securing DME (e.g., wheelchairs, oxygen, walkers)?
- 3.9.2. Did the PO have a method for communicating between the vehicle and the PACE center?
- 3.9.3. 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. 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. 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 personnel were determined to be free of communicable disease
 - Documentation of completed competencies
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.
 - 3.1. **Did the PO conduct a background check on all personnel 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 licensed, 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?**
 - 3.5. **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. 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 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.
 - 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 noncompliance 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 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?
- 3.2.2. 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?

3.3. 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?

Analysis of Potential Non-Compliance

I. Root Cause Analysis

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.

II. Impact Analysis

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.

III. 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.

Universe Record Layout	Universe Data Collection Start Date	Universe Data Collection End Date
Table 1 Table 2 Table 3 Table 4 Table 5 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 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 PO's decision was rendered or should have been rendered (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	<p>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.</p> <p>Enter NA if the participant is not a Medicare beneficiary.</p>	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. Options include: participant, designated representative, or caregiver.	Participant
F	Date Service Determination Request Made	<p>Date the Service Determination Request was made by the participant, designated representative, or caregiver.</p> <p>Submit in MM/DD/YYYY format (e.g., 01/01/2023).</p>	02/01/2023
G	Date Service Determination Request Brought to the full IDT	<p>Date the service determination request was brought to the full IDT.</p> <p>Submit in MM/DD/YYYY format (e.g., 01/01/2023).</p> <p>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.</p>	02/02/2023
H	Extension	<p>Enter Y if the PO took an extension when processing the service determination request.</p> <p>Enter N if the PO did not take an extension.</p>	Y

Column ID	Field Name	Description	Example
I	Extension Date	<p>Enter the date the IDT made the decision to extend the service determination request notification timeframe.</p> <p>Submit in MM/DD/YYYY format (e.g., 01/01/2023).</p> <p>Enter NA if the service determination request was not extended.</p>	02/03/2023
J	Extension Notification Date	<p>Enter the date the IDT notified the participant and/or the designated representative, in writing, of the IDT's decision to extend the service determination request timeframe.</p> <p>Submit in MM/DD/YYYY format (e.g., 01/01/2023).</p> <p>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.</p>	02/03/2023
K	Category of the Request	<p>Provide the category or type of service delivery request. Examples include: Center Days, Eye Wear, Dental, Home Care, Medications, etc.</p>	Home Care
L	Description of the Request	<p>Provide a description of the service determination request.</p>	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	<p>Enter the date the first assessment was completed in response to the service determination request.</p> <p>Submit in MM/DD/YYYY format (e.g., 01/01/2023).</p> <p>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).</p>	02/01/2023
N	Date of the last assessment completed in response to the service determination request	<p>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.</p> <p>Submit in MM/DD/YYYY format (e.g., 01/01/2023).</p> <p>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).</p>	02/03/2023
O	How many assessments were completed in response to the service determination request?	<p>Enter the total number of assessments completed in response to the service determination request.</p> <p>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).</p>	3
P	Assessment(s) In-person	<p>Enter Y if all assessments that were completed were conducted in-person.</p> <p>Enter N if any assessments that were completed were not conducted in-person.</p> <p>Enter NA if no assessment was completed in response to the service determination request.</p>	Y

Column ID	Field Name	Description	Example
Q	Request Disposition	<p>Valid entries include: Approved, Denied, Partially Denied, or Withdrawn.</p> <p>Enter Approved if the request was approved, in full, as requested.</p> <p>Enter Denied if all of the requested services were denied.</p> <p>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.</p> <p>Enter Withdrawn if the participant and/or the designated representative requested to withdraw the service determination request prior to the organization rendering a decision.</p>	Partially Denied
R	Immediate Approval	<p>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.</p> <p>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.</p>	N
S	For Immediate Approvals, which IDT member approved the request?	<p>For Immediate Approvals, which IDT member 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.</p> <p>Enter NA if the request was not immediately approved.</p>	NA
T	Reason for Denial	<p>If the request was denied or partially denied, please enter a brief explanation of why the request was denied.</p> <p>Enter NA if the request was approved or withdrawn.</p>	Participant needed assistance with chore services, which the IDT assessed could be completely with 4 additional hours of homecare per week.

Column ID	Field Name	Description	Example
U	Date of Oral Notification	<p>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).</p> <p>Submit in MM/DD/YYYY format (e.g., 01/01/2023).</p> <p>Enter NA if oral notification was not provided or not documented.</p>	02/03/2023
V	Date of Written Notification	<p>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).</p> <p>Submit in MM/DD/YYYY format (e.g., 01/01/2023).</p> <p>Enter NA if written notification was not provided or not documented.</p>	02/03/2023
W	Date Service Provided	<p>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).</p> <p>Submit in MM/DD/YYYY format (e.g., 01/01/2023).</p> <p>Enter NA if the request was denied, withdrawn or if there was no documentation of the effectuation (provision) of the service.</p>	02/04/2023

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 PO’s decision was rendered or should have been rendered (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	<p>If the participant has Medicare, enter the Medicare Beneficiary Identifier.</p> <p>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.</p> <p>Enter NA if the participant is not a Medicare beneficiary.</p>	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 if the appeal was submitted by the participant or the participant’s designated representative.	Participant
G	Date Appeal Received	<p>Date the appeal was received by the PO.</p> <p>Submit in MM/DD/YYYY format (e.g., 01/01/2023).</p>	03/01/2023
H	Time Appeal Received	<p>Enter the time the expedited appeal was received by the PO.</p> <p>Submit in HH:MM format (e.g., 23:54).</p> <p>Enter NA for standard appeals (i.e., if the appeal was not expedited).</p>	NA

Column ID	Field Name	Description	Example
I	Expedited	Enter Y if the appeal was processed as expedited. 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. Enter N if the PO did not take an extension on an expedited appeal. 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". 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. 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	<p>Valid entries include: Approved, Denied, Partially Denied or Withdrawn.</p> <p>Enter Approved if all of the requested services were approved as requested.</p> <p>Enter Denied if all of the requested services were denied.</p> <p>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.</p> <p>Enter Withdrawn if the participant and/or designated representative requested to withdraw the appeal prior to a decision being rendered.</p>	Approved
O	Reason for Denial	<p>If the appeal was denied or partially denied, please enter a brief explanation of why the request was denied.</p> <p>Enter NA if the appeal was approved or withdrawn.</p>	Glasses were denied because the participant was assessed to have 20/20 vision.
P	Date of Written Notification	<p>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.</p> <p>Submit in MM/DD/YYYY format (e.g., 01/01/2023).</p> <p>Enter NA if written notification was not provided or not documented.</p>	03/10/2023
Q	Time of Written Notification	<p>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.</p> <p>Submit in HH:MM format (e.g., 23:59).</p> <p>Enter NA if the appeal was not expedited (i.e., was processed as a standard appeal) or if written notification was not provided.</p>	NA

Column ID	Field Name	Description	Example
R	Date Service Provided	<p>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).</p> <p>Submit in MM/DD/YYYY format (e.g., 01/01/2023).</p> <p>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.</p>	05/01/2023

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	<p>If the participant has Medicare, enter the Medicare Beneficiary Identifier.</p> <p>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.</p> <p>Enter NA if the participant is not a Medicare beneficiary.</p>	6M52L458T10
D	Participant ID	The identification number the PO uses to identify the participant.	123456
E	Person who submitted the Grievance	Indicate if the grievance was submitted by the participant, caregiver or family.	Participant
F	Date Grievance Received	Date the grievance was received by the PO. Submit in MM/DD/YYYY format (e.g., 01/01/2023).	04/01/2023
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	Grievance Resolution	<p>Enter Y if the grievance was fully resolved (i.e., all issues within the grievance were resolved).</p> <p>Enter N if all issues in the grievance were not resolved or none of the issues were resolved.</p>	Y
J	Date of Resolution Notification, Oral and/or Written	<p>Date notification of the grievance resolution was provided by the PO to the participant, family, and/or caregiver. If both oral and written notification was provided, enter the first notification date. Submit in MM/DD/YYYY format.</p> <p>Enter NA if the grievance was not resolved or if no notification of the grievance resolution was made.</p> <p>Enter NNR if the participant, family, or caregiver specifically requested not to receive notification about the grievance resolution.</p>	04/05/2023

Table 4: List of Personnel (LOP) Record Layout

- Include all personnel employed during the data collection period (i.e., volunteer, part-time, full time, and contracted staff).
- Include any personnel hired during the data collection period.
- 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 (i.e., drivers).
- 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., 01/01/2023).	12/01/2023
E	Date of Termination	Date the employee was terminated or resigned from the PO. Submit in MM/DD/YYYY format (e.g., 01/01/2023). 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. 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. Enter N if the employee does not require a license in order to perform their duties with the PO.	Y

Column ID	Field Name	Description	Example
I	IDT Member	<p>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.</p> <p>Enter N if the employee is not a member of any of the PO's IDTs.</p>	Y
J	IDT Role	<p>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.</p> <p>Enter NA if the individual is not a part of an IDT.</p>	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	<p>If the participant has Medicare, enter the Medicare Beneficiary Identifier.</p> <p>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.</p> <p>Enter NA if the participant is not a Medicare beneficiary.</p>	6M52L458T10
D	Participant ID	The identification number the PO uses to identify the participant.	1234
E	PACE Center	<p>If the PO has more than one center, enter the name of the participant’s assigned center.</p> <p>If there is only one center, enter NA.</p>	Center 1
F	Date of Enrollment	Date the participant was enrolled in the PO. Submit in MM/DD/YYYY format (e.g., 01/01/2023).	05/01/2018
G	Date of Disenrollment	<p>Date the participant disenrolled from the PO. Submit in MM/DD/YYYY format (e.g., 01/01/2023).</p> <p>Enter NA if the participant is still enrolled.</p>	NA
H	Reason for Disenrollment	<p>Provide the reason for the disenrollment.</p> <p>Enter NA if the participant is still enrolled.</p>	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
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. Enter Y if the participant's living arrangement changed significantly during the data collection period. 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. This includes: <ul style="list-style-type: none"> • Admissions/observations from an emergency room • 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. 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
P	Hospitalization / Emergency Room Reason	<p>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?</p> <p>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.</p> <p>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, or decreased oxygen saturation).</p>	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	Direct SNF Admission	<p>At any point during the data collection period, was the participant admitted directly to the SNF from the PACE center or participant's home for a service other than respite care?</p> <p>Enter Y if the participant had a direct SNF admission during the data collection period.</p> <p>Enter N if the participant did not have a direct SNF admission during the data collection period or if the direct SNF admission was for respite care.</p>	Y

Column ID	Field Name	Description	Example
S	Specialist Consultations/ Visits	<p>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?</p> <ul style="list-style-type: none"> • Cardiology • Endocrinology • Gastroenterology • Oncology • Ophthalmology • Pulmonary Medicine • Rheumatology <p>If Yes, enter each type of specialty.</p> <p>If No, enter N.</p>	Cardiology, Oncology, Rheumatology

Column ID	Field Name	Description	Example
T	Diagnoses	<p>Did the participant have any of the following diagnoses/conditions during the data collection period?</p> <ul style="list-style-type: none"> • AIDS • Anemia • Auto-immune disorder (any type – specify the type in the response) • Cancer (any type – specify the type in the response) • Cellulitis • Cerebrovascular Accident (CVA) • Chronic Obstructing Pulmonary Disease (COPD) • Congestive Heart Failure (CHF) • Dementia • Diabetes Mellitus • Hemolytic Uremic Syndrome • Hepatitis C • Hereditary Angioedema • Human immunodeficiency virus (HIV) • Mental Illness (any type- specify the type in the response) • Multiple Sclerosis • Myasthenia Gravis • Paroxysmal Nocturnal Hemoglobinuria • Pneumonia • Sepsis <p>If Yes, enter each diagnosis and where applicable specify the type.</p> <p>If No, enter N.</p>	AIDS, Hepatitis C, Cancer - lung
U	CHF Exacerbation	<p>Enter Y if the participant was diagnosed with a CHF exacerbation during the data collection period.</p> <p>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.</p>	Y

Column ID	Field Name	Description	Example
V	COPD Exacerbation	<p>Enter Y if the participant was diagnosed with a COPD exacerbation during the data collection period.</p> <p>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.</p>	N
W	Transplant	<p>Enter Y if the participant has ever undergone a transplant (this is not limited to the time the participant was enrolled in the PO and applies to any type of transplant).</p> <p>Enter N if the participant has never undergone a transplant.</p>	N
X	Received Comfort Care	<p>Enter Y if the participant received comfort care during the data collection period that is considered end-of-life care, and as a result, they are no longer receiving curative or maintenance care for one or more of their health conditions.</p> <p>Enter N if the participant received comfort care during the data collection period meant to treat a condition or maintain health and no services were stopped or eliminated as a result of the comfort care, or if the participant did not receive any form of comfort care.</p>	N
Y	Date Comfort Care Began	<p>Enter the date comfort care began. Enter multiple dates, if applicable.</p> <p>Submit in MM/DD/YYYY format (e.g., 01/01/2023).</p> <p>Enter NA if the response to the previous field “Received Comfort Care” was N.</p>	NA

Column ID	Field Name	Description	Example
Z	Received Home Care	<p>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.</p> <p>Enter Unskilled if the participant only received unskilled home care during the data collection period.</p> <p>Enter NA if the participant did not receive home care during the data collection period.</p>	Skilled
AA	Assistance with Administering Medications	<p>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.</p> <p>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.</p>	Y
AB	Current Center Attendance	<p>Enter the number of days per month the participant is scheduled to attend the PACE center at the time the universe is completed.</p> <p>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.</p>	2
AC	Number of Falls with Injury	<p>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.</p>	1
AD	Number of Pressure Ulcers	<p>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.</p>	1
AE	Number of Confirmed Abuse Reports	<p>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.</p>	0

Column ID	Field Name	Description	Example
AF	Unexpected Death	<p>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.</p> <p>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.</p>	N
AG	Functional Decline	<p>Enter Y if the participant experienced a functional decline, as defined by the PO, during the data collection period.</p> <p>Enter N if the participant did not experience a functional decline during the data collection period.</p>	N
AH	Number of Infections	Enter the number of infections the participant had during the data collection period. This includes all types of infections as defined by the PO's infection control plan.	2
AI	Incontinent	<p>Enter Y if the participant was routinely incontinent during the data collection period.</p> <p>Enter N if the participant was not routinely incontinent or had acute/transient incontinence during the data collection period.</p>	Y
AJ	Indwelling Catheter	<p>Enter Y if the participant had an indwelling catheter during the data collection period.</p> <p>Enter N if the participant did not have an indwelling catheter during the data collection period.</p>	N
AK	Significant Weight Loss	<p>Enter Y if the participant had a weight loss of more than 5% within a 30 day period or 10% within a 180 day period.</p> <p>Enter N if the participant did not have a weight loss of more than 5% within a 30 day period or 10% within a 180 day period.</p>	N

Column ID	Field Name	Description	Example
AL	Restraints	<p>Enter Y if physical or chemical restraints were used on the participant at any point during the data collection period,</p> <p>Enter N if physical or chemical restraints were not used on the participant at any point during the data collection period.</p>	N
AM	Oxygen Use	<p>Enter Y if the participant required oxygen on a regular basis at any point during the data collection period.</p> <p>Enter N if the participant did not require oxygen on a regular basis at any point during the data collection period.</p>	N
AN	Dialysis	<p>Enter Y if the participant received dialysis during the data collection period.</p> <p>Enter N if the participant did not receive dialysis during the data collection period.</p>	N
AO	Impaired Vision	<p>Enter Y if the participant had impaired vision (i.e., blindness or severely impaired vision without corrective lenses) during the data collection period.</p> <p>Enter N if the participant did not have impaired vision during the data collection period.</p>	Y

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	<p>If the participant has Medicare, enter the Medicare Beneficiary Identifier.</p> <p>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.</p> <p>Enter NA if the participant is not a Medicare beneficiary.</p>	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., 01/01/2023).	02/01/2023
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, such as dentist, podiatrist, cardiologist, dermatologist, neurologist, oncologist, chiropractors, massage therapists, etc.;
 - 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.
- Do not include any entities whose contracts were terminated prior to the start of the data collection period.

Column ID	Field Name	Description	Example
A	Provider/ Practice/ Facility Name	Name of the provider, practice or facility. 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
B	Specialty or Facility Types	Description of the specialty type or facility type. For practices that may handle multiple specialties, please include all specialties that they provide on behalf of the PACE organization.	Oncology
C	Contract Status	Enter Active if a contract is in effect with the provider / facility at the time of the universe submission. 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. 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
D	Contract Start Date	Enter the date the contract became effective. Enter NA if the contract status is currently pending.	11/01/2019
E	Contract Termination Date	Enter the date the contract was terminated. Enter NA if the contract status is currently active or pending.	NA

Column ID	Field Name	Description	Example
F	Limitations / Restrictions	<p>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.</p> <p>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.</p> <p>Enter NA if the contract status is currently pending.</p>	Y

PRA Disclosure Statement

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. The time required to complete this information collection is estimated to average 780 hours per response, including the time to review instructions, search existing data resources, gather the data needed, and complete and review the information collection. 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.