

§ 460.48

42 CFR Ch. IV (10–1–04 Edition)

of the PACE organization's discrimination in enrollment or disenrollment or practice that would deny or discourage enrollment.

(2) For each violation regarding excessive premiums specified in § 460.40(e), \$25,000 plus double the excess amount above the permitted premium charged a participant by the PACE organization. (The excess amount charged is deducted from the penalty and returned to the participant).

(3) For each misrepresentation or falsification of information, specified in § 460.40(f)(1), \$100,000.

(4) For any other violation specified in § 460.40, \$25,000.

(b) The provisions of section 1128A of the Act (other than subsections (a) and (b)) apply to a civil money penalty under this section in the same manner as they apply to a civil money penalty or proceeding under section 1128A(a).

§ 460.48 Additional actions by CMS or the State.

After consultation with the State administering agency, if CMS determines that the PACE organization is not in substantial compliance with requirements in this part, CMS or the State administering agency may take one or more of the following actions:

(a) Condition the continuation of the PACE program agreement upon timely execution of a corrective action plan.

(b) Withhold some or all payments under the PACE program agreement until the organization corrects the deficiency.

(c) Terminate the PACE program agreement.

§ 460.50 Termination of PACE program agreement.

(a) *Termination of agreement by CMS or State.* CMS or a State administering agency may terminate at any time a PACE program agreement for cause, including, but not limited to the circumstances in paragraphs (b) or (c) of this section.

(b) *Termination due to uncorrected deficiencies.* CMS or the State administering agency may terminate a PACE program agreement if CMS or the State administering agency determines that both of the following circumstances exist:

(1) Either—

(i) There are significant deficiencies in the quality of care furnished to participants; or

(ii) The PACE organization failed to comply substantially with conditions for a PACE program or PACE organization under this part, or with terms of its PACE program agreement.

(2) Within 30 days of the date of the receipt of written notice of a determination made under paragraph (b)(1) of this section, the PACE organization failed to develop and successfully initiate a plan to correct the deficiencies, or failed to continue implementation of the plan of correction.

(c) *Termination due to health and safety risk.* CMS or a State administering agency may terminate a PACE program agreement if CMS or the State administering agency determines that the PACE organization cannot ensure the health and safety of its participants. This determination may result from the identification of deficiencies that CMS or the State administering agency determines cannot be corrected.

(d) *Termination of agreement by PACE organization.* A PACE organization may terminate an agreement after timely notice to CMS, the State administering agency, and participants, as follows:

(1) To CMS and the State administering agency, 90 days before termination.

(2) To participants, 60 days before termination.

§ 460.52 Transitional care during termination.

(a) The PACE organization must develop a detailed written plan for phase-down in the event of termination, which describes how the organization plans to take the following actions:

(1) Inform participants, the community, CMS and the State administering agency in writing about termination and transition procedures.

(2) Assist participants to obtain reinstatement of conventional Medicare and Medicaid benefits.

(3) Transition participants' care to other providers.

(4) Terminate marketing and enrollment activities.

(b) An entity whose PACE program agreement is in the process of being terminated must provide assistance to each participant in obtaining necessary transitional care through appropriate referrals and making the participant's medical records available to new providers.

§ 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.

Subpart E—PACE Administrative Requirements

§ 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 ac-

cordance 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 60 days before the change takes effect.

(4) Changes in organizational structure must be approved in advance by CMS and the State administering agency.

(5) Changes in organizational structure approved by CMS and the State administering agency must be forwarded to the consumer advisory committee described in § 460.62(c) of this part for dissemination to participants as appropriate.

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

§ 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.