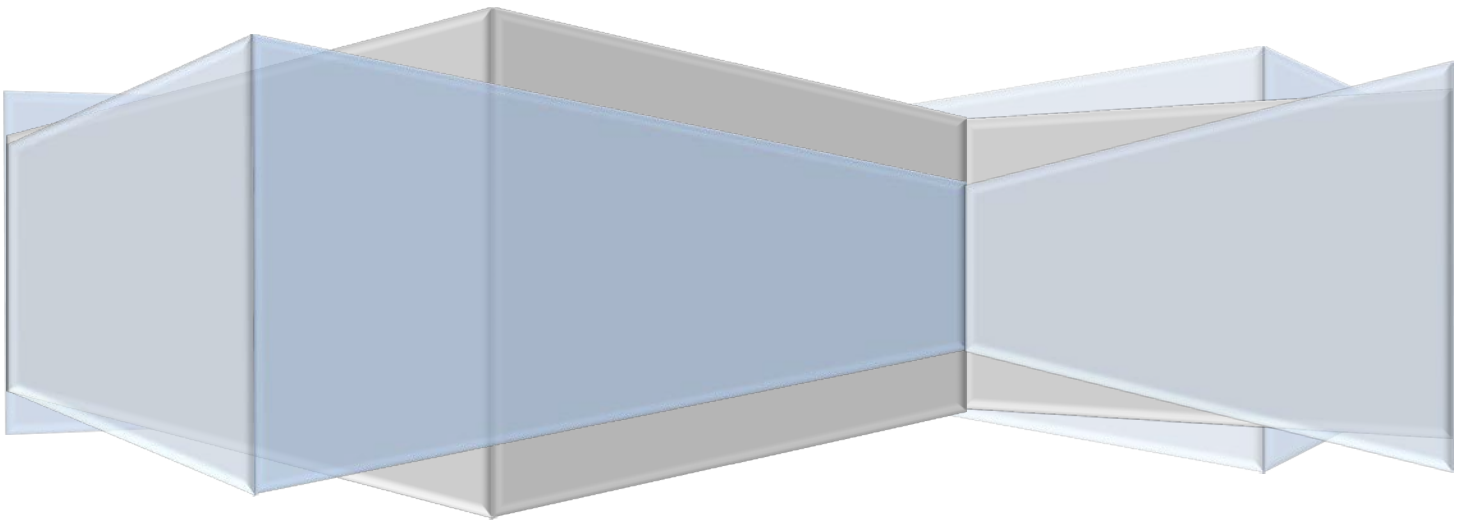
OMB Control Number: 0938-1327 (Expires: 02/28/2023)

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

Audit Process and Data Request



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Audit Purpose and General Guidelines

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

2. **Audit Review**: During the audit, CMS will review data and documentation collected prior to and during the audit fieldwork, as well as conduct real-time observations of participants and equipment. CMS reserves the right to access all relevant documentation or information related to our audit, and may expand our collection of information in order to evaluate participant impact or outcomes.

3. **Universe Data and Documentation Collection Periods**: The data/document collection period for this protocol will be for a period of 6 months prior to, and including, the date of the audit engagement letter unless otherwise specified. Data collection periods for specific universes have been defined in Table 1 below. CMS reserves the right to expand the data/document collection period to ensure sufficient universe size and/or evaluate participant impact.

   NOTE: The universe data collection period for the On-call universe begins 3 months prior to the date of the audit engagement letter and ends on the date of the audit engagement letter.

   Data Collection Periods by Universe:

   Table 1

Universe	Universe Data Collection Start Date	Universe Data Collection End Date
Service Delivery Request Universe	6 months prior to the date of the audit engagement letter	Date of the audit engagement letter
Appeal Universe	6 months prior to the date of the audit engagement letter	Date of the audit engagement letter
Grievance Universe	6 months prior to the date of the audit engagement letter	Date of the audit engagement letter
List of Personnel Universe	6 months prior to the date of the audit engagement letter	Date of the audit engagement letter
List of Participant Medical Records Universe	6 months prior to the date of the audit engagement letter	Date of the audit engagement letter
On-Call Universe	3 months prior to the date of the audit engagement letter	Date of the audit engagement letter

4. **Responding to Documentation Requests**: The PACE organization (PO) is expected to allow access to any supporting documentation requested during the audit and upload the supporting

documentation, as requested, to the Health Plan Management System (HPMS) using the designated file names as indicated in the Document Request Log (DRL). Documentation requests may include requests for portions of the medical record, or the full medical record when warranted. Documents must be uploaded within the timeframes specified by the CMS Audit Team. Additionally, some elements or sample review may be done remotely and organizations will be expected to provide full case files to CMS upon request.

5. **Issues of Non-Compliance Disclosed Prior to Notification of the Audit**: 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.

   Issues identified by CMS or the 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 and any data that is not relevant to the audit elements included in this document.

   POs must provide a description of each disclosed issue and the status of correction using the Pre-Audit Issue Summary template (Attachment III). Attachment III is due 5 business days after the audit engagement letter is issued. 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.

   When CMS determines that a disclosed issue was promptly identified, corrected, and the risk to participants has been mitigated, CMS will not apply the Immediate Corrective Action Required condition classification to that condition. CMS may require organizations to submit a completed root cause analysis and/or impact analysis for any disclosed issue of non-compliance.

6. **Root Cause Analysis/Impact Analysis**: Root Cause Analyses and/or Impact Analyses must be submitted by the PO when they are requested by the CMS audit team. Each Root Cause Analysis describes the nature of the problem and a description of why the non-compliance occurred. 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 PACE organization must then identify which of those participants were subject to or impacted by the issues of non-compliance 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) and may require the organization to submit additional case files or provide access to participant medical records. In the event an Impact Analysis cannot be produced, is incomplete, or is determined by means of validation to be inaccurate, CMS will report that the scope of non-compliance cannot be determined and impacted an unknown number of participants within the PO.

7. **Calculation of Score:** CMS will classify each condition cited during the course of the audit as an Observation (0 points), Corrective Action Required (CAR) (1 point) or an Immediate Corrective Action Required (ICAR) (2 points).

   After all conditions have been classified, CMS will take the sum of the points and divide that number by the number of audit elements (i.e., four audit elements) tested to determine the PO's overall PACE audit score. Observations will be recorded in the draft and final reports but will receive a score of zero and, as a result, will not affect the audit score.

8. **Informing PO of Results:** CMS will provide daily updates regarding potential conditions identified during the audit. The CMS Audit Team will be as timely and transparent as possible when communicating potential conditions. A preliminary summary of conditions identified during the audit will also be presented during the exit conference. POs will have an opportunity to ask questions and discuss potential findings during the daily updates and the exit conference. Following the exit conference the PO will receive a Draft Audit Report. Once the Draft Audit Report is issued, POs will have 10 business days from the date of issuance to comment on conditions identified in the report. If the PO submits comments, CMS will review and respond to each comment before issuing a Final Audit Report.

Universe Preparation & Submission

1. **Responding to Universes and Documentation Requests:** The PO is expected to submit accurate and timely universe and documentation submissions within the timeframes identified below. CMS may request revised universes if data issues are identified. The resubmission request may occur before and/or after the entrance conference depending on when the issue was identified. POs will have a maximum of 3 attempts to provide complete and accurate universes, whether these attempts all occur prior to the entrance conference or they include submissions prior to and after the entrance conference. When multiple attempts are made, CMS will only use the last universe submitted. If the PO fails to provide accurate and timely universe submissions, CMS will document this in the PO's audit report and this may impact condition classifications.

2. **Documentation and Data Submission Timeframes**: Universes and documentation collected prior to and during the audit are used to determine PO compliance with the PACE requirements within the four identified audit elements. 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);

   2.2. Documentation and Data Universes due within 20 business days of the audit engagement letter: POs will provide universes of all service delivery requests, appeals, grievances, personnel employed during the data collection period, and participants enrolled during the data collection period. POs will also submit a universe of all after-hours calls that occurred during the last three months of the data collection period. In addition to data universes, the PO will provide the documents identified in 2.2.1.

   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; and

   2.2.2 Data Universes:
   - Table 1: Service Delivery Requests (SDR)
   - Table 2: Appeal Requests (AR)
   - Table 3: Grievance Requests (GR)
   - Table 4: List of Personnel (LOP)
   - Table 5: List of Participant Medical Records (LOPMR)
   - Table 6: On-call (OC)

   2.3. Documentation due the first day of the onsite portion of audit fieldwork: The PO will submit the following documentation when auditors arrive onsite for the audit fieldwork.

   - Completed Onsite Observation Participant List (Attachment IV).

   NOTE: Organizations must submit the information identified in Attachment IV in writing but

do not need to submit the information using the excel template Attachment IV and may submit the information in another format so long as all requested information is included. Requests for observation data will typically be limited to participants assigned to an IDT at the center where CMS auditors are conducting the onsite portion of the audit. However, CMS reserves the right to request data for participants from other PACE centers, as needed, to ensure all of the observations can be completed. For example, if medication administration or wound care is not being provided at the center where the onsite audit is conducted, CMS auditors may request data from other PACE centers in order to determine whether observations may be completed at an alternative site. The audit team will identify the subset of participants for whom information must be provided.

3. **Pulling and Submitting Universes:** POs must submit each universe in the Microsoft Excel (.xlsx) file format with a header row that corresponds to the record layouts shown in Appendix A, Tables 1-6.

   For the service delivery request, appeal and grievance universes, cases that fall in the data collection period must be submitted based on the date the request/grievance was processed/resolved (or should have been processed/resolved). The date the request or grievance was received may fall outside of the data collection period. Service delivery request and appeal universes should be all inclusive, regardless of whether the request was determined to be approved, denied, or partially denied/partially approved.

   For the personnel universe, POs must include all personnel who were employed at any time during the data collection period. This includes part-time employees, full-time employees, contracted employees, volunteers, and temporary employees. For contracted employees, the PO should only include those employees that provided services to participants in the participant's home, a PACE center, an Alternative Care Setting (ACS) or transporting a participant (i.e., PACE driver). This includes employees of contracted agencies who provide services to PACE participants, if that employee provides care at one of the settings identified above. POs do not need to include employees of institutional contracted providers such as nursing facilities and hospitals. POs do not need to submit actual personnel records for each employee, only the information identified in Appendix A, Table 4.

   For the participant medical record universe, POs must include all participants who were enrolled at any point during the data collection period. This includes participants who were enrolled prior to or during the data collection period, regardless of whether or not they are still enrolled (e.g., disenrolled or expired). POs do not need to submit medical records with the universes for each participant, only the information identified in Appendix A, Table 5.

   For the on-call universe, POs must submit all information relating to all calls received after-hours. Unlike the other universes, the on-call universe only needs to include calls that occurred in the last three months of the data collection period.

4. **CMS Analysis of Universes:** CMS will complete data entry tests on all of the universes to ensure there are no blank entries and data is properly formatted. In addition to analyzing universes throughout the audit for varying compliance standards, CMS will also perform the timeliness tests on the universes identified in Table 2 below.

Table 2

Table #	Record Layout	Universe	Applicable Audit Element	Compliance Standard To Apply	CFR Ref.	Test
1	SDR	Service Delivery Requests	SDAG	• Notification is provided to the participant/representative no later than 72 hours following the date the request was received by the IDT. • Notification is provided to the participant/representative no later than 8 days following the date the request was received by the IDT, if an extension was taken.	460.104(d)(2)(ii) and 460.104(d)(2)(iii)	Notification
2	AR	Appeal Requests	SDAG	• Notification is provided to the participant/representative no later than 30 days from the date of receipt for a standard appeal. • Notification is provided to the participant/representative no later than 72 hours from receipt of a request for an expedited appeal. • Notification is provided to the participant/representative no later than 17 days from receipt of a request for an expedited appeal for which an extension is taken.	460.122(c)(5), 460.122(f)(2), and 460.122(f)(3)	Notification

5. **Selecting Samples**: Auditors will review the universes collected from the PO and select samples in accordance with the instructions noted below. For elements done via desk review (e.g., the Service Delivery Request, Appeals, and Grievance (SDAG) element and/or Personnel), samples will be provided to the PO two business days before the review of each element. Onsite observations conducted as part of the Provision of

Services element will be selected from the Onsite Observation Participant List (Attachment IV) on the first day of the onsite audit. Medical record samples for the Provision of Services Element will be provided for informational purposes to the PO one hour prior to the start of the review of medical records. The PO is not expected to upload any medical record documentation within the one hour timeframe following receipt of the samples. PACE organizations are required to allow CMS immediate access to the medical records for each sample within that time, in whatever manner was agreed upon by the audit team and organization.

Audit Elements

I. Service Delivery Requests, Appeals and Grievances (SDAG)

1. **Select Sample Cases:** CMS will select 40 targeted sample cases. When selecting sample cases, CMS will attempt to ensure that the sample set is representative of various types of service 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 delivery requests
    - 10 approved service delivery requests
    - 5 denied appeals
    - 5 approved appeals
    - 10 grievances

    CMS reserves the right to adjust the number of service delivery 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 5 approved appeals, CMS may add additional denied appeals or additional approved service delivery requests to make up the total number of samples. Additionally, CMS may add samples or case review in order to further investigate potential non-compliance or participant impact.

2. **Review Sample Case Documentation:** CMS will review all sample case file documentation to determine compliance with regulatory requirements including: identifying the request, processing the request, notifying participants timely and appropriately, and providing any approved services. The PO will need to provide the following documents via HPMS during the audit:

    2.1. For service delivery requests:
    - Documentation of the initial request (received in writing, orally, etc.) including any system notes, progress notes, logs, or other data related to the receipt of the service delivery request
    - All assessments conducted in response to the service delivery request and any IDT notes or discussions regarding the assessment
    - Documentation of the IDT's decision to approve or deny the request based on assessment(s) conducted in response to the request by the IDT
    - Documentation of the involvement of the IDT in reviewing the service delivery request including disciplines involved in the review
    - For service delivery request denials:
        - A copy of the written notification of the denial including the specific reason for the denial and the participant's appeal rights
        - Documentation of oral notification of the denial including the reason for the denial and documentation that appeal rights were provided orally
    - For service delivery request approvals:
        - If oral notification was provided, medical record notes and/or documentation of notification to the participant/designated representative
        - If written notification was provided, a copy of the written notification provided to the participant/designated representative
        - Documentation showing the service and/or item was provided (e.g., an annotation in the participant's medical record, assessments, progress notes)
    - Any other reports, system notes, or logs that document denial or approval of the request

and participant notification
- If applicable, documentation regarding any extension that was taken including the rationale for the extension and who requested the extension

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 delivery request denial
- Documentation identifying the third-party reviewers and their credentials
- 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 and State administering agency's approval of the extension (if applicable)
- Documentation of the third-party decision, including:
  - For denials: a copy of the written notification letter provided to the participant including their external appeal rights available through Medicare and/or Medicaid
  - For denials: documentation that CMS was notified of an appeal decision that was wholly or partially adverse to the participant
  - For approvals: documentation of written notification of the decision
- 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
- For approvals, documentation that the service and/or item was provided (e.g., an annotation in the participant's medical record, progress notes)

2.3. For grievances:
- Documentation of the initial complaint/grievance including system notes, progress notes, logs, or other data related to the grievance
- Documentation detailing each issue in the complaint/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 complaint/grievance, including appropriate correspondence with other departments within the organization and a description of the final resolution
- Documentation showing resolution notification of each issue identified in the complaint/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

3. <u>Apply Compliance Standard</u>: At a minimum, CMS will evaluate cases against the criteria in this section. CMS may review factors not specifically addressed in these questions if it is determined that there are other requirements not being met.

3.1 Did the PO appropriately process service delivery requests, appeals and grievances?

3.1.1 Did the PO appropriately identify, classify, and process service delivery requests, appeals and grievances?
3.1.2 Did the PO use the appropriate personnel to review service delivery requests and appeals?
3.1.3 Did the PO conduct assessments, as required, in response to a service delivery request?
3.1.4 Did the PO process untimely service delivery requests as appeals?
3.1.5 Did the PO provide participants with a reasonable opportunity to present evidence in-person, as well as in writing, during an appeal?
3.1.6 Did the PO continue providing services to a Medicaid participant, during an appeal, if the participant requested to continue the services?
3.1.7 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 delivery request, appeal or grievance?

3.2.1 Did the PO provide oral and written notification of service delivery request denials that included the specific reason for the denial in understandable language?
3.2.2 Did the PO provide oral and written notification of service delivery request 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 provide appropriate written notification for appeal decisions?
3.2.4 Did the PO notify the participant of the grievance resolution(s)?

3.3 Did the PO notify the participant and/or designated representative of the service delivery request, appeals and grievance decisions within the required timeframes?

3.3.1 Did the PO notify the participant or designated representative of the decision to approve or deny a service delivery request within 72 hours from the date the request was received by the IDT?
3.3.2 Did the PO appropriately extend the timeframe for approving or denying a service delivery request, if applicable?
3.3.3 Did the PO notify the participant of an appeal decision within 30 days or, for expedited appeals, within 72 hours after the PO receives the appeal?
3.3.4 Did the PO appropriately extend the timeframe for approving or denying an expedited appeal, if applicable?

3.4 Did the PO effectuate/provide approved service delivery requests and appeals?

4. **Sample Case Results:** CMS will test each of the 40 cases. If CMS requirements are not met, conditions (findings) are cited. If CMS requirements are met, no conditions (findings) are cited. **NOTE:** Cases and conditions may have a one-to-one or a one-to-many relationship. For example, one case may have a single condition or multiple conditions of non-compliance.

II. Provision of Services

1. **Select Sample Cases:** This element will be tested using both medical record review and onsite observations/inspections.

   Medical Record Review: CMS will select 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 may expand the scope of review or add medical records as needed in order to appropriately investigate potential compliance issues discovered during the review of audit elements. Additionally, CMS may require access to medical records following the audit fieldwork to validate impact analyses or other submitted information.

   Participant Observations: CMS will also conduct 5 participant observations during audit fieldwork (e.g., week 2) 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 may observe more participants if issues are noted that warrant additional observations.

   Emergency Equipment: CMS will also 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.

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, staff 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
- 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 provides Medicare and Medicaid covered services, including medications, 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 interdisciplinary team (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 any communication by the IDT
- All other documentation related to a participants experience and care at the PACE organization
- 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 a participants attendance at the PACE center

<u>Participant observations:</u>

- 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

<u>Equipment:</u>

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

3. **Apply Compliance Standards:** At a minimum, CMS will evaluate sample cases against the following criteria. CMS may review factors not specifically addressed in these questions if it is determined that there are other requirements not being met.

3.1 Did the PO provide adequate care/services to the participants (including but not limited to transportation, dietary, medical care, etc.)?

3.1.1 Did the PO furnish mandatory services at the PACE center?

3.1.2 Did the PO provide immediate access to emergency services without prior authorization?

3.1.3 Did the PO provide access to care and services 24 hours a day as necessary?

3.1.4 Did the PO furnish services and care that meets the needs of each participant in all care settings, 24 hours a day, every day of the year?

3.2 Did the PO ensure that the IDT was appropriately involved in the participants' care?

3.2.1 Has the PACE organization established an interdisciplinary team, composed of the required members at each PACE center?

3.2.2 Is there evidence that the IDT conducted initial and periodic assessments, developed plans of care, and coordinated 24 hour care delivery?

3.2.3 Is there evidence that members of the IDT remained alert to pertinent input from other team members, participants, and representatives?

3.2.4 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 interdisciplinary team 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?

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

3.5.1 Did the PO evaluate and monitor the participants' care plans on at least a semiannual basis?

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

3.6 Did the PO provide services as approved and/or determined necessary?

3.6.1 Did the PO provide services and care as identified in the care plan and/or primary care provider orders?

3.6.2 Did the PO provide treatment and medications as identified in the care plan and/or primary care provider orders?

3.6.3 Did the PO provide all items, care and services determined necessary by the IDT

(e.g., through approved service requests)?

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

3.7.1 Do personnel wash/sanitize hands as appropriate?

3.7.2 Do personnel don and doff personal protective equipment as appropriate?

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

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

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

3.9.2 Does the PO have a method for communicating between the vehicle and the PACE center?

3.9.3 Does the PO provide training to drivers on managing the special needs of the participants and handling emergency situations?

4. Sample Case Results: CMS will test each of the 30 medical records, 5 participant observations, and emergency equipment and vehicle inspections. If CMS requirements are not met, conditions (findings) are cited. If CMS requirements are met, no conditions (findings) are cited. **NOTE:** Cases and conditions may have a one-to-one or a one-to-many relationship. For example, one case may have a single condition or multiple conditions of non-compliance.

III. Personnel Records

1. **Select Sample Cases:** CMS will select 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, contract, volunteers, etc. Additionally, CMS may add additional samples or case review in order to further investigate potential non-compliance or participant impact.

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:** At a minimum, CMS will evaluate cases against the following criteria. CMS may review factors not specifically addressed in these questions if it is determined that there are other related PACE requirements not being met.

    3.1 Did the PO conduct a background check on personnel prior to their date of hire?

    3.2 Did the PO conduct an OIG exclusion check for 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 staff 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?

4. **Sample Case Results:** CMS will test each of the 10 files. If CMS requirements are not met, conditions (findings) are cited. If CMS requirements are met, no conditions (findings) are cited. **NOTE:** Cases and conditions may have a one-to-one or a one-to-many relationship. For example, one case may have a single condition or multiple conditions of non-compliance.

IV. Quality Assessment

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

2. **Review Quality Improvement Documentation:** CMS will review relevant documentation and information related to the PO's quality improvement program. The PO will need to produce the following documents during the audit and may be requested to produce screenshots or copies of any of the following:

    - Documentation that the PO collects, analyzes, and uses data 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 staff and contracted services including: competency of clinical staff, 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 issue(s), if applicable
    - Documentation that staff members and contractors are involved in the development and implementation of the QI program
    - Documentation that the results of quality initiatives are communicated to staff and contractors

3. **Apply Compliance Standards:** At a minimum, CMS will evaluate all available documentation against the following criteria. CMS may review factors not specifically addressed in these questions if it is determined that there are other requirements not being met.

    3.1. Did the PO develop and/or implement an effective, data driven quality improvement program?

    3.1.1. Does 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 staff and contracted services, and nonclinical areas, such as grievances, appeals, transportation services, meals, and environmental issues?

    3.1.2. Does the PO use the minimum required data (utilization, participant and caregiver satisfaction, participant assessments, effectiveness and safety of staff and contracted services, and nonclinical data) to improve the delivery of PACE services?

    3.2. Did the PO ensure that the appropriate staff were involved in the development and implementation of QI activities and did the PO appropriately disseminate information related to the QI activities?

4. **Review Results:** CMS will use all available documentation to assess whether CMS requirements are met. If CMS requirements are not met, conditions (findings) are cited. If CMS requirements are met, no conditions (findings) are cited. **NOTE:** Conditions may have a one-to-one or a one-to-many relationship. For example, one issue may result in a single condition or multiple conditions of non-compliance.

Appendix

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

The universes for the PACE audits must be submitted as a Microsoft Excel (.xlsx) file with a header row. Do not include additional information outside of what is dictated in the record layout.

Please 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.

Table 1: Service Delivery Requests (SDR) Record Layout

- Include all requests processed by the PO as service delivery requests.
- 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
C	Participant ID	The identification number the PO uses to identify the participant.	1234
D	Person who Submitted the Service Request	Indicate if the request was submitted by the participant or designated representative (which may include a caregiver, family member, POA, legal guardian, etc.).	Participant
E	Date Service Delivery Request Received	Date the service delivery request was received by the interdisciplinary team (IDT). Submit in MM/DD/YYYY format (e.g., 01/01/2020).	02/01/2020
F	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
G	Description of the Request	Provide a description of the service delivery 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
H	Date(s) Assessment(s) Performed	Enter the date(s) the IDT member(s) completed required assessments in response to the service delivery request. If more than one assessment was completed, enter all dates separated by a comma. Submit in MM/DD/YYYY format (e.g., 01/01/2020). Enter NA if an assessment was not completed or if the assessment(s) was not completed in response to the service delivery request (e.g., do not include semi-annual assessments if they were not done in response to the requested service).	02/01/2020, 02/02/2020, 02/03/2020
I	Discipline(s) Performing Assessment(s)	Indicate which IDT members completed assessments. If more than one discipline completed an assessment, include all applicable disciplines separated by commas. Enter NA if an assessment was not completed or was not completed in response to the service delivery request.	PCP,RN,PT
J	Assessment(s) In-person	Enter Y if any assessment or assessments were completed and were conducted in-person. Enter N if assessments were completed but none of the assessments were conducted in-person. Enter NA if no assessment was completed or was not completed in response to the service delivery request.	Y

Column ID	Field Name	Description	Example
K	Request Disposition	Valid fields include: Approved, Denied, Partially Approved/Denied, or Withdrawn. Enter approved if all of the requested services and/or items were approved as requested. Enter denied if all of the requested services and/or items were denied. Enter partially approved/denied if the request was not fully approved as requested and/or the PO provided a modified or alternative service to the participant. Enter Withdrawn if the participant and/or the designated representative requested to withdraw the service delivery request prior to the organization rendering a decision.	Approved
L	Reason for Denial	If the request was denied or partially denied, please enter a brief explanation of why the request was denied. Enter NA if the request was approved or withdrawn.	Glasses were denied because the participant was assessed to have 20/20 vision.
M	Extension	Enter Y if the PO took an extension when processing the service delivery request in order to allow more time to render a decision. Enter N if the PO did not take an extension.	N
N	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). Submit in MM/DD/YYYY format (e.g., 01/01/2020). Enter NA if oral notification was not provided or not documented.	02/03/2020

Column ID	Field Name	Description	Example
O	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). Submit in MM/DD/YYYY format (e.g., 01/01/2020). Enter NA if written notification was not provided or not documented.	02/03/2020
P	Date Service Provided	Enter the date that the approved service or item was provided to the participant. Please enter a date for any request that was partially or fully approved. Submit in MM/DD/YYYY format (e.g., 01/01/2020). Enter NA if the request was denied, withdrawn or if there was no documentation of the effectuation (provision) of the service.	02/04/2020

Table 2: Appeal Requests (AR) Record Layout

- Include all requests processed as standard or expedited appeals received by the PO.
- 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	Participant ID	The identification number the PO uses to identify the participant.	12345
D	Person who Submitted the Appeal	Indicate if the request was submitted by the participant, caregiver or family.	Caregiver
E	Date Appeal Received	Date the appeal was received by the PO. Submit in MM/DD/YYYY format (e.g., 01/01/2020).	03/01/2020
F	Time Appeal Received	This column only applies to expedited appeals. Enter the time the appeal was received by the PO. Submit in HH:MM format (e.g., 23:54). Enter NA for standard appeals (i.e., if the appeal was not expedited).	NA
G	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
H	Extension	This column only applies to expedited appeals. 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).	N

Column ID	Field Name	Description	Example
I	Category of the Appeal/ Appeal Type	Provide the category or type of appeal request. Valid fields 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	Dentures
J	Description of the Appeal/ Specific Issue	Provide a description of the appeal.	The participant requested full upper and lower dentures.
K	Request Disposition	Valid fields include: Approved, Denied, Partially Approved/Denied or Withdrawn. Enter approved if all of the requested services and/or items were approved as requested. Enter denied if all of the requested services and/or items were denied. Enter partially approved/denied if the request was not fully approved as requested and/or the PO provided a modified or alternative service to the participant. Enter Withdrawn if the participant and/or designated representative requested to withdraw the appeal prior to a decision being rendered.	Approved
L	Reason for Denial	If the appeal was denied or partially denied, please enter a brief explanation of why the request was denied. Enter NA if the appeal was approved or withdrawn.	Glasses were denied because the participant was assessed to have 20/20 vision.
M	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. Submit in MM/DD/YYYY format (e.g., 01/01/2020). Enter NA if written notification was not provided or not documented.	03/10/2020

Column ID	Field Name	Description	Example
N	Time of Written Notification	This column only applies to expedited appeals. 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 appeal. Submit in HH:MM format (e.g., 23:59). Enter NA if the appeal was not expedited (i.e., was processed as a standard appeal) or if written notification was not provided.	NA
O	Date Service Provided	Enter the date that the approved service or item was provided to the participant. Please enter a date for any appeal that was partially or fully approved. Submit in MM/DD/YYYY format (e.g., 01/01/2020). 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.	05/01/2020

Table 3: Grievance Requests (GR) Record Layout

- Include all complaints processed as grievances.
- Submit grievances based on the date the PO's decision was rendered or should have been rendered (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	Participant ID	The identification number the PO uses to identify the participant.	123456
D	Person who submitted the Grievance	Indicate if the grievance was submitted by the participant, caregiver or family.	Participant
E	Date Grievance Received	Date the grievance was received by the PO. Submit in MM/DD/YYYY format (e.g., 01/01/2020).	04/01/2020
F	Category of the Grievance/ Grievance Type	Provide the category or type of grievance. Valid fields 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	Home Care
G	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.
H	Grievance Resolution	Enter Y if the grievance was fully resolved (i.e., all issues within the grievance were resolved). Enter N if all issues in the grievance were not resolved or none of the issues were resolved.	Y

I	Date of Resolution Notification, Oral and/or Written	Date notification of the grievance resolution was provided by the PO to the participant and/or caregiver. If both oral and written notification was provided, enter the first notification date. Submit in MM/DD/YYYY format (e.g., 01/01/2020). Enter NA if the grievance was not resolved or if no notification of the grievance resolution was made. Enter NNR if the participant, family or caregiver specifically requested not to receive notification about the grievance resolution.	04/05/2020

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 contract).
- 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 all personnel terminated prior to the data collection period.

Column ID	Field Name	Description	Example
A	Employee First Name	First name of the employee.	John
B	Employee Last Name	Last name of the employee.	Smith
C	Job Title	Provide the job title of the employee. Examples: Home Health Aide, Physical Therapist, etc.	Physical Therapist
D	Job Description	Provide a brief description of the job duties.	Provides physical therapy
E	Date of Hire	Date the employee was hired by the PO. Submit in MM/DD/YYYY format (e.g., 01/01/2020).	12/01/2018
F	Date of Termination	Date the employee was terminated or resigned from the PO. Submit in MM/DD/YYYY format (e.g., 01/01/2020). Enter NA if the employee is still working for the PO.	NA
G	Type of Employment	Provide the type of employment for the employee. Valid entries are: contract, Full-time, Part-time, Volunteer, or Other.	Full-time
H	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
I	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
J	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. Enter N if the employee is not a member of the PO's IDT.	Y

K	IDT Role	Enter the discipline(s) the individual represents on the IDT. Valid entries are: PCP, RN, MSW, Home Care Coordinator, OT, PT, Dietitian, Recreational Therapist/Activities Coordinator, Personal Care Attendant, Transportation, Center Manager, Other. 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 data collection period.
- PACE organizations 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 PACE organization may maintain.

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	Participant ID	The identification number the PO uses to identify the participant.	1234
D	Medicare Beneficiary Identifier	If the participant has Medicare, enter the Medicare Beneficiary Identifier. Enter NA if the participant is not a Medicare participant.	6M52L458T10
E	PACE Center	If the PO has more than one center, enter the name of the participant's assigned center. 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., 01/01/2020).	05/01/2018
G	Date of Disenrollment	Date the participant disenrolled from the PO. Submit in MM/DD/YYYY format (e.g., 01/01/2020). Enter NA if the participant is still enrolled.	NA
H	Reason for disenrollment	Provide the reason for the disenrollment. Enter NA if the participant is still enrolled.	NA
I	Number of Hospital Admissions/ Observations	Enter the number of hospital admissions and/or observations that occurred during the data collection period. This includes: • Admissions/observations from an emergency room, • Direct admissions, • Unplanned admissions, and • Planned admissions.	2
J	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

Column ID	Field Name	Description	Example
K	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
L	Hospitalization/ Emergency Room Reason	Were any ER visits or hospitalizations (admission or observation) a result of hypoglycemia, hyperglycemia, or decreased oxygen saturation? 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, or decreased oxygen saturation. 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, or decreased oxygen saturation.	Y
M	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
N	Currently in SNF/NF	Enter Y if the participant was in a SNF or NF at the time that the universe is completed. Enter N if the participant was not in a SNF or NF at the time that the universe is completed. Enter N if the participant was disenrolled (voluntarily, involuntarily or deceased) at the time the universe is completed.	N
O	Direct SNF Admission	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? Enter Y if the participant had a direct SNF admission during the data collection period. 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.	Y

Column ID	Field Name	Description	Example
P	Specialist Consultations/ Visits	Did the participant have a consultation/visit with or was the participant examined or treated by any of the following types of specialties during the data collection period? Cardiology Gastroenterology Hematology Oncology Pulmonary Medicine Rheumatology If Yes, enter **each** type of specialty. If No, enter N.	Cardiology, Oncology, Rheumatology
Q	Diagnosis of Diabetes Mellitus (DM)	Enter Y if the participant had a diagnosis of diabetes mellitus during the data collection period. Enter N if the participant did not have a diagnosis of diabetes mellitus during the data collection period.	N
R	Diagnosis of Congestive Heart Failure (CHF)	Enter Y if the participant had a diagnosis of congestive heart failure during the data collection period. Enter N if the participant did not have a diagnosis of congestive heart failure during the data collection period.	Y
S	CHF Exacerbation	Enter Y if the participant was diagnosed with a CHF exacerbation during the data collection period. 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
T	Diagnosis of Chronic Obstructing Pulmonary Disease (COPD)	Enter Y if the participant had a diagnosis of chronic obstructive pulmonary disease during the data collection period. Enter N if the participant did not have a diagnosis of chronic obstructive pulmonary disease during the data collection period.	N
U	Diagnosis of Dementia	Enter Y if the participant had a diagnosis of dementia during the data collection period. Enter N if the participant did not have a diagnosis of dementia during the data collection period.	N

Column ID	Field Name	Description	Example
V	Other Diagnoses	Did the participant have any of the following diagnoses/conditions during the data collection period? AIDS Hepatitis C Cancer (any type – specify the type in the response) Auto-immune disorder (any type – specify the type in the response) Anemia Multiple Sclerosis Myasthenia Gravis Hunter's Syndrome Paroxysmal Nocturnal Hemoglobinuria Hemolytic Uremic Syndrome Hereditary Angioedema If Yes, enter each diagnosis and where applicable specify the type. If No, enter N.	AIDS, Hepatitis C, Cancer - lung
W	Transplant	Has the participant ever undergone a transplant surgery? 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). Enter N if the participant has never undergone a transplant.	N
X	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. Enter unskilled if the participant only received unskilled home care during the data collection period. Enter NA if the participant did not receive home care during the data collection period.	Skilled
Y	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. 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
Z	Pain Management	Enter Y if the participant received any treatment or modality used to treat, reduce, control, or eliminate pain during the data collection period. Enter N if the participant did not receive any treatment or modality used to treat, reduce, control, or eliminate pain during the data collection period.	Y
AA	Opioid Utilization	Was the participant prescribed one or more opioid medications during the data collection period? Enter Y if the participant was prescribed one or more opioid medications. Enter N if the participant was not prescribed any opioid medications.	Y
AB	Current Center Attendance	Enter the frequency that the participant attends the PACE center at the time the universe is completed. For example, 5 days per week, 2 times per month, etc. Enter 0 if the participant was disenrolled (voluntarily, involuntarily or deceased) at the time the universe is completed.	3 days per week
AC	Skilled Therapy	Enter Y if the participant received any physical or occupational therapy services that were provided by licensed personnel during the data collection period. Enter N if the participant did not receive any physical or occupational therapy services that were provided by licensed personnel during the data collection period.	Y
AD	Number of Falls Reported in PACE Quality data	Enter the number of falls the participant had that were reported in the PACE Quality Data during the data collection period.	1
AE	Functional Decline	Enter Y if the participant experienced a functional decline, as defined by the PO, during the data collection period. Enter N if the participant did not experience a functional decline during the data collection period.	N
AF	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
AG	Pressure Ulcers	Enter Y if the participant had a stage II, III, IV, or unstageable pressure ulcer at any time during the data collection period. Enter N if the participant did not have a stage II, III, IV, or unstageable pressure ulcer during the data collection period.	N

Column ID	Field Name	Description	Example
AH	Incontinent	Enter Y if the participant was routinely incontinent during the data collection period. Enter N if the participant was not routinely incontinent or had acute/transient incontinence during the data collection period.	Y
AI	Indwelling Catheter	Enter Y if the participant had an indwelling catheter during the data collection period. Enter N if the participant did not have an indwelling catheter during the data collection period.	N
AJ	Significant Weight Loss	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. 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.	N
AK	Restraints	If physical or chemical restraints were used on the participant at any point during the data collection period, please describe the type of restraint used. Enter N if physical or chemical restraints were not used on the participant at any point during the data collection period.	N
AL	Oxygen Use	Enter Y if the participant required oxygen on a regular basis at any point during the data collection period. Enter N if the participant did not require oxygen on a regular basis at any point during the data collection period.	N
AM	Dialysis	Enter Y if the participant received dialysis during the data collection period. Enter N if the participant did not receive dialysis during the data collection period.	N
AN	Impaired Vision	Enter Y if the participant had impaired vision (i.e., blindness or severely impaired vision without corrective lenses) during the data collection period. Enter N if the participant did not have impaired vision during the data collection period.	Y

Table 6: On-Call (OC) Record Layout

- Include all after hour calls received by the PO.
- 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	Participant ID	The identification number the PO uses to identify the participant.	1234
D	Caller Information	Identify who made the call (e.g., participant, daughter, spouse, caregiver).	Daughter
E	Date of Call	Date the call was received. Submit in MM/DD/YYYY format (e.g., 01/01/2020).	02/01/2019
F	Time of Call	Time the call was received. Submit in HH:MM format (e.g., 23:54).	20:15
G	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.
H	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.