

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

Chapter 2 – Administrative Requirements

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(Rev. 2, Issued: 06-09-11)

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10 - Introduction

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

The purpose of this chapter is to provide information about the requirements established relating to the organizational structure, the governing body and program integrity of the PACE organization as well as the relationships between entities. These requirements are essential to the PACE organization's ability to ensure the health and safety of the participants and provide a well functioning organizational environment in which appropriate care can occur.

20 - PACE Organizational Structure

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

A PACE organization must be, or be a distinct part of, one of the following:

- An entity of city, county, State, or Tribal government;
- A private not-for-profit entity organized for charitable purposes under Section 501(c)(3) of the Internal Revenue Code of 1986. The entity may be a corporation, a subsidiary of a larger corporation, or a department of a corporation;
- A for-profit entity, subject to a demonstration waiver. CMS notes that Sections 1894(a)(3)(B) and 1934(a)(3)(B) of the Act allow private, for-profit entities to participate in PACE, subject to a demonstration waiver described in Section 1894(h) and 1934(h) of the Act. (For-profit entities wishing to participate in PACE applied for a demonstration waiver under Section 1894(h) and 1934(h) of the Act. CMS issued a Federal Register notice on July 24, 2009 announcing July 26, 2010 as the closing date for submission of proposals for the for-profit demonstration project for PACE). While participating in the PACE for-profit demonstration, they must meet all requirements set forth in PACE regulations. CMS explicitly stated they would expect the PACE organization to retain all key administrative functions including marketing and enrollment, quality assurance and program improvement, and contracting for institutional providers and other key staff.

A potential PACE organization must supply evidence that core staff have been chosen and accepted specific key positions in their official application submission.

In the event of a change of ownership, CMS would apply the general provisions described in 42 CFR § 422.550 [Effect of change of ownership or leasing of facilities during term of contract.]

[42 CFR §§ 460.12, 460.32, 460.60(a); 71 FR 71263 (Dec. 8, 2006)]

20.1 - Program Director

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

The organization must employ, or contract with in accordance with 42 CFR § 460.70, a program director who is responsible for oversight and administration of the entity.

The program director should be responsible for the effective planning, organization, administration and evaluation of the organization's operations. The program director should also ensure that decisions about medical, social, and supportive services are not unduly influenced by the fiscal manager. The program director should be responsible for ensuring that appropriate personnel perform their functions within the organization. The program director should inform employees and contract providers of all organization policies and procedures. If the PACE organization is part of a larger health system, the program director should clearly define and inform the PACE organization staff (employees and contractors) of the policies applicable to the PACE organization.

[42 CFR § 460.60; 71 FR 71262 (Dec. 8, 2006)]

20.2 - Medical Director

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

The PACE organization must employ, or contract with in accordance with 42 CFR § 460.70, a medical director who is responsible for the delivery of participant care, for clinical outcomes, and for the implementation, as well as oversight of, the quality assessment and performance improvement program.

The medical director is responsible for achieving the best clinical outcomes possible for all participants. CMS requires the medical director to use the organization's data to demonstrate internal improvements in outcomes over time.

[42 CFR § 460.60(c); 71 FR 71263 (Dec. 8, 2006)]

20.3 - Organizational Chart

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

The organizational chart is requested at the time of application or expansion request and when there are changes in key personnel:

- The PACE organization must have a current organizational chart showing officials in the PACE organization and relationships to any other organizational entities;
- The chart for a corporate entity must indicate the PACE organization's relationship to the corporate board and to any parent, affiliate, or subsidiary corporate entities;

- A PACE organization planning a change in organizational structure must notify CMS and the State Administering Agency, in writing, at least 14 days before the change takes effect.

NOTE: A change in organizational structure is one that may affect the philosophy, mission, and operations of the PACE organization and impact care delivery to participants. This would include any change in ownership, relationships to another corporate board and to any parent, affiliate, or subsidiary corporate entities, the PACE governing body, its officials, program director and medical director.

[42 CFR §§ 460.32(a)(4), 460.60(d)]

30 - Governing Body

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

The governing body must create and foster an environment that provides quality care that is consistent with the participant needs and the program mission.

A PACE organization must be operating under the control of an identifiable governing body (for example, a board of directors) or a designated person functioning as a governing body with full legal authority and responsibility for the following:

- Governance and operation of the organization;
- Development of policies consistent with the mission;
- Management and provision of all services, including the management of contractors;
- Establishment of personnel policies that address adequate notice of termination by employees or contractors with direct patient care responsibilities. These policy and procedures need to be in compliance with local, state and federal guidelines;
- Fiscal operations;
- Development of policies on participant health and safety, including a comprehensive, systemic operational plan to ensure the health and safety of participants;
- Quality assessment and performance improvement program (QAPI). The purpose of this requirement is to link the development, implementation, and coordination of the ongoing QAPI program with all aspects of the PACE program.

[42 CFR § 460.62(a); 71 FR 71264 (Dec. 8, 2006)]

40 - Participant Advisory Committee

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

A PACE organization must establish a participant advisory committee to provide advice to the governing body on matters of concern to participants. Participants and representatives of participants must constitute a majority of the membership of this committee. The participant advisory committee must provide the liaison to the governing body with meeting minutes that include participant issues.

[42 CFR § 460.62(b)]

40.1 - Participant Representation on the Governing Body

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

A PACE organization must ensure participant representation on issues related to participant care. This shall be achieved by having a participant representative on the governing body (this representation may take the form of a participant, his/her caregiver, or an advisory committee member). The participant representative is a liaison of the participant advisory committee to the PACE organization governing body. The participant representative must present issues from the participant advisory committee to the governing body.

[42 CFR § 460.62(c)]

50 - Program Integrity

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

50.1 - Persons with Criminal Convictions

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

A PACE organization must not employ individuals or contract with organizations or individuals:

- Who have been excluded from participation in the Medicare or Medicaid programs;
- Who have been convicted of criminal offenses related to their involvement in Medicaid, Medicare, other health insurance or health care programs, or social service programs under Title XX of the Act, or
- In any capacity where an individual's contact with participants would pose a potential risk because the individual has been convicted of physical, sexual, drug, or alcohol abuse.

Verification of criminal background check may be done through a database check such as Department of Justice or State criminal background databases. The PACE organization will maintain a copy of this verification in the employee's personnel record, and this verification needs to be done upon hire or at some other duration established by CMS or in accordance with state requirements, whichever is most stringent.

[42 CFR § 460.68]

50.2 - Direct or Indirect Interest in Contracts

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

The PACE organization shall identify members of its governing body or any immediate family member having direct or indirect interest in any contract that supplies any administrative or care-related service or materials to the PACE organization. PACE organizations must develop policies and procedures for handling any direct or indirect conflict of interest by a member of the governing body or by the member's immediate family. In the event of a direct or indirect conflict of interest by a member of the PACE organization's governing body or his or her immediate family member, the board member must (1) fully disclose the exact nature of the conflict to the board of directors and have the disclosure documented; and (2) recuse himself or herself from discussing, negotiating, or voting on any issue or contract that could result in an inappropriate conflict.

Examples of indirect interests are holdings in the name of the spouse, dependent child, or other relative who resides with the member of the governing body. These requirements are intended to protect participants by preventing fraud under Medicare and Medicaid by preventing members of the governing body with conflicts of interest from inappropriately influencing PACE organization decisions.

CMS remains committed to working with rural and Tribal communities to help them address the challenges of developing successful PACE programs. Due to potential limited availability of individuals willing to and capable of performing key functions for the PACE organization, there is a special need for flexibility in rural and Tribal areas, and CMS remains committed to allowing waivers to promote PACE in medically underserved areas.

[42 CFR § 460.68(b); 71 FR 71269 (Dec. 8, 2006)]

50.3 - Disclosure Requirements

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

A PACE organization must have a formal process in place to gather information related to persons with criminal convictions (section [50.1](#) above) and direct or indirect interest in contracts (section [50.2](#) above) and must be able to respond in writing to a request for information from CMS within a reasonable amount of time.

[42 CFR § 460.68(c)]

50.4 - Privacy Policy

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

A PACE organization must abide by all applicable Federal and State laws regarding confidentiality and disclosure for mental health records, medical records and other participant health information (PHI)

(See <http://www.cms.hhs.gov/HIPAAGenInfo/Downloads/HIPAAALaw.pdf> to obtain further information on current HIPAA regulations).

[42 CFR § 460.200(e)(4)]

50.5 - De-identified Health Information and Limited Data Set

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

If it is necessary to disclose PHI, there are two methods to accomplish the release of information. The organization may de-identify the information. The de-identified information is not PHI because it does not identify an individual and there is no reasonable basis to believe that the information can be used to identify an individual. De-identified information, therefore, is outside the purview of the Health Insurance Portability and Accountability Act of 1996 (HIPAA) privacy standards.

Under the HIPAA privacy requirements there are two ways to de-identify PHI:

- The organization may de-identify in accordance with “generally accepted statistical and scientific principles and methods”; or
- The organization may remove all identifiers of an individual or of relatives, employers or household members of the individual listed in the safe harbor method in the regulation:
 - o Names;
 - o All geographic subdivisions smaller than a State;
 - o All elements of dates (except year) for dates directly related to an individual, including birth date, admission date, discharge date, date of death, and all ages over 89 and all elements of dates (including year) indicative of such age, except that such ages and elements may be aggregated into a single category of age 90 or older;
 - o Telephone numbers;
 - o Fax numbers;

- o Electronic mail addresses;
- o Social security numbers;
- o Medical record numbers;
- o Health plan beneficiary numbers;
- o Account numbers;
- o Certificate/license numbers;
- o Vehicle identifiers and serial numbers, including license plate numbers;
- o Device identifiers and serial numbers;
- o Web URLs;
- o IP address numbers;
- o Biometric identifiers, including finger and voice prints;
- o Full face photographic images and any comparable images; and
- o Any other unique identifying number, characteristic, or code.

Additionally, the PACE organization does not have actual knowledge that the information could be used alone or in combination with other information to identify an individual who is the subject of the information.

The organization may assign a code or other means of record identification to allow information de-identified to be re-identified.

The PACE organization should have the following HIPAA Compliance for Safeguarding PHI:

- The organization has a contingency plan and disaster recovery plan for all PHI;
- The organization has security policy and procedures for data.

[45 CFR § 164.514(a) and (b)]

60 - Fiscal Soundness

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

60.1 - Fiscally Sound Operation

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

A PACE organization must have a fiscally sound operation, as demonstrated by the following:

- Total assets greater than total unsubordinated liabilities;
- Sufficient cash flow and adequate liquidity to meet obligations as they become due;
- A net operating surplus or a financial plan for maintaining solvency that is satisfactory to CMS and the State Administering Agency.

A PACE organization under the three-year trial period is required to submit quarterly financial statements to CMS within 45 days from the end of each quarter of the PACE organization's fiscal year. After the trial period, if CMS or the State Administering Agency determines that an organization's performance requires more frequent monitoring and oversight due to concerns about fiscal soundness, CMS or the State Administering Agency may require a PACE organization to submit monthly or quarterly financial statements, or both. The financial statements shall include a balance sheet, income statement, and a cash flow statement. In addition to the quarterly financial statements, PACE organizations under a three year trial period are required to submit their latest independently prepared audit report containing their audited financial statements along with the auditor's opinion and auditor notes. PACE organizations operating within larger sponsoring entities must also submit their sponsoring entities' independently prepared audit report. The audit reports are due within 180 days from an organization's fiscal year end.

CMS no longer accepts hardcopy documentation. Instead, PACE organizations are required to upload a PDF or zip file of their quarterly financial statements and annual audit reports to the fiscal soundness module within the Health Plan Management System (HPMS).

In addition to the financial statements PACE organizations must upload 4 financial data elements (taken from the audited and quarterly financial statements) along with the financial statements. The fiscal soundness module will not accept the financial statements if the data elements are not uploaded at the same time.

If you cannot file the financial information by the regulatory deadlines shown under 42 CFR § 460.208(a), you must contact CMS before the prescribed due date. Failure to submit on time without notifying CMS places your company in non-compliance status and could result in your company receiving a non-compliance letter with the requirement of a corrective action plan to resolve the deficiency.

[42 CFR §§ 460.80(a), 460.208(c)]

60.2 - Insolvency Plan

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

The PACE organization must have a documented plan in the event of insolvency, approved by the Centers for Medicare & Medicaid Services, and the State Administering Agency, which provides for the following:

- Continuation of benefits for the duration of the period for which capitation payment has been made;
- Continuation of benefits to participants who are confined in a hospital on the date of insolvency until their discharge;
- Protection of participants from liability for payment of fees that are the legal obligation of the PACE organization.

[42 CFR § 460.80(b)]

60.3 - Arrangements to Cover Expenses

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

A PACE organization must demonstrate that it has arrangements to cover expenses in the amount of at least the sum of the following in the event it becomes insolvent:

- One month's total capitation revenue to cover expenses the month before insolvency;
- One month's average payment to all contractors, based on the prior quarter's average payment, to cover expenses the month after the date it declares insolvency or ceases operation;
- Arrangements to cover expenses may include, but are not limited to, the following:
 - o Insolvency insurance or reinsurance;
 - o Hold harmless arrangement;
 - o Letters of credit, guarantees, net worth, restricted State reserves, or State law provisions.

[42 CFR § 460.80(c)]

70 - Emergency and Disaster Preparedness

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

The PACE organization must establish, implement, and maintain documented procedures to manage medical and nonmedical emergencies and disasters that are likely to threaten the health or safety of the participants, staff, or the public. Additional information on requirements regarding emergencies can be found in Chapter 7 of the PACE Manual.

[42 CFR § 460.72(c)(1)]

70.1 - Emergencies Defined

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

Emergencies include, but are not limited to, the following:

- Fire;
- Equipment, water, or power failure;
- Care-related emergencies;
- Natural disasters likely to occur in the organization's geographic area (An organization is not required to develop emergency plans for natural disasters that typically do not affect its geographic location).

[42 CFR § 460.72(c)(2)]

70.2 - Emergency Training

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

A PACE organization must provide appropriate training and periodic orientation to all staff (employees and contractors) and participants to ensure that staff demonstrate a knowledge of emergency procedures, including informing participants what to do, where to go, and whom to contact in case of an emergency.

[42 CFR § 460.72(c)(3)]

70.3 - Availability of Emergency Equipment

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

Emergency equipment, including easily portable oxygen, airways, suction and emergency drugs, along with staff who know how to use the equipment, must be on the premises of every center at all times and be immediately available. The organization must have a documented plan to obtain emergency medical assistance from sources outside the center when needed.

[42 CFR § 460.72(4)]

70.4 - Annual Test of Emergency and Disaster Plan

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

At least annually, a PACE organization must actually test, evaluate and document the effectiveness of its emergency and disaster plans.

[42 CFR § 460.72(c)(5)]

Transmittals Issued for this Chapter

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