

(2) Denies the application and notifies the entity in writing of the basis for the denial and the process for requesting reconsideration of the denial.

(c) *Deemed approval.* An application is deemed approved if HCFA fails to act on the application within 90 days after one of the following dates:

(1) The date the application is submitted by the organization.

(2) The date HCFA receives all requested additional information.

(d) *Date of submission.* For purposes of the 90-day time limit described in this section, the date that an application is submitted to HCFA is the date on which the application is delivered to the address designated by HCFA.

**§ 460.22 Service area designation.**

(a) An entity must state in its application the service area it proposes for its program.

(b) HCFA, in consultation with the State administering agency, may exclude from designation an area that is already covered under another PACE program agreement to avoid unnecessary duplication of services and avoid impairing the financial and service viability of an existing program.

**§ 460.24 Limit on number of PACE program agreements.**

(a) *Numerical limit.* Except as specified in paragraph (b) of this section, HCFA does not permit the number of PACE organizations with which agreements are in effect under this part or under section 9412(b) of the Omnibus Budget Reconciliation Act of 1986, to exceed the following:

(1) As of August 5, 1997—40.

(2) As of each succeeding August 5, the numerical limit for the preceding year plus 20, without regard to the actual number of agreements in effect on a previous anniversary date. (For example, the limit is 60 on August 5, 1998 and 80 on August 5, 1999.)

(b) *Exception.* The numerical limit does not apply to a private, for-profit PACE organization that meets the following conditions:

(1) Is operating under a demonstration project waiver under section 1894(h) and 1934(h) of the Act.

(2) Was operating under a waiver and subsequently qualifies for PACE orga-

nization status in accordance with sections 1894(a)(3)(B)(ii) and 1934(a)(3)(B)(ii) of the Act.

**Subpart C—PACE Program Agreement**

**§ 460.30 Program agreement requirement.**

(a) A PACE organization must have an agreement with HCFA and the State administering agency for the operation of a PACE program by the PACE organization under Medicare and Medicaid.

(b) The agreement must be signed by an authorized official of the PACE organization.

**§ 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. HCFA 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 HCFA and an assurance that the rights and protections will be provided.

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

**§ 460.34**

**42 CFR Ch. IV (10–1–00 Edition)**

(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 assessment and performance improvement program.

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

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

(12) The capitation rates for Medicare and Medicaid.

(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.

**§ 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 HCFA may impose sanctions.**

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

(a) 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.

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

(c) Discriminates in enrollment or disenrollment among Medicare beneficiaries or Medicaid recipients, 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.

(d) 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 recipients whose medical condition or history indicates a need for substantial future medical services.

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

(f) Misrepresents or falsifies information that is furnished—

(1) To HCFA or the State under this part; or

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

(g) 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.

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

(i) 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.

**§ 460.42 Suspension of enrollment or payment by HCFA.**

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