

(c) Information obtained by the State administering agency.

**§ 460.20 Notice of CMS determination.**

(a) *Time limit for notification of determination.* Within 90 days after an entity submits a complete application to CMS, CMS takes one of the following actions:

- (1) Approves the application.
- (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.
- (3) Requests additional information needed to make a final determination.

(b) *Additional information requested.* If CMS requests from an entity additional information needed to make a final determination, within 90 days after CMS receives all requested information from the entity, CMS takes one of the following actions:

- (1) Approves the application.
- (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 CMS 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 CMS 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 CMS is the date on which the application is delivered to the address designated by CMS.

**§ 460.22 Service area designation.**

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

(b) CMS, 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, CMS 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 organization status in accordance with sections 1894(a)(3)(B)(i) and 1934(a)(3)(B)(ii) of the Act.

**§ 460.26 Submission and evaluation of waiver requests.**

(a) A PACE organization must submit its waiver request through the State administering agency for initial review. The State administering agency forwards waiver requests to CMS along with any concerns or conditions regarding the waiver.

(b) CMS evaluates a waiver request from a PACE organization on the basis of the following information:

- (1) The adequacy of the description and rationale for the waiver provided by the PACE organization, including any additional information requested by CMS.

(1) Information obtained by CMS and the State administering agency in on-site reviews and monitoring of the PACE organization.

(c) Requirements related to the following principles may not be waived:

- (1) A focus on frail elderly qualifying individuals who require the level of care provided in a nursing facility.

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(2) The delivery of comprehensive, integrated acute and long-term care services.

(3) An interdisciplinary team approach to care management and service delivery.

(4) Capitated, integrated financing that allows the provider to pool payments received from public and private programs and individuals.

(5) The assumption by the provider of full financial risk.

[67 FR 61505, Oct. 1, 2002]

EFFECTIVE DATE NOTE: At 67 FR 61505, Oct. 1, 2002, § 460.26 was added, effective Oct. 31, 2002.

**§ 460.28 Notice of CMS determination on waiver requests.**

(a) *Time limit for notification of determination.* Within 90 days after receipt of a waiver request, CMS takes one of the following actions:

(1) Approves the request.

(2) Denies the request and notifies the PACE organization in writing of the basis for the denial.

(b) *Date of receipt.* For purposes of the 90-day time limit described in this section, the date that a waiver request is received by CMS from the State administering agency is the date on which the request is delivered to the address designated by CMS.

(c) *Waiver approval.* (1) A waiver request is deemed approved if CMS fails to act on the request within 90 days after the date the waiver request is received by CMS.

(2) CMS may withdraw approval of a waiver for good cause.

[67 FR 61505, Oct. 1, 2002]

EFFECTIVE DATE NOTE: At 67 FR 61505, Oct. 1, 2002, § 460.28 was added, effective Oct. 31, 2002.

**Subpart C—PACE Program Agreement**

**§ 460.30 Program agreement requirement.**

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

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

EFFECTIVE DATE NOTE: At 67 FR 61505, Oct. 1, 2002, § 460.30 was amended by revising paragraph (b) and adding paragraph (c), effective Oct. 31, 2002. For the convenience of the user, the revised and added text is set forth as follows:

**§ 460.30 Program agreement requirement.**

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(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.

**§ 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.