

(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-PAACE 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 ob-

jectives 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 Medicaid-covered services, as specified in the State's approved Medicaid plan.

(b) Multidisciplinary assessment and treatment planning.

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

(d) Social work services.

(e) Restorative therapies, including physical therapy, occupational therapy, and speech-language pathology services.

(f) Personal care and supportive services.

(g) Nutritional counseling.

(h) Recreational therapy.

(i) Transportation.

(j) Meals.

(k) Medical specialty services including, but not limited to the following:

(1) Anesthesiology.

(2) Audiology.

(3) Cardiology.

(4) Dentistry.

(5) Dermatology.

(6) Gastroenterology.

(7) Gynecology.

(8) Internal medicine.

(9) Nephrology.

(10) Neurosurgery.

(11) Oncology.

(12) Ophthalmology.

(13) Oral surgery.

(14) Orthopedic surgery.

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- (15) Otorhinolaryngology.
- (16) Plastic surgery.
- (17) Pharmacy consulting services.
- (18) Podiatry.
- (19) Psychiatry.
- (20) Pulmonary disease.
- (21) Radiology.
- (22) Rheumatology.
- (23) General surgery.
- (24) Thoracic and vascular surgery.
- (25) Urology.
- (1) Laboratory tests, x-rays and other diagnostic procedures.
- (m) Drugs and biologicals.
- (n) Prosthetics, orthotics, durable medical equipment, corrective vision devices, such as eyeglasses and lenses, hearing aids, dentures, and repair and maintenance of these items.
- (o) Acute inpatient care, including the following:
  - (1) Ambulance.
  - (2) Emergency room care and treatment room services.
  - (3) Semi-private room and board.
  - (4) General medical and nursing services.
  - (5) Medical surgical/intensive care/coronary care unit.
  - (6) Laboratory tests, x-rays and other diagnostic procedures.
  - (7) Drugs and biologicals.
  - (8) Blood and blood derivatives.
  - (9) Surgical care, including the use of anesthesia.
  - (10) Use of oxygen.
  - (11) Physical, occupational, respiratory therapies, and speech-language pathology services.
  - (12) Social services.
- (p) Nursing facility care.
  - (1) Semi-private room and board.
  - (2) Physician and skilled nursing services.
  - (3) Custodial care.
  - (4) Personal care and assistance.
  - (5) Drugs and biologicals.
  - (6) Physical, occupational, recreational therapies, and speech-language pathology, if necessary.
  - (7) Social services.
  - (8) Medical supplies and appliances.
  - (q) Other services determined necessary by the multidisciplinary team to improve and maintain the participant's overall health status.

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**§ 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) Sections 411.15(g) and (k) of this chapter that may prevent payment for PACE program services to PACE participants.

**§ 460.96 Excluded services.**

The following services are excluded from coverage under PACE:

(a) Any service that is not authorized by the multidisciplinary 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 non-medical items for personal convenience such as telephone charges and radio or television rental (unless specifically authorized by the multidisciplinary 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