(b) The agreement must be signed by an authorized official of CMS, the PACE organization and the State administering agency.

(c) CMS may only sign program agreements with PACE organizations that are located in States with approved State plan amendments electing PACE as an optional benefit under their Medicaid State plan.

[64 FR 66279, Nov. 24, 1999, as amended at 67 FR 61505, Oct. 1, 2002]

§ 460.32 Content and terms of PACE program agreement.

(a) *Required content.* A PACE program agreement must include the following information:

(1) A designation of the service area of the organization's program. The area may be identified by county, zip code, street boundaries, census tract, block, or tribal jurisdictional area, as applicable. CMS and the State administering agency must approve any change in the designated service area.

(2) The organization's commitment to meet all applicable requirements under Federal, State, and local laws and regulations, including provisions of the Civil Rights Act, the Age Discrimination Act, and the Americans With Disabilities Act.

(3) The effective date and term of the agreement.

(4) A description of the organizational structure of the PACE organization and information on administrative contacts, including the following:

(i) Name and phone number of the program director.

(ii) Name of all governing body members.

(iii) Name and phone number of a contact person for the governing body.

(5) A participant bill of rights approved by CMS and an assurance that the rights and protections will be provided.

(6) A description of the process for handling participant grievances and appeals.

(7) A statement of the organization's policies on eligibility, enrollment, voluntary disenrollment, and involuntary disenrollment.

(8) A description of services available to participants.

(9) A description of the organization's quality improvement program.

(10) A statement of the levels of performance required by CMS on standard quality measures.

(11) A statement of the data and information required by CMS and the State administering agency to be collected on participant care.

(12) The state's Medicaid capitation rate or Medicaid payment rate methodology, and the methodology used to calculate the Medicare capitation rate.

(13) A description of procedures that the organization will follow if the PACE program agreement is terminated.

(b) *Optional content.* (1) An agreement may provide additional requirements for individuals to qualify as PACE program eligible individuals, in accordance with § 460.150(b)(4).

(2) An agreement may contain any additional terms and conditions agreed to by the parties if the terms and conditions are consistent with sections 1894 and 1934 of the Act and regulations in this part.

[64 FR 66279, Nov. 24, 1999, as amended at 71 FR 71334, Dec. 8, 2006; 84 FR 25672, June 3, 2019]

§ 460.34 Duration of PACE program agreement.

An agreement is effective for a contract year, but may be extended for additional contract years in the absence of a notice by a party to terminate.

Subpart D—Sanctions, Enforcement Actions, and Termination

§ 460.40 Violations for which CMS may impose sanctions.

(a) In addition to other remedies authorized by law, CMS may impose any of the sanctions specified in §§ 460.42 and 460.46 if CMS determines that a PACE organization commits any of the following violations:

(1) Fails substantially to provide to a participant medically necessary items and services that are covered PACE services, if the failure has adversely affected (or has substantial likelihood of adversely affecting) the participant.

(2) Involuntarily disenrolls a participant in violation of § 460.164.

(3) Discriminates in enrollment or disenrollment among Medicare beneficiaries or Medicaid beneficiaries, or both, who are eligible to enroll in a PACE program, on the basis of an individual's health status or need for health care services.

(4) Engages in any practice that would reasonably be expected to have the effect of denying or discouraging enrollment, except as permitted by § 460.150, by Medicare beneficiaries or Medicaid beneficiaries whose medical condition or history indicates a need for substantial future medical services.

(5) Imposes charges on participants enrolled under Medicare or Medicaid for premiums in excess of the premiums permitted.

(6) Misrepresents or falsifies information that is furnished—

(i) To CMS or the State under this part; or

(ii) To an individual or any other entity under this part.

(7) Prohibits or otherwise restricts a covered health care professional from advising a participant who is a patient of the professional about the participant's health status, medical care, or treatment for the participant's condition or disease, regardless of whether the PACE program provides benefits for that care or treatment, if the professional is acting within his or her lawful scope of practice.

(8) Operates a physician incentive plan that does not meet the requirements of section 1876(i)(8) of the Act.

(9) Employs or contracts with any individual who is excluded from participation in Medicare or Medicaid under section 1128 or section 1128A of the Act (or with any entity that employs or contracts with that individual) for the provision of health care, utilization review, medical social work, or administrative services.

(10) Makes payment to any individual or entity that is included on the preclusion list, defined in § 422.2 of this chapter.

(b) If CMS or the State administering agency makes a determination under § 460.50 that could lead to termination of a PACE program agreement, CMS may impose any of the sanctions specified at §§ 460.42 and 460.46. If CMS or the State administering agency determines that the circumstances in § 460.50(b)(1) exist, neither CMS nor the State administrating agency has to determine that the circumstances in § 460.50(b)(2) exist prior to imposing a CMP or enrollment and/or payment suspension.

[64 FR 66279, Nov. 24, 1999, as amended at 81 FR 80561, Nov. 15, 2016; 83 FR 16756, Apr. 16, 2018; 84 FR 25672, June 3, 2019; 88 FR 22345, Apr. 12, 2023]

§ 460.42 Suspension of enrollment or payment by CMS.

(a) *Enrollment.* If a PACE organization commits one or more violations specified in § 460.40, CMS may suspend enrollment of Medicare beneficiaries after the date CMS notifies the organization of the violation.

(b) *Payment.* If a PACE organization commits one or more violations specified in § 460.40, for individuals enrolled after the date CMS notifies the PACE organization of the violation, CMS may take the following actions:

(1) Suspend Medicare payment to the PACE organization.

(2) Deny payment to the State for medical assistance for services furnished under the PACE program agreement.

(c) *Term of suspension.* A suspension or denial of payment remains in effect until CMS is satisfied that the following conditions are met:

(1) The PACE organization has corrected the cause of the violation.

(2) The violation is not likely to recur.

§ 460.46 Civil money penalties.

(a) CMS may impose civil money penalties up to the maximum amounts specified in paragraphs (a)(1) through (4) of this section. These amounts will be adjusted in accordance with the Federal Civil Penalties Inflation Adjustment Act Improvements Act of 2015 (Sec. 701 of Pub. L. 114–74) and updated amounts specified in 45 CFR part 102.

(1) For each violation regarding enrollment or disenrollment specified in § 460.40(a)(3) or (4), $100,000 plus $15,000 for each individual not enrolled as a result of the PACE organization's discrimination in enrollment or disenrollment or practice that would deny or discourage enrollment.