Programs of All-Inclusive Care for the Elderly (PACE)

Chapter 16 – Sanctions, Enforcement Actions and Termination

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10 - Introduction (*Rev. 2, Issued: 06-09-11; Effective: 06-03-11; Implementation: 06-03-11*)

PACE is a partnership between CMS, the State, and the PACE organization. CMS and the State work together to ensure the benefits and services provided are of high quality and meet the requirements set forth in the statute and regulations and by the State in which the PACE organization resides. When compliance actions fail to achieve the desired result or an instance of non-compliance is especially egregious, CMS may take enforcement action. CMS recognizes that in addition to the sanctions, enforcement actions and termination set forth below, each State will have their own actions that may be implemented when a PACE organization is out of compliance.

20 - Enforcement

(Rev. 2, Issued: 06-09-11; Effective: 06-03-11; Implementation: 06-03-11)

Enforcement activity begins when: (1) deficiencies are serious enough to escalate directly to the enforcement activity stage and/or; (2) core compliance deficiencies remain unresolved during the compliance activity stage after providing the PACE organization with the appropriate notice and opportunity to correct the deficiencies.

Enforcement actions (also known as "intermediate sanctions") include the following two categories of actions: (1) enrollment and/or payment suspensions and; (2) civil money penalties (CMPs). Enrollment and payment suspensions are imposed for serious contractual deficiencies defined by statute and are designed to ensure the deficiencies which formed the basis for the sanction are corrected and not likely to recur. CMPs are also intended to be imposed for serious contractual deficiencies defined by statute. Depending on the particular deficiency and statutory basis for taking the action, CMS may impose both suspensions of enrollment and payment and a CMP.

[42 CFR § 460.40]

30 - Violations for which CMS May Impose Sanctions (*Rev. 2, Issued: 06-09-11; Effective: 06-03-11; Implementation: 06-03-11*)

There are specific violations for which CMS may impose sanctions on the PACE organization and they are as follows:

- The PACE organization fails substantially in furnishing the medically necessary items and services to the participant that are covered by PACE if the failure has adversely affected (or has a substantial likelihood of adversely affecting) the participant;
- The PACE organization involuntary disenrolls a participant in violation of 42 CFR § 460.164;

- The PACE organization discriminates on the basis of an individual's health status or need for health care services in the enrollment or disenrollment process, among Medicare beneficiaries or Medicaid recipients, or both, who are eligible to enroll in a PACE program;
- The PACE organization engages in any practice that would reasonably be expected to have the effect of denying or discouraging enrollment, except as permitted by 42 CFR § 460.150 by Medicare beneficiaries or Medicaid recipients whose medical condition or history indicates a need for substantial future medical services;
- The PACE organization imposes premium charges on a participant enrolled under Medicare or Medicaid that is more than the allowable amount;
- The PACE organization misrepresents or falsifies information that is furnished to CMS or the State or, to an individual or any other entity under Part 460;
- The PACE organization prohibits or restricts a covered healthcare professional, who is acting within their lawful scope of practice, from advising a participant (their patient) about the patient's health status, medical care, or treatment for the participant's condition or disease, regardless of whether the PACE program provides the benefits for that care or treatment;
- The PACE organization operates a physician incentive plan that does not meet the requirements of Section 1876(i)(8) of the Act;
- The PACE organization employs or contracts with any individual who is excluded from participation in Medicare or Medicaid under Section 1128 or 1128A of the Act (or with any entity that employs or contracts with such an individual) for the provision of health care, utilization review, medical social work, or administrative services.

[42 CFR § 460.40]

40 - Suspension of Enrollment or Payment by CMS

(Rev. 2, Issued: 06-09-11; Effective: 06-03-11; Implementation: 06-03-11)

CMS may suspend enrollment of Medicare beneficiaries due to the above mentioned violation after the date CMS notifies the PACE organization of the violation. For individuals enrolled after the date CMS notifies the PACE organization of the violation, CMS may suspend Medicare payment to the PACE organization and deny payment to the State of Federal Financial Participation for medical assistance for services furnished under the PACE program agreement. The State Administering Agency determines if suspension of enrollment should occur with Medicaid recipients. A suspension or denial

of payment remains in effect until CMS is satisfied that the PACE organization has corrected the cause of the violation and the violation is not likely to recur.

[42 CFR § 460.42; 71 FR 71259 (Dec. 8, 2006)]

50 - CMP

(*Rev. 2, Issued: 06-09-11; Effective: 06-03-11; Implementation: 06-03-11*)

There are certain violations for which CMS will impose a civil money penalty (CMP). The penalty is amounts up to the following maximum amounts, depending on the type of violation.

CMP violations include:

- For each violation regarding enrollment or disenrollment specified in 42 CFR § 460.40(c) or (d), \$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;
- For each violation regarding excessive premiums specified in 42 CFR § 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);
- For each misrepresentation or falsification of information as specified in 42 CFR § 460.40(f)(1), \$100,000;
- For any other violation specified in 42 CFR § 460.40, \$25,000;
 - 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).

[42 CFR § 460.46]

60 - Additional Actions by CMS or the State

(Rev. 2, Issued: 06-09-11; Effective: 06-03-11; Implementation: 06-03-11)

After CMS consults with the State Administering Agency, if CMS determines the PACE organization is not in substantial compliance with the PACE requirements, CMS or the State Administering Agency can take one or more of the following actions:

• The continuation of the PACE Program Agreement is contingent on the PACE organization's timely execution of a corrective action plan;

- The PACE organization must correct the deficiency or CMS and/or the State Administering Agency can withhold some or all payments under the PACE agreement;
- Termination of the PACE Program Agreement.

[42 CFR § 460.48]

70 - Termination of the PACE Program Agreement

(Rev. 2, Issued: 06-09-11; Effective: 06-03-11; Implementation: 06-03-11)

CMS or the State Administering Agency may terminate a PACE Program Agreement at any time for cause and a PACE organization may terminate an agreement after appropriate notice to CMS, State Administering Agency and its participants. CMS or the State Administering Agency may terminate a PACE Program Agreement with the PACE organization for cause including, but not limited to, the following:

- There are significant deficiencies in the quality of care furnished to participants or the PACE organization has failed to comply substantially with conditions for a PACE program or PACE organization under the Part 460 regulations or with the terms of its PACE Program Agreement; and, within 30 days of the date of receipt of the written notice regarding the deficiencies, the PACE organization failed to develop and successfully initiate a plan to correct the deficiencies or failed to continue implementation of such a plan, or CMS and the State Administering Agency determined that the deficiencies cannot be corrected; or
- CMS or the State Administering Agency determines that the PACE organization cannot ensure the health and safety of its participants. The determination may result from the identification of deficiencies that CMS or the State Administering Agency determines cannot be corrected.

If the PACE organization initiates the termination, it is required to give CMS and the State Administering Agency 90 days notice and participants 60 days notice before termination in order to provide sufficient time to transition participants to alternative care. If a participant is eligible for Medicaid, the State should provide assistance in arranging for the alternative care. Neither the State nor CMS considers termination lightly. The primary concern is protecting the health and safety of the participant and all possible ramifications of terminating a program agreement, including the likelihood of participants becoming institutionalized, will be considered before taking such severe action.

[42 CFR § 460.50; 71 FR 71261 (Dec. 8, 2006)]

70.1 - Transitional Care

(Rev. 2, Issued: 06-09-11; Effective: 06-03-11; Implementation: 06-03-11)

The PACE organization must develop a detailed written plan for phase-down in the event of termination. Such plan must describe how the organization plans to take the following actions:

- The plan must include a process for informing participants, the community, CMS and the State Administering Agency in writing about the termination and transition phases;
- The steps that the PACE organization will take to assist participants to obtain reinstatement of conventional Medicare and Medicaid benefits;
- Transitioning the participants' care to other providers;
- Termination of marketing and enrollment activities.

An entity whose PACE Program Agreement is in the process of being terminated must implement its phase-down plan discussed above and provide assistance to each participant in obtaining necessary transitional care through appropriate referrals and ensuring that the participants' medical records are available to new providers.

[42 CFR § 460.52]

70.2 - Termination Procedures

(Rev. 2, Issued: 06-09-11; Effective: 06-03-11; Implementation: 06-03-11)

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; and (2) reasonable notice and opportunity for a hearing, including the right to appeal an initial determination, before terminating the agreement.

CMS may terminate an agreement without invoking any of the above mentioned procedures 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.

[42 CFR § 460.54]

Transmittals Issued for this Chapter

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