BluePeak Advisors is a division of Gallagher Benefit Services, Inc.

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

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On November 10, 2022, the Centers for Medicare and Medicaid Services (CMS) announced the release of the final audit protocol for the Programs of All-Inclusive Care for the Elderly (PACE). The protocol and supporting data collection instruments (CMS-10630) will be used for PACE audits beginning in 2023 and are available for download on CMS' website at: https://www.cms.gov/Medicare/Compliance-and-Audits/Part-C-and-Part-D-Compliance-and-Audits/PACE_Audits.

The CMS audit download includes the following:

- 2023 Audit protocol
- Pre-Audit Issue Summary (PAIS)
- PACE Supplemental Questionnaire
- Corrective Action Plan Processes
- Audit Survey
- New Impact analysis worksheets

The new Protocols reflect the new regulatory provisions from the January 19, 2021 Final Rule https://www.federalregister.gov/documents/2021/01/19/2021-00538/medicare-and-medicaid-programs-contract-year-2022-policy-and-technical-changes-to-the-medicare. CMS will perform its audit activities based on the following:

- 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
- Compliance and quality improvement

Beginning in audit year 2023, the number of data collection instruments will increase from twenty-two (22) to the following twenty-four (24) documents:

- A PACE Audit Protocol
- A Pre-audit issue summary document
- A PACE supplemental questionnaire
- A Corrective Action Plan Process document
- A root cause analysis template (for use as needed)
- 18 Impact Analyses templates (for use as needed), and
- An audit feedback questionnaire (voluntary)

PACE Audit Purpose & Scope

The purpose of the PACE Organization Audit is to evaluate PACE Organizations' (POs') compliance with regulatory requirements in the following four areas related to PACE, which include Service Determination Requestions, Appeals and Grievances (SDAG), Provision of Services, Personnel Records, and Compliance and Quality Improvement. The Centers for Medicare and Medicaid Services (CMS) will perform its audit activities based on the instructions included in the Audit Protocol referenced.

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.

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

Pre-audit Documentation Requirements

Documentation due within 5 business days of the audit engagement letter include:

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

The 2023 Audit protocols had minimal changes to these attachments. However, like Medicare Advantage, there is a requirement to provide all non-compliance disclosed to CMS prior to the date of the audit engagement letter:

> "**Important Note**: *PACE Plans 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.*[1]"

[1] https://www.cms.gov/Medicare/Compliance-and-Audits/Part-C-and-Part-D-Compliance-and-Audits/PACE_Audits

PACE Audit Documentation Requirements

CMS has made significant changes to the 2023 data universes and sample case documentation in the service determination, appeals, and service provision data elements. These incorporate new compliance standards consistent with the final regulations. Data universes, documentation, and monitoring reports are due within twenty (20) business days of the audit engagement letter.

Data Universes now include seven (7) Data Universe Tables, including a new data universe ,Table 7, for addressing Contracted Entities and Providers

- 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)

CMS has significantly updated the Universes for the SDAG and LOPMR universes. The new SDAG universe reflects changes to regulatory policy. The new LOPMR universe adds significant data requests including use of specialists and end of life care.

The CEP data universe includes a request for all contracted providers including specialists, home care companies, hospitals, urgent care, and any contracts with nursing facilities and contracted residential care facilities. The CEP data universe includes, for each provider contract, the contract type, contract status, contract start date, contract termination date, and if there are any restrictions on the availability of services.

Audit Element Review: Service Determination Requestions, Appeals and Grievances (SDAG), Provision of Services, and Personnel Records

CMS will test sample cases, review sample case documentation, and apply a compliance standard to each audit element.

Service Determination Requests, Appeals and Grievances (SDAG)

Selection of 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:

- Ten (10) denied service determination requests
- Ten (10) approved service determination requests
- Five (5) denied appeals
- Five (5) approved appeals
- Ten (10) grievances

Review of 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 of the audit protocol for each of the following service determination request, appeal, and grievance sample selected. Documentation will be submitted through HPMS for review by CMS.

Application of Compliance Standard

The criteria used to evaluate cases include, but are not limited to, the compliance standards in the audit protocol, which are organized in question format and include:

- Did the PO appropriately process service determination requests, appeals and grievances?
- Did the PO appropriately notify participants and/or their designated representatives of any decision relating to a service determination request, appeal or grievance?
- Did the PO process service determination requests and appeals within required timeframes and take appropriate extensions?
- Did the PO effectuate/provide approved services as expeditiously as the participant's condition required?

Provision of Services

Selection of 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 thirty (30) targeted medical records that appear clinically significant.

Participant Observations

CMS will also conduct up to five (5) participant observations during audit fieldwork in order to ensure participants are receiving appropriate care and services that were indicated to be necessary.

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 (1) 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.

Review of Sample Case Documentation

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.

Application of Compliance Standard

The criteria used to evaluate cases include, but are not limited to, the compliance standards in the audit protocol, which are organized in question format and include:

- Did the PO furnish comprehensive services necessary to meet the needs of all participants?
- Did the PO ensure that the IDT was appropriately involved in participant care?
- Did the PO perform assessments as required?
- Did the PO maintain a complete, accurate, and accessible medical record?
- Did the PO develop and document an appropriate care plan for the participants?
- Did the PO provide care and services necessary to meet the medical, physical, emotional, and social needs of each participant?
- Did the PO follow appropriate infection control standards when providing care?
- Did the PO have emergency equipment immediately available (suction, oxygen, medications, etc.)?
- Did the PO have a method of providing safe transportation to participants?

Personnel Records

Selection of Sample Cases

CMS will initially select up to ten (10) targeted personnel records

Review of 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

Application of Compliance Standard

The criteria used to evaluate cases include, but are not limited to, the compliance standards in the audit protocol, which are organized in question format and include:

- Did the PO conduct a background check on all personnel prior to their date of hire?
- Did the PO conduct an OIG exclusion check for all personnel prior to their date of hire?
- Did the PO ensure that personnel were appropriately licensed, if applicable?
- Did the PO ensure that all personnel with direct participant contact were medically cleared of communicable diseases before engaging in direct participant contact?
- Did the PO ensure that personnel completed competencies before working independently?

Audit Element Review: Compliance And Quality Improvement

CMS will review interview compliance and quality personnel, review documentation, and apply a compliance standard to this audit element.

Compliance and Quality Improvement Interview

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.

Documentation Review

CMS will review relevant documentation and information related to the PO's compliance oversight and quality improvement programs.

Application of Compliance Standard

The criteria used to evaluate documentation include, but are not limited to, the compliance standards in the audit protocol, which are organized in question format and include:

- Did the PO adopt and implement an effective compliance oversight program?
- Did the PO develop and implement an effective, data-driven quality improvement program?
- 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

As issues of non-compliance are identified, CMS outlines three options for requesting additional information for each potential issue of non-compliance:

Root Cause Analysis

CMS will request a Root Cause Analysis for each potential issue of noncompliance identified during the review. 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. POs will have up to two (2) business days to complete the requested Root Cause Analysis templates.

Impact Analysis

CMS may also request an impact analysis on identified potential non-compliance. CMS will identify the sample cases that must be reviewed by the organization. The PO must then identify all parties subject to or impacted by the issue of noncompliance generally from the beginning of the data collection period through the audit exit conference. POs will have up to ten (10) business days to complete the requested Impact Analysis templates.

CMS has added to and expanded the Impact Analysis templates for the 2023 Audit Process to eighteen (18) from sixteen (16) in 2022.

Additional Records Review

CMS may request additional case files, documentation, data or provide access to participant medical records after CMS concludes audit fieldwork if there is a need to validate the accuracy of information the PACE Organization submitted.

PACE Organization Burden of Effort for 2023 protocol

In the Supporting Statement - A The PACE Organization (PO) Monitoring and Audit Process in Part 460 of 42 CFR CMS-10630, OMB 0938-1327, CMS outlined the burden estimates for PACE Organizations:

> *"Trial year and routine audits will use the same audit protocol. As a result, the burden estimate is the same for both trial year and routine audits. Based on revisions to the audit protocol, CMS has revised burden estimates for the PACE audits beginning in 2023. CMS estimates a total of four people (identified above) from each PO, working simultaneously, will be used for each audit. We estimate an average of 25 hours per person prior to the audit start to assemble data and review the information for completeness, 80 hours per person for the actual administration of the audit, 40 hours per person to review and respond to the documentation requests, impact analyses (asapplicable) and the draft audit report, and 50 hours per person to submit and implement corrective action and audit close out activities.* ***This is a total of approximately*** *195 hours per person for each PO, or* ***780 hours total per PO. The average number of POs that will receive an audit annually is 40.***[2]*"*

[2] https://govaffairs.unitypoint.org/wp-content/uploads/PACEAuditFinal_Statement.pdf