§ 460.54 Termination procedures.

(a) Except as provided in paragraph (b) of this section, if CMS terminates an agreement with a PACE organization, it furnishes the PACE organization with the following:

(1) A reasonable opportunity to develop and implement a corrective action plan to correct the deficiencies that were the basis of CMS’s determination that cause exists for termination.

(2) Reasonable notice and opportunity for hearing (including the right to appeal an initial determination) before terminating the agreement.

(b) CMS may terminate an agreement without invoking the procedures described in paragraph (a) of this section if CMS determines that a delay in termination, resulting from compliance with these procedures before termination, would pose an imminent and serious risk to the health of participants enrolled with the organization.

§ 460.60 PACE organizational structure.

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

(1) An entity of city, county, State, or Tribal government.

(2) 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.

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

(c) Medical director. The organization must employ, or contract with in accordance with §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.

(d) Organizational chart. (1) The PACE organization must have a current organizational chart showing officials in the PACE organization and relationships to any other organizational entities.

(2) 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.

(3) 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.

§ 460.62 Governing body.

(a) Governing body. 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:

(1) Governance and operation of the organization.

(2) Development of policies consistent with the mission.

(3) Management and provision of all services, including the management of contractors.

(4) Establishment of personnel policies that address adequate notice of termination by employees or contractors with direct patient care responsibilities.

(5) Fiscal operations.

(6) Development of policies on participant health and safety, including a
(7) Quality assessment and performance improvement program. 

(b) Participant advisory committee. (1) 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. 

(2) The participant advisory committee must provide the liaison to the governing body with meeting minutes that include participant issues. 

(c) Participant representation on the governing body. (1) 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. 

(2) The participant representative is a liaison of the participant advisory committee to the PACE organization governing body. 

(3) Duty of the participant representative. The participant representative must present issues from the participant advisory committee to the governing body. 

[64 FR 66279, Nov. 24, 1999, as amended at 71 FR 71334, Dec. 8, 2006] 

§ 460.64 Personnel qualifications for staff with direct participant contact. 

(a) General qualification requirements. Each member of the PACE organization’s staff that has direct participant contact, (employee or contractor) must meet the following conditions: 

(1) Be legally authorized (for example, currently licensed, registered or certified if applicable) to practice in the State in which he or she performs the function or action; 

(2) Only act within the scope of his or her authority to practice; 

(3) Have 1 year of experience with a frail or elderly population; 

(4) Meet a standardized set of competencies for the specific position description established by the PACE organization and approved by CMS before working independently. 

(5) Be medically cleared for communicable diseases and have all immunizations up-to-date before engaging in direct participant contact. 

(b) Federally-defined qualifications for physician. In addition to the qualification specified in paragraph (a) of this section, a physician must meet the qualifications and conditions in § 410.20 of this chapter. 

[71 FR 71334, Dec. 8, 2006] 

§ 460.66 Training. 

(a) The PACE organization must provide training to maintain and improve the skills and knowledge of each staff member with respect to the individual’s specific duties that results in his or her continued ability to demonstrate the skills necessary for the performance of the position. 

(b) The PACE organization must develop a training program for each personal care attendant to establish the individual’s competency in furnishing personal care services and specialized skills associated with specific care needs of individual participants. 

(c) Personal care attendants must exhibit competency before performing personal care services independently. 

[64 FR 66279, Nov. 24, 1999, as amended at 71 FR 71335, Dec. 8, 2006] 

§ 460.68 Program integrity. 

(a) Persons with criminal convictions. A PACE organization must not employ individuals or contract with organizations or individuals— 

(1) Who have been excluded from participation in the Medicare or Medicaid programs; 

(2) 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 

(3) 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. 

(b) Direct or indirect interest in contracts. The PACE organization shall identify members of its governing body or any immediate family member having a direct or indirect interest in any
contract that supplies any administrative or care-related service or materials to the PACE organization.

(1) 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.

(2) 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—
   (i) Fully disclose the exact nature of the conflict to the board of directors and have the disclosure documented; and
   (ii) Recuse himself or herself from discussing, negotiating, or voting on any issue or contract that could result in an inappropriate conflict.

(c) Disclosure and recusal requirements. A PACE organization must have a formal process in place to gather information related to paragraphs (a) and (b) of this section and must be able to respond in writing to a request for information from CMS within a reasonable amount of time.

§ 460.70 Contracted services.

(a) General rule. The PACE organization must have a written contract with each outside organization, agency, or individual that furnishes administrative or care-related services not furnished directly by the PACE organization except for emergency services as described in §460.100.

(b) Contract requirements. A contract between a PACE organization and a contractor must meet the following requirements:
   (1) The PACE organization must contract only with an entity that meets all applicable Federal and State requirements, including, but not limited to, the following:
      (i) An institutional contractor, such as a hospital or skilled nursing facility, must meet Medicare or Medicaid participation requirements.
      (ii) A practitioner or supplier must meet Medicare or Medicaid requirements applicable to the services it furnishes.
   (iii) A contractor must comply with the requirements of this part with respect to service delivery, participant rights, and quality assessment and performance improvement activities.
   (2) A contractor must be accessible to participants, located either within or near the PACE organization’s service area.
   (3) A PACE organization must designate an official liaison to coordinate activities between contractors and the organization.
   (c) List of contractors. A current list of contractors must be on file at the PACE center and a copy must be provided to anyone upon request.
   (d) Content of contract. Each contract must be in writing and include the following information:
      (1) Name of contractor.
      (2) Services furnished (including work schedule if appropriate).
      (3) Payment rate and method.
      (4) Terms of the contract, including beginning and ending dates, methods of extension, renegotiation, and termination.
      (5) Contractor agreement to do the following:
         (i) Furnish only those services authorized by the PACE interdisciplinary team.
         (ii) Accept payment from the PACE organization as payment in full, and not bill participants, CMS, the State administering agency, or private insurers.
         (iii) Hold harmless CMS, the State, and PACE participants if the PACE organization does not pay for services performed by the contractor in accordance with the contract.
         (iv) Not assign the contract or delegate duties under the contract unless it obtains prior written approval from the PACE organization.
         (v) Submit reports required by the PACE organization.
         (vi) Agree to perform all the duties related to its position as specified in this part.
         (vii) Participate in interdisciplinary team meeting as required.
         (viii) Agree to be accountable to the PACE organization.
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§ 460.72 Physical environment.

(a) Space and equipment—(1) Safe design. A PACE center must meet the following requirements:

(i) Be designed, constructed, equipped, and maintained to provide for the physical safety of participants and to demonstrate the skills necessary for performance of their position.

(ii) Be designed, constructed, equipped, and maintained to provide for the physical safety of participants, personnel, and visitors.

(ii) Ensure a safe, sanitary, functional, accessible, and comfortable environment for the delivery of services that protects the dignity and privacy of the participants.

(2) Primary care clinic. The PACE center must include sufficient suitable space and equipment to provide primary medical care and suitable space for team meetings, treatment, therapeutic recreation, restorative therapies, socialization, personal care, and dining.

(3) Equipment maintenance. (i) A PACE organization must implement, and maintain a written plan to ensure that all equipment is maintained in accordance with the manufacturer’s recommendations.

(ii) A PACE organization must perform the manufacturer’s recommended maintenance on all equipment as indicated in the organization’s written plan.

(b) Fire safety—(1) General rule. Except as otherwise provided in this section—

that apply to the type of setting in which the center is located. The Director of the Office of the Federal Register has approved the NFPA 101® 2000 edition of the Life Safety Code, issued January 14, 2000, for incorporation by reference in accordance with 5 U.S.C. 552(a) and 1 CFR part 51. A copy of the Code is available for inspection at the CMS Information Resource Center, 7500 Security Boulevard, Baltimore, MD or at the National Archives and Records Administration (NARA). For information on the availability of this material at NARA, call 202-741-6030, or go to: http://www.archives.gov/federal_register/code_of_federal_regulations/ibr_locations.html. Copies may be obtained from the National Fire Protection Association, 1 Batterymarch Park, Quincy, MA 02269; and

(ii) Chapter 19.3.6.3.2, exception number 2 of the adopted edition of the LSC does not apply to PACE centers.

(2) Exceptions. (i) The Life Safety Code provisions do not apply in a State in which CMS determines that a fire and safety code imposed by State law adequately protects participants and staff.

(ii) CMS may waive specific provisions of the Life Safety Code that, if rigidly applied, would result in unreasonable hardship on the Pace center, but only if the waiver does not adversely affect the health and safety of the participants and staff.

(3) Beginning March 13, 2006, a PACE center must be in compliance with Chapter 9.2.9 Emergency Lighting.

(4) Beginning March 13, 2006, Chapter 19.3.6.3.2, exception number 2 does not apply to PACE centers.

(5) Notwithstanding any provisions of the 2000 edition of the Life Safety Code to the contrary, a PACE center may install alcohol-based hand rub dispensers in its facility if—

(i) Use of alcohol-based hand rub dispensers does not conflict with any State or local codes that prohibit or otherwise restrict the placement of alcohol-based hand rub dispensers in health care facilities;

(ii) The dispensers are installed in a manner that minimizes leaks and spills that could lead to falls;

(iii) The dispensers are installed in a manner that adequately protects against inappropriate access;

(iv) The dispensers are installed in accordance with chapter 18.3.2.7 or chapter 19.3.2.7 of the 2000 edition of the Life Safety Code, as amended by NFPA Temporary Interim Amendment 00–1(101), issued by the Standards Council of the National Fire Protection Association on April 15, 2004. The Director of the Office of the Federal Register has approved NFPA Temporary Interim Amendment 00–1(101) for incorporation by reference in accordance with 5 U.S.C. 552(a) and 1 CFR part 51. A copy of the amendment is available for inspection at the CMS Information Resource Center, 7500 Security Boulevard, Baltimore, MD and at the Office of the Federal Register, 800 North Capitol Street NW., Suite 700, Washington, DC. Copies may be obtained from the National Fire Protection Association, 1 Batterymarch Park, Quincy, MA 02269; and

(v) The dispensers are maintained in accordance with dispenser manufacturer guidelines.

(c) Emergency and disaster preparedness—(1) Procedures. 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.

(2) Emergencies defined. Emergencies include, but are not limited, to the following:

(i) Fire.

(ii) Equipment, water, or power failure.

(iii) Care-related emergencies.

(iv) 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.)

(3) Emergency training. 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
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§ 460.74 Infection control.

(a) Standard procedures. The PACE organization must follow accepted policies and standard procedures with respect to infection control, including at least the standard precautions developed by the Centers for Disease Control and Prevention.

(b) Infection control plan. The PACE organization must establish, implement, and maintain a documented infection control plan that meets the following requirements:

(1) Ensures a safe and sanitary environment.

(2) Prevents and controls the transmission of disease and infection.

(c) Contents of infection control plan. The infection control plan must include, but is not limited to, the following:

(1) Procedures to identify, investigate, control, and prevent infections in every Pace center and in each participant’s place of residence.

(2) Procedures to record any incidents of infection.

(3) Procedures to analyze the incidents of infection to identify trends and develop corrective actions related to the reduction of future incidents.

§ 460.76 Transportation services.

(a) Safety, accessibility, and equipment. A PACE organization’s transportation services must be safe, accessible, and equipped to meet the needs of the participant population.

(b) Maintenance of vehicles. (1) If the PACE organization owns, rents, or leases transportation vehicles, it must maintain these vehicles in accordance with the manufacturer’s recommendations.

(2) If a contractor provides transportation services, the PACE organization must ensure that the vehicles are maintained in accordance with the manufacturer’s recommendations.

(c) Communication with PACE center. The PACE organization must ensure that transportation vehicles are equipped to communicate with the PACE center.

(d) Training. The PACE organization must train all transportation personnel (employees and contractors) in the following:

(1) Managing the special needs of participants.

(2) Handling emergency situations.

(e) Changes in care plan. As part of the interdisciplinary team process, PACE organization staff (employees and contractors) must communicate relevant changes in a participant’s care plan to transportation personnel.

§ 460.78 Dietary services.

(a) Meal requirements. (1) Except as specified in paragraphs (a)(2) or (a)(3) of this section, the PACE organization must ensure, through the assessment and care planning process, that each participant receives nourishing, palatable, well-balanced meals that meet the participant’s daily nutritional and special dietary needs. Each meal must meet the following requirements:

(i) Be prepared by methods that conserve nutritive value, flavor, and appearance.

(ii) Be prepared in a form designed to meet individual needs.

(iii) Be prepared and served at the proper temperature.

(2) The PACE organization must provide substitute foods or nutritional
supplements that meet the daily nutritional and special dietary needs of any participant who has any of the following problems:
(i) Refuses the food served.
(ii) Cannot tolerate the food served.
(iii) Does not eat adequately.
(3) The PACE organization must provide nutrition support to meet the daily nutritional needs of a participant, if indicated by his or her medical condition or diagnosis. Nutrition support consists of tube feedings, total parenteral nutrition, or peripheral parenteral nutrition.

(b) Sanitary conditions. The PACE organization must do the following:
(1) Procure foods (including nutritional supplements and nutrition support items) from sources approved, or considered satisfactory, by Federal, State, Tribal, or local authorities with jurisdiction over the service area of the organization.
(2) Store, prepare, distribute, and serve foods (including nutritional supplements and nutrition support items) under sanitary conditions.
(3) Dispose of garbage and refuse properly.

§ 460.80 Fiscal soundness.
(a) Fiscally sound operation. A PACE organization must have a fiscally sound operation, as demonstrated by the following:
(1) Total assets greater than total unsubordinated liabilities.
(2) Sufficient cash flow and adequate liquidity to meet obligations as they become due.
(3) A net operating surplus or a financial plan for maintaining solvency that is satisfactory to CMS and the State administering agency.

(b) Insolvency plan. The organization must have a documented plan in the event of insolvency, approved by CMS and the State administering agency, which provides for the following:
(1) Continuation of benefits for the duration of the period for which capitation payment has been made.
(2) Continuation of benefits to participants who are confined in a hospital on the date of insolvency until their discharge.
(3) Protection of participants from liability for payment of fees that are the legal obligation of the PACE organization.

(c) Arrangements to cover expenses. (1) 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:
(i) One month's total capitation revenue to cover expenses the month before insolvency.
(ii) 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 operations.
(2) Arrangements to cover expenses may include, but are not limited to, the following:
(i) Insolvency insurance or reinsurance.
(ii) Hold harmless arrangement.
(iii) Letters of credit, guarantees, net worth, restricted State reserves, or State law provisions.

§ 460.82 Marketing.
(a) Information that a PACE organization must include in its marketing materials. (1) A PACE organization must inform the public about its program and give prospective participants the following written information:
(i) An adequate description of the PACE organization's enrollment and disenrollment policies and requirements.
(ii) PACE enrollment procedures.
(iii) Description of benefits and services.
(iv) Premiums.
(v) Other information necessary for prospective participants to make an informed decision about enrollment.
(2) Marketing information must be free of material inaccuracies, misleading information, or misrepresentations.

(b) Approval of marketing information. (1) CMS must approve all marketing information before distribution by the PACE organization, including any revised or updated material.
(2) CMS reviews initial marketing information as part of an entity’s application for approval as a PACE organization, and approval of the application includes approval of marketing information.

(3) Once a PACE organization is under a PACE program agreement, any revisions to existing marketing information and new information are subject to the following:

   (i) Time period for approval. CMS approves or disapproves marketing information within 45 days after CMS receives the information from the organization.

   (ii) Deemed approval. Marketing information is deemed approved, and the organization can distribute it, if CMS and the State administering agency do not disapprove the marketing material within the 45-day review period.

   (c) Special language requirements. A PACE organization must furnish printed marketing materials to prospective and current participants as specified below:

      (1) In English and in any other principal languages of the community.

      (2) In Braille, if necessary.

   (d) Information on restriction of services. (1) Marketing materials must inform a potential participant that he or she must receive all needed health care, including primary care and specialist physician services (other than emergency services), from the PACE organization or from an entity authorized by the PACE organization.

      (2) All marketing materials must state clearly that PACE participants may be fully and personally liable for the costs of unauthorized or out-of-PACE program agreement services.

   (e) Prohibited marketing practices. A PACE organization must ensure that its employees or its agents do not use prohibited marketing practices which include the following:

      (1) Discrimination of any kind, except that marketing may be directed to individuals eligible for PACE by reason of their age.

      (2) Activities that could mislead or confuse potential participants, or misrepresent the PACE organization, CMS, or the State administering agency.

      (3) Gifts or payments to induce enrollment.

      (4) Contracting outreach efforts to individuals or organizations whose sole responsibility involves direct contact with the elderly to solicit enrollment.

      (5) Unsolicited door-to-door marketing.

   (f) Marketing Plan. A PACE organization must establish, implement, and maintain a documented marketing plan with measurable enrollment objectives and a system for tracking its effectiveness.

Subpart F—PACE Services

§ 460.90 PACE benefits under Medicare and Medicaid.

If a Medicare beneficiary or Medicaid recipient chooses to enroll in a PACE program, the following conditions apply:

(a) Medicare and Medicaid benefit limitations and conditions relating to amount, duration, scope of services, deductibles, copayments, coinsurance, or other cost-sharing do not apply.

(b) The participant, while enrolled in a PACE program, must receive Medicare and Medicaid benefits solely through the PACE organization.

§ 460.92 Required services.

The PACE benefit package for all participants, regardless of the source of payment, must include the following:

(a) All Medicare-covered items and services.

(b) All Medicaid-covered items and services, as specified in the State’s approved Medicaid plan.

(c) Other services determined necessary by the interdisciplinary team to improve and maintain the participant’s overall health status.

[71 FR 71335, Dec. 8, 2006]

§ 460.94 Required services for Medicare participants.

(a) Except for Medicare requirements that are waived for the PACE program, as specified in paragraph (b) of this section, the PACE benefit package for Medicare participants must include the following services:

   (1) The scope of hospital insurance benefits described in part 409 of this chapter.