

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

Chapter 15 – Organization Monitoring and Auditing **Table of Contents** *(Rev. 2, Issued: 06-09-11)*

Transmittals for Chapter 15

10 - Introduction

20 - General Monitoring and Auditing Requirements

20.1 - PACE Organization Responsibilities

20.2 - Technical Assistance

30 - Audit

30.1 - Pre-Audit Activities

30.2 - Audit Process

30.3 - Audit Team

30.4 - Audit Categories

30.5 - Trial Period

30.6 - Trial Period Review

30.7 - Scope of Review

30.8 - Biennial

30.9 - Focused

40 - Post Audit

40.1 - CAR/CAP

40.2 - Release from Corrective Action Plan

50 - Disclosure of Results

60 - State Administering Agency

60.1 - Readiness Review

60.2 - Monitoring During Trial Period

60.3 - Annual Monitoring

60.4 - Monitoring of Corrective Action Plans

70 - Financial Recordkeeping and Reporting Requirements

70.1 - Accurate Reports

70.2 - Accrual Accounting

70.3 - Accepted Reporting Practices

70.4 - Trial Period Reporting Requirements

70.5 - Annual Reporting Requirements

80 - HPMS Quality Data Submission

10 - Introduction

(Rev. 2, Issued: 06-09-11; Effective: 06-03-11; Implementation: 06-03-11)

The PACE program agreement is a three-way agreement between the PACE organization, CMS and the State Administering Agency. Monitoring and auditing are the responsibility of CMS and the State Administering Agency.

[42 CFR §§ 460.30, 460.112]

20 - General Monitoring and Auditing Requirements

(Rev. 2, Issued: 06-09-11; Effective: 06-03-11; Implementation: 06-03-11)

As noted above, the State Administering Agency and CMS have primary responsibility to ensure that every PACE organization maintains compliance with State and Federal requirements. This function includes the monitoring and effectiveness evaluation of organizational structure, procedures, protocols, and policies of each PACE organization.

20.1 - PACE Organization Responsibilities

(Rev. 2, Issued: 06-09-11; Effective: 06-03-11; Implementation: 06-03-11)

- The PACE organization shall collect data, maintain records and submit reports as required by CMS and the State Administering Agency. A PACE organization must submit to CMS and the State Administering Agency all reports that CMS and the State Administering Agency require to monitor the operation, cost, quality, and effectiveness of the program and establish payment rates. The PACE organization shall allow CMS and the State Administering Agency access to data and records including, but not limited to, participant health outcomes data, financial books and records, medical records, personnel records, any aspect of services furnished, reconciliation of participants' benefit liabilities and determination of Medicare and Medicaid amounts payable;
- The PACE organization agrees to require that all related entities, contractors or subcontractors agree that the State Administering Agency, the U.S. Department of Health and Human Services, CMS, or their designee(s) have the right to inspect, evaluate and audit any pertinent contracts, books, documents, papers, and records of any related entity contractor(s) or subcontractor(s) involving transactions related to the PACE Program Agreement.

[42 CFR §§ 460.70, 460.200(a), (b), and (c), 460.204(d); 71 FR 71324 (Dec. 8, 2006)]

20.2 - Technical Assistance

(Rev. 2, Issued: 06-09-11; Effective: 06-03-11; Implementation: 06-03-11)

CMS or the State Administering Agency may perform conference calls, webinars, or onsite visits to assist the PACE organization with operational or clinical issues. A PACE organization may request this assistance, or CMS or the State Administering Agency may provide technical assistance as a result of identified issues or opportunities for improvement.

30 - Audit

(Rev. 2, Issued: 06-09-11; Effective: 06-03-11; Implementation: 06-03-11)

30.1 - Pre-Audit Activities

(Rev. 2, Issued: 06-09-11; Effective: 06-03-11; Implementation: 06-03-11)

The pre-audit activities are very similar to those required for a Technical Advisory Visit (TAV). The PACE organization is required to provide operational and policy documents for review. Staff must be scheduled to be available for interview regarding administrative, clinical and Part D elements. In addition, documentation to validate actions performed concerning findings from the TAV, prior audits, Level Two Reporting, monitoring outcomes and compliance actions may be requested during this phase or during the course of the audit. This aspect may include the results of previous routine and focused audits, including audits the State Administering Agency or other State and Federal entities may have conducted. A notice including the audit date, draft agenda, documentation request and other additional requirements will be sent to the PACE organization.

30.2 - Audit Process

(Rev. 2, Issued: 06-09-11; Effective: 06-03-11; Implementation: 06-03-11)

30.3 - Audit Team

(Rev. 2, Issued: 06-09-11; Effective: 06-03-11; Implementation: 06-03-11)

The audit team consists of administrative and clinical staff from CMS and the State Administering Agency. The team reviews clinical, administrative and Part D elements as noted within the PACE Audit Guide. An external version of the guide is located on the CMS website at:

<http://www.cms.hhs.gov/PACE/Downloads/2008%20PACE%20Audit%20Guide.pdf>.

30.4 - Audit Categories

(Rev. 2, Issued: 06-09-11; Effective: 06-03-11; Implementation: 06-03-11)

Every PACE organization must have, as required by Sections 1894(a)(9) and (e)(4) and 1934(a)(9) and (e)(4), an **annual audit during the PACE organization's trial period** - the first three contract years following the PACE organization program's effective date. **Routine or Biennial audits** are conducted at least every two years following a PACE organization's successful completion of the trial period audits. A **Focused audit** may be performed if CMS or the State Administering Agency determines that additional monitoring or auditing is required due to identified issues of non-compliance, operational

deficiencies or significant audit findings. Focused audits may occur during the trial period or thereafter.

CMS does not share its method of evaluation or protocols with PACE organizations. PACE organizations must comply with all PACE regulations and preparations for audits should focus on a self-evaluation of the organization's compliance with PACE regulations. The PACE organizations must comply with local policies and procedures and performance on monitoring requirements such as quarterly HPMS reporting elements. The elements covered include, but are not limited to, the following:

Element	Title
Section 1 – Clinical PACE Elements	
PRS 02	Personnel Training
PRS 04	Oversight of Direct Patient Care
ENV 01	Physical Environment
ENV 02	Infection Control
TRS 01	Transportation Services
DTY 01	Dietary Services
SDY 01	Service Delivery
SDY 02	Emergency Care
SDY 03	Interdisciplinary Team
SDY 04	Participant Assessment
SDY 05	Plan of Care
QAP 04	Internal Quality Assessment and Performance Improvement Activities
Section 2 A – Administrative PACE Elements	
CTS 01	Contracted Services
FIN 01	Fiscal Soundness
PRT 04	Explanation of rights
PRT 06	Grievance Process
PRT 07	PACE Organization's Appeals Process
PRT 08	Additional Appeal Rights Under Medicare or Medicaid
MKT 03	Enrollment Process
MKT 08	Voluntary Disenrollment
MKT 09	Involuntary Disenrollment
Section 2B – Operational Part D Elements	
ER 13	Confirmation of Enrollment for Members of Employer Group/Union
PR 02	Use of SSN/HICN
EP01	Electronic Prescribing
CB 01	Collecting/Updating Enrollees' Other health Insurance Information
CB03	TrOOP Status at Disenrollment
CP06	Internal Monitoring and Auditing Procedures
CP07	Response to Detected Offenses and Corrective Action Plan
CP08	Comprehensive Fraud and Abuse Plan

Element	Title
CL01	Online Claims Processing System
CL02	Data Elements Needed to Link Medicare Parts A, B and D Data
CL03	Processing Systems
CL04	Disputed Claims
CL06	Certification of Claims Data
PA 01	Certification of Monthly Enrollment and Payment Data Relating to CMS Payment
PA02	Submission of Prescription Drug Event Data
PA03	Overpayment and Underpayment Requirements

30.5 - Trial Period

(Rev. 2, Issued: 06-09-11; Effective: 06-03-11; Implementation: 06-03-11)

Trial period means the first three contract years in which a PACE organization operates under a PACE Program Agreement, including any contract year during which the entity operated under a PACE demonstration waiver program. The first contract year can extend from 12 months up to 23 months for purposes of the audit period, that is, to December 31st of the year following the effective date of the contract. The first trial period audit can be conducted at any point during this 12 to 23-month period.

[42 CFR §§ 460.6, 460.190(a)]

30.6 - Trial Period Review

(Rev. 2, Issued: 06-09-11; Effective: 06-03-11; Implementation: 06-03-11)

During the trial period, CMS, in cooperation with the State Administering Agency, conducts comprehensive annual reviews of the operations of a PACE organization to ensure compliance.

[42 CFR § 460.190(a)]

30.7 - Scope of Review

(Rev. 2, Issued: 06-09-11; Effective: 06-03-11; Implementation: 06-03-11)

As noted above, the review includes the utilization of the PACE Audit Guide. In addition, the review may include performance of the following:

- An onsite visit to the PACE organization, which may include, but is not limited to, the following:
 - o Review of participants' charts;
 - o Interviews with staff;

- o Interviews with participants and caregivers; and,
- o Interviews with contractors;
- Observation of program operations, including marketing, participant services, enrollment and disenrollment procedures, grievances, and appeals;
- A comprehensive assessment of an organization's fiscal soundness;
- A comprehensive assessment of the organization's capacity to furnish all PACE services to all participants; and
- Any other elements that CMS or the State Administering Agency find necessary.

[42 CFR § 460.190(b)]

30.8 - Biennial

(Rev. 2, Issued: 06-09-11; Effective: 06-03-11; Implementation: 06-03-11)

At the conclusion of the trial period, CMS, in cooperation with the State Administering Agency, continues to conduct reviews of a PACE organization, as appropriate. These reviews take into account the performance level of the PACE organization with respect to the quality of care provided and compliance of the organization in meeting the PACE program requirements. Such reviews include an on-site visit at least every two years.

[42 CFR § 460.192]

30.9 - Focused

(Rev. 2, Issued: 06-09-11; Effective: 06-03-11; Implementation: 06-03-11)

After the trial period, CMS or the State Administering Agency may determine that a PACE organization has some areas of their program that need further monitoring. In these situations, CMS or the SAA may perform Focused Audits on these or other areas. These audits may be announced, unannounced, onsite or offsite.

[42 CFR § 460.192]

40 - Post Audit

(Rev. 2, Issued: 06-09-11; Effective: 06-03-11; Implementation: 06-03-11)

CMS, the State Administering Agency or their designees will deliver an audit report containing findings, deficiencies, corrective action required, recommendations, notes and conclusions to the PACE organization concerning the audit. A letter detailing instructions, as noted below, is mailed to the primary contact for the PACE organization.

[42 CFR § 460.196(a)]

40.1 - CAR/CAP

(Rev. 2, Issued: 06-09-11; Effective: 06-03-11; Implementation: 06-03-11)

A PACE organization must take action to correct deficiencies identified during reviews. Corrective Action Required (CAR) and Corrective Action Plan (CAP) are formal processes where CMS informs PACE organizations that they are out of compliance with CMS requirements. Corrective Action Required (CAR)/Corrective Action Plan (CAP) may result from a PACE audit or result from other ad-hoc compliance events unrelated to an audit. For example, CMS issues a compliance warning letter to a PACE organization and the PACE organization fails to satisfactorily resolve the matter cited in the warning letter.

More specifically, Corrective Action Required (CAR) letters are issued when CMS identifies an area of concern that requires a formal plan for a demonstrated cure. A Corrective Action Required (CAR) should be considered when a PACE organization has not provided a satisfactory response to a single warning letter on a specific subject (an egregious single event) or the issue is of a highly serious nature.

A Corrective Action Required (CAR) letter may also be issued by CMS directly to the PACE organization when CMS has identified an ad hoc compliance event. Once a PACE organization receives a CAR letter, they would respond to CMS with either a dispute of findings or a Corrective Action Plan (CAP).

The PACE organization must provide a plan containing actions, activities, policies and procedures that will be implemented to correct the deficiencies and to be in compliance. The PACE organization must respond promptly to the deficiencies following receipt of formal notice from CMS via an HPMS email. The Corrective Action Plan is promptly reviewed by CMS following receipt of the PACE organization's submission of the Corrective Action Plan. If the Corrective Action Plan is unacceptable, the PACE organization will be provided an opportunity to promptly resubmit a revised Corrective Action Plan. CMS will review the revised Corrective Action Plan and provide a prompt response.

Corrective Action Plans are public documents which are posted on the CMS website at <http://www.cms.hhs.gov/MCRAdvPartDEnrolData/>.

[42 CFR § 460.196(b)]

40.2 - Release from Corrective Action Plan

(Rev. 2, Issued: 06-09-11; Effective: 06-03-11; Implementation: 06-03-11)

Once CMS accepts the Corrective Action Plan, the PACE organization must implement the CAP. The amount of time allowed to implement a Corrective Action Plan depends on the number of deficiencies and the complexity of the deficiencies. CMS or the State

Administering Agency monitors the implementation and effectiveness of corrective actions to determine if adequate progress is being made on the CAP before giving consideration to releasing the PACE organization from its Corrective Action Plan.

The Corrective Action Plan process ends when the PACE organization has fully implemented the CAP and CMS formally releases the PACE organization from the Corrective Action Plan. The Corrective Action Plan release process occurs via an HPMS-generated notice.

CMS or the State Administering Agency may take enforcement action if the PACE organization fails to submit an acceptable Corrective Action Plan to CMS or if the PACE organization fails to satisfactorily implement an accepted Corrective Action Plan. Failure to develop and implement a Corrective Action Plan within the timeframes specified by CMS may result in sanctions or termination of a PACE organization's contract by CMS or the State Administering Agency.

[42 CFR § 460.194(b) and (c)]

50 - Disclosure of Results

(Rev. 2, Issued: 06-09-11; Effective: 06-03-11; Implementation: 06-03-11)

CMS and the State Administering Agency promptly report the results of reviews to the PACE organization, along with any recommendations for changes to the organization's program. The results are made available to the public upon request and are posted on the CMS website. In addition, CMS and the State Administering Agency require that the PACE organization post a notice of the availability of the results of the most recent review and any Corrective Action Plans or responses related to the most recent review. The PACE organization must also make the results available for examination in a place readily accessible to participants.

[42 CFR § 460.196]

60 - State Administering Agency

(Rev. 2, Issued: 06-09-11; Effective: 06-03-11; Implementation: 06-03-11)

The State Administering Agency assures that its responsibilities under Sections 1894 and 1934 of the Social Security Act will be met. All relevant provisions are included in the contract with the PACE entities, either as a contractor or State Administering Agency responsibility. Both scheduled and unscheduled on-site reviews will be conducted by State Administering Agency staff.

[42 CFR §§ 460.30, 460.32, 460.190, 460.192]

60.1 - Readiness Review

(Rev. 2, Issued: 06-09-11; Effective: 06-03-11; Implementation: 06-03-11)

The State Administering Agency will perform a Readiness Review of the applicant entity that assures the entity has fully developed its policies and procedures, obtained commitments from key staff, developed its solvency plan and has a facility that meets State and Federal requirements at the time of the application.

[42 CFR § 460.12(b)(1); 71 FR 71252 (Dec. 8, 2006)]

60.2 - Monitoring During Trial Period

(Rev. 2, Issued: 06-09-11; Effective: 06-03-11; Implementation: 06-03-11)

During the trial period, the State Administering Agency, in cooperation with CMS, will conduct comprehensive reviews of a PACE organization to ensure compliance with State and Federal requirements. At the conclusion of the trial period, the State Administering Agency, in cooperation with CMS, will continue to conduct reviews of a PACE organization, as appropriate, taking into account the quality of care furnished and the organization's compliance with State and Federal requirements.

[42 CFR §§ 460.190, 460.192(a)]

60.3 - Annual Monitoring

(Rev. 2, Issued: 06-09-11; Effective: 06-03-11; Implementation: 06-03-11)

The State Administering Agency assures that at least annually it will reevaluate whether a participant meets the level of care required under the State Medicaid plan for coverage of nursing facility services. The State Administering Agency understands that this determination may be waived if there is no reasonable expectation of improvement or significant change in the participant's conditions because of the severity of a chronic condition or the degree of impairment of functional capacity. The State Administering Agency assures that it will make reviews conducted in accordance with 42 CFR §§ 460.190 and 460.192 available to the public upon request.

[42 CFR §§ 460.160(b)(a), 460.196(b)]

60.4 - Monitoring of Corrective Action Plans

(Rev. 2, Issued: 06-09-11; Effective: 06-03-11; Implementation: 06-03-11)

CMS works in partnership with the State Administering Agency to monitor the effectiveness of corrective actions required to be taken by the PACE organization.

[42 CFR § 460.194]

70 - Financial Recordkeeping and Reporting Requirements

(Rev. 2, Issued: 06-09-11; Effective: 06-03-11; Implementation: 06-03-11)

70.1 - Accurate Reports

(Rev. 2, Issued: 06-09-11; Effective: 06-03-11; Implementation: 06-03-11)

A PACE organization must provide CMS and the State Administering Agency with accurate financial reports that are:

- Prepared using an accrual basis of accounting; and
- Verifiable by qualified auditors.

[42 CFR § 460.204(a)]

70.2 - Accrual Accounting

(Rev. 2, Issued: 06-09-11; Effective: 06-03-11; Implementation: 06-03-11)

A PACE organization must maintain an accrual accounting recordkeeping system that does the following:

- Accurately documents all financial transactions;
- Provides an audit trail to source documents;
- Generates financial statements.

[42 CFR § 460.204(b)]

70.3 - Accepted Reporting Practices

(Rev. 2, Issued: 06-09-11; Effective: 06-03-11; Implementation: 06-03-11)

Except as specified under Medicare principles of reimbursement, a PACE organization must follow standardized definitions, accounting, statistical, and reporting practices that are widely accepted in the health care industry.

[42 CFR § 460.204(c)]

70.4 - Trial Period Reporting Requirements

(Rev. 2, Issued: 06-09-11; Effective: 06-03-11; Implementation: 06-03-11)

Throughout a trial period, the PACE organization is required to submit a quarterly financial statement to CMS within forty-five days after the last day of each quarter of the organization's fiscal year. These statements are not required to be certified by an independent certified public accountant. After the trial period, CMS and/or the State Administering Agency may require a PACE organization to submit monthly and/or quarterly financial statements, or both, if there are concerns about the fiscal soundness of the organization.

[42 CFR § 460.208(c)]

70.5 - Annual Reporting Requirements

(Rev. 2, Issued: 06-09-11; Effective: 06-03-11; Implementation: 06-03-11)

CMS requires the PACE organization to submit an annual financial statement with appropriate footnotes no later than 180 days after the end of the organization's fiscal year. The financial statement must be certified by an independent certified public accountant and, at a minimum, include the following items:

- Certification statement;
- Balance sheet;
- Statement of revenues and expenses; and
- Source and use of funds statement.

[42 CFR § 460.208(a) and (b)]

80 - HPMS Quality Data Submission

(Rev. 2, Issued: 06-09-11; Effective: 06-03-11; Implementation: 06-03-11)

PACE organizations are required to maintain a health information system that collects, analyzes, integrates, and reports data necessary to measure their performance and to develop their QAPI.

HPMS is a CMS internal health information system that collects, analyzes, integrates, and reports data to measure the organization's performance and to develop and implement procedures to furnish data pertaining to the provision of care to external oversight entities in the manner and at the time intervals specified by CMS and the State Administering Agency. A PACE organization must submit to CMS and the State Administering Agency all reports required to monitor the operation, costs, quality, and effectiveness of the PACE program and established payment rates.

In developing procedures for external reporting, the PACE organization must include the submission of CMS monitoring data which is specified as "participant data" in Appendix L of the PACE Program Agreement. CMS requires the data to be reported quarterly/seasonally through the HPMS system. A listing of the nine data elements can be found in Chapter 10 Section 30.

PACE programs are required to submit Data Elements for Monitoring on a quarterly basis via the HPMS. HPMS information may be used by CMS and State Administering Agencies in the time period before or after signing the program agreement which contains these reporting requirements. PACE organizations are provided with instructions on the HPMS: The HPMS Connectivity Guide, HPMS User's Guide and HPMS Connectivity for States. These materials can also be found on the CMS Web site at http://www.cms.hhs.gov/PACE/09_AdditionalResources.asp.

[42 CFR §§ 460.134, 460.140, 460.200, 460.202, 460.204; 71 FR 71307 (Dec. 8, 2006)]

Transmittals Issued for this Chapter

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[Back to top of Chapter](#)