Centers for Medicare & Medicaid Services, HHS § 460.94

(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 includes 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.
(2) The scope of supplemental medical insurance benefits described in part 410 of this chapter.

(b) Waivers of Medicare coverage requirements. The following Medicare requirements are waived for purposes of the PACE program and do not apply:

(1) The provisions of subpart F of part 409 of this chapter that limit coverage of institutional services.

(2) The provisions of subparts G and H of part 409 of this chapter, and parts 412 through 414 of this chapter that relate to payment for benefits.

(3) The provisions of subparts D and E of part 409 of this chapter that limit coverage of extended care services or home health services.

(4) The provisions of subpart D of part 409 of this chapter that impose a 3-day prior hospitalization requirement for coverage of extended care services.

(5) Section 411.15(g) and § 411.15(k) of this chapter that may prevent payment for PACE program services that are provided to PACE participants.

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

§ 460.96 Excluded services.

The following services are excluded from coverage under PACE:

(a) Any service that is not authorized by the interdisciplinary team, even if it is a required service, unless it is an emergency service.

(b) In an inpatient facility, private room and private duty nursing services (unless medically necessary), and nonmedical items for personal convenience such as telephone charges and radio or television rental (unless specifically authorized by the interdisciplinary team as part of the participant’s plan of care).

(c) Cosmetic surgery, which does not include surgery that is required for improved functioning of a malformed part of the body resulting from an accidental injury or for reconstruction following mastectomy.

(d) Experimental medical, surgical, or other health procedures.

(e) Services furnished outside of the United States, except as follows:

(1) In accordance with § 424.122 and § 424.124 of this chapter.

(2) As permitted under the State’s approved Medicaid plan.

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

§ 460.98 Service delivery.

(a) Plan. A PACE organization must establish and implement a written plan to furnish care that meets the needs of each participant in all care settings 24 hours a day, every day of the year.

(b) Provision of services. (1) The PACE organization must furnish comprehensive medical, health, and social services that integrate acute and long-term care.

(2) These services must be furnished in at least the PACE center, the home, and inpatient facilities.

(3) The PACE organization may not discriminate against any participant in the delivery of required PACE services based on race, ethnicity, national origin, religion, sex, age, sexual orientation, mental or physical disability, or source of payment.

(c) Minimum services furnished at each PACE center. At a minimum, the following services must be furnished at each PACE center:

(1) Primary care, including physician and nursing services.

(2) Social services.

(3) Restorative therapies, including physical therapy and occupational therapy.

(4) Personal care and supportive services.

(5) Nutritional counseling.

(6) Recreational therapy.

(7) Meals.

(d) Pace Center operation. (1) A PACE organization must operate at least one PACE center either in, or contiguous to, its defined service area with sufficient capacity to allow routine attendance by participants.

(2) A PACE organization must ensure accessible and adequate services to meet the needs of its participants. If necessary, a PACE organization must increase the number of PACE centers, staff, or other PACE services.

(3) If a PACE organization operates more than one center, each Pace center must offer the full range of services and have sufficient staff to meet the needs of participants.
(e) Center attendance. The frequency of a participant’s attendance at a center is determined by the interdisciplinary team, based on the needs and preferences of each participant.

[64 FR 66279, Nov. 24, 1999, as amended at 71 FR 71334, 71335, Dec. 8, 2006]

§ 460.100 Emergency care.

(a) Written plan. A PACE organization must establish and maintain a written plan to handle emergency care. The plan must ensure that CMS, the State, and PACE participants are held harmless if the PACE organization does not pay for emergency services.

(b) Emergency care. Emergency care is appropriate when services are needed immediately because of an injury or sudden illness and the time required to reach the PACE organization or one of its contract providers, would cause risk of permanent damage to the participant’s health. Emergency services include inpatient and outpatient services that meet the following requirements:

(1) Are furnished by a qualified emergency services provider, other than the PACE organization or one of its contract providers, either in or out of the PACE organization’s service area.

(2) Are needed to evaluate or stabilize an emergency medical condition.

(c) An emergency medical condition means a condition manifesting itself by acute symptoms of sufficient severity (including severe pain) such that a prudent layperson, with an average knowledge of health and medicine, could reasonably expect the absence of immediate medical attention to result in the following:

(1) Serious jeopardy to the health of the participant.

(2) Serious impairment to bodily functions.

(3) Serious dysfunction of any bodily organ or part.

(d) Explanation to participant. The organization must ensure that the participant or caregiver, or both, understand when and how to get access to emergency services and that no prior authorization is needed.

(e) On-call providers. The plan must provide for the following:

(1) An on-call provider, available 24 hours per day to address participant questions about emergency services and respond to requests for authorization of urgently needed out-of-network services and post stabilization care services following emergency services.

(2) Coverage of urgently needed out-of-network and post-stabilization care services when either of the following conditions are met:

(i) The services are preapproved by the PACE organization.

(ii) The services are not preapproved by the PACE organization because the PACE organization did not respond to a request for approval within 1 hour after being contacted or cannot be contacted for approval.

(3) Definitions. As used in this section, the following definitions apply:

(i) Post stabilization care means services provided subsequent to an emergency that a treating physician views as medically necessary after an emergency medical condition has been stabilized. They are not emergency services, which POs are obligated to cover. Rather, they are non-emergency services that the PO should approve before they are provided outside the service area.

(ii) Urgent care means the care provided to a PACE participant who is out of the PACE service area, and who believes their illness or injury is too severe to postpone treatment until they return to the service area, but their life or function is not in severe jeopardy.

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

§ 460.102 Interdisciplinary team.

(a) Basic requirement. A PACE organization must meet the following requirements:

(1) Establish an interdisciplinary team at each Pace center to comprehensively assess and meet the individual needs of each participant.

(2) Assign each participant to an interdisciplinary team functioning at the PACE center that the participant attends.

(b) Composition of interdisciplinary team. The interdisciplinary team must be composed of at least the following members:

(1) Primary care physician.

(2) Registered nurse.

(3) Master’s-level social worker.
§ 460.104 Participant assessment.

(a) Initial comprehensive assessment—

(1) Basic requirement. The interdisciplinary team must conduct an initial comprehensive assessment on each participant. The assessment must be completed promptly following enrollment.

(2) As part of the initial comprehensive assessment, each of the following members of the interdisciplinary team must evaluate the participant in person, at appropriate intervals, and develop a discipline-specific assessment of the participant’s health and social status:

(i) Primary care physician.

(ii) Registered nurse.

(iii) Master’s-level social worker.

(iv) Physical therapist.

(v) Occupational therapist.

(vi) Recreational therapist or activity coordinator.

(vii) Dietitian.

(viii) Home care coordinator.

(3) At the recommendation of individual team members, other professional disciplines (for example, speech-language pathology, dentistry, or audiology) may be included in the comprehensive assessment process.

(b) Comprehensive assessment criteria. The comprehensive assessment must include, but is not limited to, the following:

(i) Physical and cognitive function and ability.

(ii) Medication use.

(iii) Participant and caregiver preferences for care.

(iv) Socialization and availability of family support.

(v) Current health status and treatment needs.

(vi) Nutritional status.

(vii) Home environment, including home access and egress.

(viii) Participant behavior.

(ix) Psychosocial status.

(x) Medical and dental status.

(xi) Participant language.

(b) Development of plan of care. The interdisciplinary team must promptly consolidate discipline-specific assessments into a single plan of care for each participant through discussion in team meetings and consensus of the entire interdisciplinary team. In developing the plan of care, female participants must be informed that they are
entitled to choose a qualified specialist for women’s health services from the PACE organization’s network to furnish routine or preventive women’s health services.

(c) Periodic reassessment—(1) Semi-annual reassessment. On at least a semi-annual basis, or more often if a participant’s condition dictates, the following members of the interdisciplinary team must conduct an in-person reassessment:

(i) Primary care physician.
(ii) Registered nurse.
(iii) Master’s-level social worker.
(iv) Recreational therapist or activity coordinator.
(v) Other team members actively involved in the development or implementation of the participant’s plan of care, for example, home care coordinator, physical therapist, occupational therapist, or dietitian.

(2) Annual reassessment. On at least an annual basis, the following members of the interdisciplinary team must conduct an in-person reassessment:

(i) Physical therapist.
(ii) Occupational therapist.
(iii) Dietitian.
(iv) Home care coordinator.

(d) Unscheduled reassessments. In addition to annual and semiannual reassessments, unscheduled reassessments may be required based on the following:

(1) A change in participant status. If the health or psychosocial status of a participant changes, the members of the interdisciplinary team, listed in paragraph (a)(2) of this section, must conduct an in-person reassessment.

(2) At the request of the participant or designated representative. If a participant (or his or her designated representative) believes that the participant needs to initiate, eliminate, or continue a particular service, the appropriate members of the interdisciplinary team, as identified by the interdisciplinary team, must conduct an in-person reassessment.

(i) The PACE organization must have explicit procedures for timely resolution of requests by a participant or his or her designated representative to initiate, eliminate, or continue a particular service.

(ii) Except as provided in paragraph (d)(2)(iii) of this section, the interdisciplinary team must notify the participant or designated representative of its decision to approve or deny the request from the participant or designated representative as expeditiously as the participant’s condition requires, but no later than 72 hours after the date the interdisciplinary team receives the request for reassessment.

(iii) The interdisciplinary team may extend the 72-hour timeframe for notifying the participant or designated representative of its decision to approve or deny the request by no more than 5 additional days for either of the following reasons:

(A) The participant or designated representative requests the extension.
(B) The team documents its need for additional information and how the delay is in the interest of the participant.

(iv) The PACE organization must explain any denial of a request to the participant or the participant’s designated representative orally and in writing. The PACE organization must provide the specific reasons for the denial in understandable language. The PACE organization is responsible for the following:

(A) Informing the participant or designated representative of his or her right to appeal the decision as specified in §460.122.
(B) Describing both the standard and expedited appeals processes, including the right to, and conditions for, obtaining expedited consideration of an appeal of a denial of services as specified in §460.122.
(C) Describing the right to, and conditions for, continuation of appealed services through the period of an appeal as specified in §460.122(e).

(v) If the interdisciplinary team fails to provide the participant with timely notice of the resolution of the request or does not furnish the services required by the revised plan of care, this failure constitutes an adverse decision, and the participant’s request must be automatically processed by the PACE organization as an appeal in accordance with §460.122.
(e) Changes to plan of care. Team members who conduct a reassessment must meet the following requirements:

1. Reevaluate the participant’s plan of care.
2. Discuss any changes in the plan with the interdisciplinary team.
3. Obtain approval of the revised plan from the interdisciplinary team and the participant (or designated representative).
4. Furnish any services included in the revised plan of care as a result of a reassessment to the participant as expeditiously as the participant’s health condition requires.

(f) Documentation. Interdisciplinary team members must document all assessment and reassessment information in the participant’s medical record.

[64 FR 66279, Nov. 24, 1999, as amended at 71 FR 71336, Dec. 8, 2006]

§ 460.106 Plan of care.

(a) Basic requirement. The interdisciplinary team must promptly develop a comprehensive plan of care for each participant.

(b) Content of plan of care. The plan of care must meet the following requirements:

1. Specify the care needed to meet the participant’s medical, physical, emotional, and social needs, as identified in the initial comprehensive assessment.
2. Identify measurable outcomes to be achieved.

(c) Implementation of the plan of care. The team must implement, coordinate, and monitor the plan of care whether the services are furnished by PACE employees or contractors.

(d) Evaluation of plan of care. On at least a semi-annual basis, the interdisciplinary team must reevaluate the plan of care, including defined outcomes, and make changes as necessary.

(e) Participant and caregiver involvement in plan of care. The team must develop, review, and reevaluate the plan of care in collaboration with the participant or caregiver, or both, to ensure that there is agreement with the plan of care and that the participant’s concerns are addressed.

(f) Documentation. The team must document the plan of care, and any changes made to it, in the participant’s medical record.

Subpart G—Participant Rights

§ 460.110 Bill of rights.

(a) Written bill of rights. A PACE organization must have a written participant bill of rights designed to protect and promote the rights of each participant. Those rights include, at a minimum, the ones specified in § 460.112.

(b) Explanation of rights. The organization must inform a participant upon enrollment, in writing, of his or her rights and responsibilities, and all rules and regulations governing participation.

(c) Protection of rights. The organization must protect and provide for the exercise of the participant’s rights.

§ 460.112 Specific rights to which a participant is entitled.

(a) Respect and nondiscrimination. Each participant has the right to considerate, respectful care from all PACE employees and contractors at all times and under all circumstances. Each participant has the right not to be discriminated against in the delivery of required PACE services based on race, ethnicity, national origin, religion, sex, age, sexual orientation, mental or physical disability, or source of payment. Specifically, each participant has the right to the following:

1. To receive comprehensive health care in a safe and clean environment and in an accessible manner.
2. To be treated with dignity and respect, be afforded privacy and confidentiality in all aspects of care, and be provided humane care.
3. Not to be required to perform services for the PACE organization.
4. To have reasonable access to a telephone.