operated by an approved PACE organization and that provides comprehensive healthcare services to PACE enrollees in accordance with a PACE program agreement.

**PACE program agreement** means an agreement between a PACE organization, CMS, and the State administering agency for the operation of a PACE program.

**Participant** means an individual who is enrolled in a PACE program.

**Services** includes both items and services.

**State administering agency** means the State agency responsible for administering the PACE program agreement.

**Trial period** means the first 3 contract years in which a PACE organization operates under a PACE program agreement, including any contract year during which the entity operated under a PACE demonstration waiver program.

§ 460.14 [Reserved]

§ 460.16 [Reserved]

§ 460.18 CMS evaluation of applications.

CMS evaluates an application for approval as a PACE organization on the basis of the following information:

(a) Information contained in the application.

(b) Information obtained through on-site visits conducted by CMS or the State administering agency.

(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.