

Appendix A

Changes/Additions/Deletions Made to PACE Regulatory Requirements by PACE Final Rule as Published in Federal Register June 3, 2019

Changes Made to PACE Regulatory Requirements in 42 CFR Part 460

Subpart A—Basis, Scope, and Definitions

§460.2 Basis.

This part implements sections 1894, 1905(a), and 1934 of the Act, which authorize the following:

- (a) Medicare payments to, and coverage of benefits under, PACE.
- (b) The establishment of PACE as a State option under Medicaid to provide for Medicaid payments to, and coverage of benefits under, PACE.

§460.3 Part D program requirements.

PACE organizations offering qualified prescription drug coverage and meeting the definition of a Part D plan sponsor, as defined in §423.4 of this chapter, must abide by all applicable Part D program requirements in part 423 of this chapter.

§460.4 Scope and purpose.

(a) *General.* This part sets forth the following:

(1) The requirements that an entity must meet to be approved as a PACE organization that operates a PACE program under Medicare and Medicaid.

(2) How individuals may qualify to enroll in a PACE program.

(3) How Medicare and Medicaid payments will be made for PACE services.

(4) Provisions for Federal and State monitoring of PACE programs.

(5) Procedures for sanctions and terminations.

(b) *Program purpose.* PACE provides pre-paid, capitated, comprehensive health care services designed to meet the following objectives:

(1) Enhance the quality of life and autonomy for frail, older adults.

(2) Maximize dignity of, and respect for, older adults.

(3) Enable frail, older adults to live in the community as long as medically and socially feasible.

(4) Preserve and support the older adult's family unit.

§460.6 Definitions.

As used in this part, unless the context indicates otherwise, the following definitions apply:

Contract year means the term of a PACE program agreement, which is a calendar year, except that a PACE organization's initial contract year may be from 12 to 23 months, as determined by CMS.

Medicare beneficiary means an individual who is entitled to Medicare Part A benefits or enrolled under Medicare Part B, or both.

Medicaid participant means an individual determined eligible for Medicaid who is enrolled in a PACE program.

Medicare participant means a Medicare beneficiary who is enrolled in a PACE program.

PACE stands for programs of all-inclusive care for the elderly.

PACE center is a facility which includes a primary care clinic, and areas for therapeutic recreation, restorative therapies, socialization, personal care, and dining, and which serves as the focal point for coordination and provision of most PACE services.

PACE organization means an entity that has in effect a PACE program agreement to operate a PACE program under this part.

PACE program means a program of all-inclusive care for the elderly that is 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.

Subpart B—PACE Organization Application and Waiver Process

§460.10 Purpose.

(a) Applications. This subpart sets forth the application procedures for the following:

- (1) An entity that seeks approval from CMS as a PACE organization.
- (2) A PACE organization that seeks to expand its service area or to add a new PACE center.
- (3) A PACE organization that seeks to expand its service area and to add a new PACE center.

(b) Waiver. This subpart sets forth the process by which a PACE organization may request waiver of certain regulatory requirements. The purpose of the waivers is to provide for reasonable flexibility in adapting the PACE model to the needs of particular organizations (such as those in rural areas).

Deleted: This subpart sets forth the application requirements for an entity that seeks approval from CMS as a PACE organization and the process by which a PACE organization may request waiver of certain regulatory requirements. The purpose of the waivers is to provide for reasonable flexibility in adapting the PACE model to the needs of particular organizations (such as those in rural areas).¶ [67 FR 61504, Oct. 1, 2002]¶

§460.12 Application requirements.

(a) Submission of application. An individual authorized to act for an entity that seeks to become a PACE organization or a PACE organization that seeks to expand its service area and/or add a PACE center site must submit to CMS a complete application in the form and manner specified by CMS that describes how the entity or PACE organization meets all requirements in this part.

(b) State assurance. (1) An entity's application to become a PACE organization must include an assurance from the State administering agency of the State in which the program is located indicating that the State considers the entity to be qualified to be a PACE organization and is willing to enter into a PACE program agreement with the entity.

(2) A PACE organization's application to expand its service area and/or add a PACE center site must include an assurance from the State administering agency of the State in which the program is located indicating that the State is willing to amend the PACE program agreement to include the new site and/or expand the PACE organization's service area.

(c) Service area designation. (1) An entity submitting an application to become a PACE organization or a PACE organization submitting an application seeking to expand its service area must describe the proposed service area in its application.

(2) 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.

(d) Service area and/or PACE center site expansion. CMS and the State administering agency will only approve a service area expansion or PACE center site expansion after the PACE organization has successfully completed its first trial period audit and, if applicable, has implemented an acceptable corrective action plan.

Deleted: (a) *General.* (1) An individual authorized to act for the entity must submit to CMS a complete application that describes how the entity meets all requirements in this part.¶ (2) CMS accepts applications from entities that seek approval as PACE organizations beginning on February 22, 2000 except for the following:¶ (i) Beginning on November 24, 1999, CMS accepts applications from entities that meet the requirements for priority consideration in processing of applications.¶ (ii) Beginning on January 10, 2000, CMS accepts applications from entities that meet the requirements for special consideration in processing applications.¶ (b) *State assurance.* An entity's application must be accompanied by an assurance from the State administering agency of the State in which the program is located indicating that the State—¶ (1) Considers the entity to be qualified to be a PACE organization; and¶ (2) Is willing to enter into a PACE program agreement with the entity.¶ [64 FR 66279, Nov. 24, 1999, as amended at 67 FR 61505, Oct. 1, 2002; 71 FR 71334, Dec. 8, 2006]¶

§460.14 [Reserved]

§460.16 [Reserved]

§460.18 CMS evaluation of applications.

CMS evaluates an application on the basis of the following information:

- (a) Information contained in the application.

Deleted: for approval as a PACE organization

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

Deleted: Information obtained through onsite visits conducted by CMS or the State administering agency.

§460.20 Notice of CMS determination.

(a)

Deleted: (c) Information obtained by the State administering agency.¶

Time limit for notification of determination. Within 90 days, or 45 days for applications set forth in §460.10(a)(2), after an entity submits a complete application to CMS, CMS takes one of the following actions in the form and manner specified by CMS:

Deleted: 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.

(b) Complete application. An application is only considered complete when CMS receives all information necessary to make a determination regarding approval or denial.

Deleted: (3) Requests additional information needed to make a final determination.¶

(c) Additional information requested. If CMS determines that an application is not complete because it does not include sufficient information to make a determination, CMS will request additional information within 90 days, or 45 days for applications set forth in §460.10(a)(2), after the date of submission of the application.

(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) The time limits in paragraph (a) of this section do not begin until CMS receives all requested information and the application is complete.

(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.¶

(2) If more than 12 months elapse between the date of initial submission of the application and the entity's response to the CMS request for additional information, the entity must update the application to provide the most current information and materials related to the application.

(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:¶

(d) Deemed approval. An entity's application to become a PACE organization is deemed approved if CMS fails to act on the complete application within 90 days, after the later of the following dates:

(1) The date the application is submitted by the organization.¶
(2) The date CMS receives all requested additional information.¶

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

(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.¶

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

(e) Date of submission. For purposes of the time limits 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.

§460.24 Limit on number of PACE program agreements.

Deleted: §460.22 Service area designation.¶

(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:

(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.¶

(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)(ii) and 1934(a)(3)(B)(ii) of the Act.

§460.26 Submission and evaluation of waiver requests.

(a)

A PACE organization, or an entity submitting an application to become a PACE organization, must submit its waiver request through the State administering agency for initial review.

(1) The State administering agency forwards a PACE organization's waiver requests to CMS along with any concurrence, concerns or conditions regarding the waiver.

(2) Entities submitting an application to become a PACE organization may:

(i) Submit a waiver request as a document separate from the application by submitting it first to the State administering agency which, in turn, will forward the waiver request to CMS indicating the State's concurrence, concerns or conditions regarding the waiver request; or

(ii) Submit a waiver request directly to CMS in conjunction with the application. This request must include a letter from the State administering agency indicating the State's concurrence, concerns or conditions regarding the waiver request.

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

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

(2) 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.

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

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

Deleted: (1)

Deleted: 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.

Deleted: (2) Entities submitting an application to become a PACE organization may submit a waiver request. The entity must submit its waiver request through the State administering agency for initial review. The State administering agency forwards the waiver requests to CMS along with any concerns or conditions regarding the waiver. The waiver request is submitted as a document separate from the application but may be submitted in conjunction with and at the same time as the application.¶

(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; 67 FR 63966, Oct. 16, 2002; 71 FR 71334, Dec. 8, 2006]

§460.28 Notice of CMS determination on waiver requests.

(a) General. Within 90 days after receipt of a complete waiver request, CMS takes one of the following actions, in the form and manner specified by CMS:

(1) Approves the waiver request.

(2) Conditionally approves the waiver request and notifies the PACE applicant.

(3) Denies the waiver request and notifies the PACE organization or PACE applicant of the basis for the denial.

(b) Additional information requested. A waiver request is only considered complete when CMS receives all information necessary to make a determination regarding approval or denial. If CMS determines that the waiver request is not complete because it does not include sufficient information to make a determination, CMS will request additional information from the PACE organization or PACE applicant. The 90-day time limit in paragraph (a) of this section will start when CMS receives the complete waiver request.

(c) Waiver approval. A waiver request is deemed approved if CMS fails to act on the request within 90 days after CMS receives a complete waiver request.

(d) Withdrawal of CMS approval for good cause. (1) CMS in consultation with the State administering agency may withdraw approval of a waiver for good cause.

(2) If the waiver approval is withdrawn, CMS must notify the PACE organization or PACE applicant and the State administering agency that approval of a waiver has been withdrawn and the reason for doing so and must specify the effective date of the withdrawal in the notice.

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.

(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.

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

Deleted: (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 or PACE applicant in writing of the basis of 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, as amended at 71 FR 71334, Dec. 8, 2006]¶

§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.

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

(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 improvement program.

Deleted: assessment and performance

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

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

(12) The state's Medicaid capitation rate or Medicaid payment rate methodology, and the methodology used to calculate the Medicare capitation rate.

Deleted: The Medicaid capitation rate and the methodology used to calculate the Medicare capitation rate.

(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.

[64 FR 66279, Nov. 24, 1999, as amended at 71 FR 71334, Dec. 8, 2006]

§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 CMS may impose sanctions.

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

√(1) 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.

Deleted: (a)

√(2) Involuntarily disenrolls a participant in violation of §460.164.

Deleted: (b)

√(3) Discriminates in enrollment or disenrollment among Medicare beneficiaries or Medicaid beneficiaries, 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.

Deleted: (c)

√(4) 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 beneficiaries whose medical condition or history indicates a need for substantial future medical services.

Deleted: (d)

√(5) Imposes charges on participants enrolled under Medicare or Medicaid for premiums in excess of the premiums permitted.

Deleted: (e)

√(6) Misrepresents or falsifies information that is furnished—

Deleted: (f)

√(i) To CMS or the State under this part; or

Deleted: (1)

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

Deleted: (2)

√(7) 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.

Deleted: (g)

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

Deleted: (h)

~~(9)~~ 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.

Deleted: (i)

~~(10)~~ Makes payment to any individual or entity that is included on the preclusion list, defined in §422.2 of this chapter.

Deleted: (j)

(b) If CMS or the State administering agency makes a determination that could lead to termination of a PACE program agreement under §460.50, CMS may impose any of the sanctions specified at §§460.42 and 460.46.

[64 FR 66279, Nov. 24, 1999, as amended at 81 FR 80561, Nov. 15, 2016; 83 FR 16756, Apr. 16, 2018]

§460.42 Suspension of enrollment or payment by CMS.

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

(b) *Payment.* If a PACE organization commits one or more violations specified in §460.40, for individuals enrolled after the date CMS notifies the PACE organization of the violation, CMS may take the following actions:

(1) Suspend Medicare payment to the PACE organization.

(2) Deny payment to the State for medical assistance for services furnished under the PACE program agreement.

(c) *Term of suspension.* A suspension or denial of payment remains in effect until CMS is satisfied that the following conditions are met:

(1) The PACE organization has corrected the cause of the violation.

(2) The violation is not likely to recur.

§460.46 Civil money penalties.

(a) ~~(1)~~

CMS may impose civil money penalties up to the maximum amounts specified in paragraphs (a)(1) through (4) of this section. These amounts will be adjusted in accordance with the Federal Civil Penalties Inflation Adjustment Act Improvements Act of 2015 (Sec. 701 of Pub. L. 114-74) and updated amounts specified in 45 CFR part 102.

Deleted: CMS may impose civil money penalties up to the following maximum amounts:

(1) For each violation regarding enrollment or disenrollment specified in ~~§460.40(a)(3) or (4)~~, \$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.

Deleted: §460.40 (c) or (d)

(2) For each violation regarding excessive premiums specified in ~~§460.40(a)(5)~~, \$25,000 plus double the excess amount above the permitted premium charged a participant by the PACE

Deleted: §460.40(e)

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(a)(6)(i)~~, \$100,000.

Deleted: §460.40(f)(1)

(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, including making payment to an individual or entity that is included on the preclusion list, defined in §422.2 of this chapter.

(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.

[64 FR 66279, Nov. 24, 1999, as amended at 81 FR 80561, Nov. 15, 2016; 83 FR 16756, Apr. 16, 2018]

§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) *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.

↘(b) *Medical director.* The organization must employ, or contract with in accordance 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 improvement program.

↘(c) *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) Except as provided in paragraph (d) of this section, a PACE organization planning a change in organizational structure must notify CMS and the State administering agency, in writing, at least 14 days before the change takes effect.

(d) *Change of ownership.* A PACE organization planning a change of ownership must comply with all requirements in 42 CFR part 422, subpart L, and must notify CMS and the State administering agency, in writing, at least 60 days before the anticipated effective date of the change.

[64 FR 66279, Nov. 24, 1999, as amended at 67 FR 61505, Oct. 1, 2002; 71 FR 71334, Dec. 8, 2006]

§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.

(6) Development of policies on participant health and safety, including a comprehensive, systemic operational plan to ensure the health and safety of participants.

- (7) A quality improvement program as described in §460.130.

Deleted: (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)

Deleted: (c)

Deleted: assessment and performance

Deleted: (d)

Deleted: Quality assessment and performance improvement program.

(b) *Participant advisory committee.* (1) A PACE organization must establish a participant advisory committee to provide advice to the governing body on matters of concern to participants. Participants and representatives of participants must constitute a majority of the membership of this committee.

(2) The participant advisory committee must provide the liaison to the governing body with meeting minutes that include participant issues.

(c) *Participant representation on the governing body.* (1) A PACE organization must ensure participant representation on issues related to participant care. This shall be achieved by having a participant representative on the governing body.

(2) The participant representative is a liaison of the participant advisory committee to the PACE organization governing body.

(3) *Duty of the participant representative.* The participant representative must present issues from the participant advisory committee to the governing body.

[64 FR 66279, Nov. 24, 1999, as amended at 71 FR 71334, Dec. 8, 2006]

§460.63 Compliance oversight requirements.

A PACE organization must adopt and implement effective compliance oversight requirements, which must include measures that prevent, detect, and correct non-compliance with CMS' program requirements, as well as measures that prevent, detect, and correct fraud, waste, and abuse. The compliance oversight program must, at a minimum, include establishment and implementation of procedures and a system for promptly responding to compliance issues as they are raised, investigating potential compliance problems as identified in the course of self-evaluations and audits, correcting such problems promptly and thoroughly to reduce the potential for recurrence, and ensure ongoing compliance with CMS requirements.

(a) If the PACE organization discovers evidence of misconduct related to payment or delivery of items or services, it must conduct a timely, reasonable inquiry into that conduct.

(b) The PACE organization must conduct appropriate corrective actions (for example, repayment of overpayments, disciplinary actions against responsible employees) in response to the potential violation.

(c) The PACE organization should have procedures to voluntarily self-report potential fraud or misconduct related to the PACE program to CMS and the State administering agency.

§460.64 Personnel qualifications for staff with direct participant contact.

(a) _____

General qualification requirements. Each member of the PACE organization's staff (employee or contractor) that has direct contact with participants must meet the following conditions:

Deleted: *General qualification requirements.* Each member of the PACE organization's staff that has direct participant contact, (employee or contractor) must meet the following conditions:

(1) Be legally authorized (for example, currently licensed, registered or certified if applicable) to practice in the State in which he or she performs the function or action;

(2) Only act within the scope of his or her authority to practice;

(3) Have 1 year of experience working with a frail or elderly population or, if the individual has less than 1 year of experience but meets all other requirements under paragraph (a) of this section, must receive appropriate training from the PACE organization on working with a frail or elderly population upon hiring.

Deleted: Have 1 year of experience with a frail or elderly population;

(4) Meet a standardized set of competencies for the specific position description established by the PACE organization before working independently.

Deleted: and approved by CMS

(5) Be medically cleared for communicable diseases and have all immunizations up-to-date before engaging in direct participant contact.

(b) *Federally-defined qualifications for physician.* In addition to the qualification specified in paragraph (a) of this section, a physician must meet the qualifications and conditions in §410.20 of this chapter.

[71 FR 71334, Dec. 8, 2006]

§460.66 Training.

The PACE organization must provide training to maintain and improve the skills and knowledge of each staff member with respect to the individual's specific duties that results in his or her continued ability to demonstrate the skills necessary for the performance of the position.

Deleted: (a)

[64 FR 66279, Nov. 24, 1999, as amended at 71 FR 71335, Dec. 8, 2006]

§460.68 Program integrity.

(a) *Persons with criminal convictions.* A PACE organization must not employ individuals or contract with organizations or individuals—

Deleted: (b) The PACE organization must develop a training program for each personal care attendant to establish the individual's competency in furnishing personal care services and specialized skills associated with specific care needs of individual participants.¶
(c) Personal care attendants must exhibit competency before performing personal care services independently.¶

(1) Who have been excluded from participation in the Medicare or Medicaid programs;

(2) Who have been convicted of criminal offenses related to their involvement in Medicaid, Medicare, other health insurance or health care programs, or social service programs under title XX of the Act;

Deleted: or

(3) If the PACE organization determines that an individual's contact with participants would pose a potential risk because the individual has been convicted of one or more criminal offenses related to physical, sexual, drug, or alcohol abuse or use;

Deleted: In any capacity where an individual's contact with participants would pose a potential risk because the individual has been convicted of physical, sexual, drug, or alcohol abuse.

(4) Who have been found guilty of abusing, neglecting, or mistreating individuals by a court of law or who have had a finding entered into the State nurse aide registry concerning abuse, neglect, mistreatment of residents, or misappropriation of their property; or

Deleted: ¶

(5) Who have been convicted of specific crimes for any offense described in section 1128(a) of the Social Security Act.

(b) *Direct or indirect interest in contracts.* The PACE organization shall identify members of its governing body or any immediate family member having a direct or indirect interest in any contract that supplies any administrative or care-related service or materials to the PACE organization.

(1) PACE organizations must develop policies and procedures for handling any direct or indirect conflict of interest by a member of the governing body or by the member's immediate family.

(2) In the event of a direct or indirect conflict of interest by a member of the PACE organization's governing body or his or her immediate family member, the board member must—

(i) Fully disclose the exact nature of the conflict to the board of directors and have the disclosure documented; and

(ii) Recuse himself or herself from discussing, negotiating, or voting on any issue or contract that could result in an inappropriate conflict.

(c) *Disclosure and recusal requirements.* A PACE organization must have a formal process in place to gather information related to paragraphs (a) and (b) of this section and must be able to respond in writing to a request for information from CMS within a reasonable amount of time.

[64 FR 66279, Nov. 24, 1999, as amended at 67 FR 61505, Oct. 1, 2002; 71 FR 71335, Dec. 8, 2006; 81 FR 80561, Nov. 15, 2016; 83 FR 16756, Apr. 16, 2018]

§460.70 Contracted services.

(a) *General rule.* The PACE organization must have a written contract with each outside organization, agency, or individual that furnishes administrative or care-related services not furnished directly by the PACE organization except for emergency services as described in §460.100.

(b) *Contract requirements.* A contract between a PACE organization and a contractor must meet the following requirements:

(1) The PACE organization must contract only with an entity that meets all applicable Federal and State requirements, including, but not limited to, the following:

(i) An institutional contractor, such as a hospital or skilled nursing facility, must meet Medicare or Medicaid participation requirements.

(ii) A practitioner or supplier must meet Medicare or Medicaid requirements applicable to the services it furnishes.

(iii) A contractor must comply with the requirements of this part with respect to service delivery, participant rights, and quality improvement activities.

(2) A contractor must be accessible to participants, located either within or near the PACE organization's service area.

(3) A PACE organization must designate an official liaison to coordinate activities between contractors and the organization.

Deleted: A contractor must comply with the requirements of this part with respect to service delivery, participant rights, and quality assessment and performance improvement activities.

(c) *List of contractors.* A current list of contractors must be on file at the PACE center and a copy must be provided to anyone upon request.

(d) *Content of contract.* Each contract must be in writing and include the following information:

(1) Name of contractor.

(2) Services furnished (including work schedule if appropriate).

(3) Payment rate and method.

(4) Terms of the contract, including beginning and ending dates, methods of extension, renegotiation, and termination.

(5) Contractor agreement to do the following:

(i) Furnish only those services authorized by the PACE interdisciplinary team.

(ii) Accept payment from the PACE organization as payment in full, and not bill participants, CMS, the State administering agency, or private insurers.

(iii) Hold harmless CMS, the State, and PACE participants if the PACE organization does not pay for services performed by the contractor in accordance with the contract.

(iv) Not assign the contract or delegate duties under the contract unless it obtains prior written approval from the PACE organization.

(v) Submit reports required by the PACE organization.

(6) With respect to an individual who is contracting as a program director or medical director or to be part of the interdisciplinary team as set forth at §460.60(a) and (b) and §460.102(b), the contract must specify that the individual agrees to:

(i) Perform all the duties related to its position as specified in this part.

(ii) Participate in interdisciplinary team meetings as required.

(iii) Be accountable to the PACE organization.

(iv) Cooperate with the competency evaluation program and direct participant care requirements specified in §460.71.

(e) *Contracting with another entity to furnish PACE center services.* (1) A PACE organization may only contract for PACE center services if it is fiscally sound as defined in §460.80(a) of this part and has demonstrated competence with the PACE model as evidenced by successful monitoring by CMS and the State administering agency.

(2) The PACE organization retains responsibility for all participants and may only contract for the PACE center services identified in §460.98(c).

Deleted: (vi) Agree to perform all the duties related to its position as specified in this part.¶
 (vii) Participate in interdisciplinary team meeting as required.¶
 (viii) Agree to be accountable to the PACE organization.¶
 (ix) Cooperate with the competency evaluation program and direct participant care requirements specified in §460.71.¶

Deleted: Center

Deleted: Center

Deleted: Center

Deleted: (d)

[64 FR 66279, Nov. 24, 1999, as amended at 67 FR 61505, Oct. 1, 2002; 71 FR 71335, Dec. 8, 2006; 81 FR 80561, Nov. 15, 2016; 83 FR 16756, Apr. 16, 2018]

§460.71 Oversight of direct participant care.

(a) The PACE organization must ensure that all employees and contracted staff furnishing care directly to participants demonstrate the skills necessary for performance of their position.

(1) ~~_____~~

~~The PACE organization must provide each employee and all contracted staff with an orientation that includes, at a minimum, the organization's mission, philosophy, policies on participant rights, emergency plan, ethics, the PACE benefit, and any policies related to the job duties of specific staff.~~

Deleted: The PACE organization must provide each employee and all contracted staff with an orientation. The orientation must include at a minimum the organization's mission, philosophy, policies on participant rights, emergency plan, ethics, the PACE benefit, and any policies related to the job duties of specific staff.

(2) The PACE organization must develop a competency evaluation program that identifies those skills, knowledge, and abilities that must be demonstrated by direct participant care staff (employees and contractors).

(3) The competency program must be evidenced as completed before performing participant care and on an ongoing basis by qualified professionals.

(4) The PACE organization must designate a staff member to oversee these activities for employees and work with the PACE contractor liaison to ensure compliance by contracted staff.

(b) The PACE organization must develop a program to ensure that all staff furnishing direct participant care services meet the following requirements:

(1) Comply with any State or Federal requirements for direct patient care staff in their respective settings.

(2) Comply with the requirements of §460.68(a) regarding persons with criminal convictions.

(3) Have verified current certifications or licenses for their respective positions.

(4) ~~_____~~

~~Be medically cleared for communicable diseases and have all immunizations up-to-date before engaging in direct participant contact as required under §460.64(a)(5).~~

Deleted: Are free of communicable diseases and are up to date with immunizations before performing direct patient care.

(5) Have been oriented to the PACE program.

(6) Agree to abide by the philosophy, practices, and protocols of the PACE organization.

~~(c) The PACE organization must develop a training program for each personal care attendant to establish the individual's competency in furnishing personal care services and specialized skills associated with specific care needs of individual participants.~~

~~(d) Personal care attendants must exhibit competency before performing personal care services independently.~~

[67 FR 61505, Oct. 1, 2002, as amended at 71 FR 71335, Dec. 8, 2006; 81 FR 80562, Nov. 15, 2016; 83 FR 16756, Apr. 16, 2018]

§460.72 Physical environment.

(a) *Space and equipment*—(1) *Safe design.* A PACE center must meet the following requirements:

(i) Be designed, constructed, equipped, and maintained to provide for the physical safety of participants, personnel, and visitors.

(ii) Ensure a safe, sanitary, functional, accessible, and comfortable environment for the delivery of services that protects the dignity and privacy of the participant.

(2) *Primary care clinic.* The PACE center must include sufficient suitable space and equipment to provide primary medical care and suitable space for team meetings, treatment, therapeutic recreation, restorative therapies, socialization, personal care, and dining.

(3) *Equipment maintenance.* (i) A PACE organization must establish, implement, and maintain a written plan to ensure that all equipment is maintained in accordance with the manufacturer's recommendations.

(ii) A PACE organization must perform the manufacturer's recommended maintenance on all equipment as indicated in the organization's written plan.

(b) *Fire safety*—(1) *General rule.* Except as otherwise provided in this section—

(i) A PACE center must meet the applicable provisions and must proceed in accordance with the Life Safety Code (NFPA 101 and Tentative Interim Amendments TIA 12-1, TIA 12-2, TIA 12-3, and TIA 12-4.)

(ii) Notwithstanding paragraph (b)(1)(i) of this section, corridor doors and doors to rooms containing flammable or combustible materials must be provided with positive latching hardware. Roller latches are prohibited on such doors.

(2) *Exceptions.* (i) The Life Safety Code provisions do not apply in a State in which CMS determines that a fire and safety code imposed by State law adequately protects participants and staff.

(ii) In consideration of a recommendation by the State survey agency or Accrediting Organization or at the discretion of the Secretary, may waive, for periods deemed appropriate, specific provisions of the Life Safety Code, which would result in unreasonable hardship upon a PACE facility, but only if the waiver will not adversely affect the health and safety of the patients.

(3) A PACE center may install alcohol-based hand rub dispensers in its facility if the dispensers are installed in a manner that adequately protects against inappropriate access.

(4) When a sprinkler system is shut down for more than 10 hours in a 24-hour period, the PACE must:

(i) Evacuate the building or portion of the building affected by the system outage until the system is back in service, or

(ii) Establish a fire watch until the system is back in service.

(c) [Reserved]

(d) *Standard: Building Safety.* Except as otherwise provided in this section, a PACE center must meet the applicable provisions and must proceed in accordance with the Health Care Facilities Code (NFPA 99 and Tentative Interim Amendments TIA 12-2, TIA 12-3, TIA 12-4, TIA 12-5 and TIA 12-6).

(1) Chapters 7, 8, 12, and 13 of the adopted Health Care Facilities Code do not apply to a PACE center.

(2) If application of the Health Care Facilities Code required under paragraph (d) of this section would result in unreasonable hardship for the PACE center, CMS may waive specific provisions of the Health Care Facilities Code, but only if the waiver does not adversely affect the health and safety of patients.

(e) The standards incorporated by reference in this section are approved for incorporation by reference by the Director of the Office of the Federal Register in accordance with 5 U.S.C. 552(a) and 1 CFR part 51. You may inspect a copy at the CMS Information Resource Center, 7500 Security Boulevard, Baltimore, MD or at the National Archives and Records Administration (NARA). For information on the availability of this material at NARA, call 202-741-6030, or go to: http://www.archives.gov/federal_register/code_of_federal_regulations/ibr_locations.html. If any changes in this edition of the Code are incorporated by reference, CMS will publish a document in the FEDERAL REGISTER to announce the changes.

(1) National Fire Protection Association, 1 Batterymarch Park, Quincy, MA 02169, www.nfpa.org, 1.617.770.3000.

(i) NFPA 99, Standards for Health Care Facilities Code of the National Fire Protection Association 99, 2012 edition, issued August 11, 2011.

(ii) TIA 12-2 to NFPA 99, issued August 11, 2011.

(iii) TIA 12-3 to NFPA 99, issued August 9, 2012.

(iv) TIA 12-4 to NFPA 99, issued March 7, 2013.

(v) TIA 12-5 to NFPA 99, issued August 1, 2013.

(vi) TIA 12-6 to NFPA 99, issued March 3, 2014.

(vii) NFPA 101, Life Safety Code, 2012 edition, issued August 11, 2011;

(viii) TIA 12-1 to NFPA 101, issued August 11, 2011.

(ix) TIA 12-2 to NFPA 101, issued October 30, 2012.

(x) TIA 12-3 to NFPA 101, issued October 22, 2013.

(xi) TIA 12-4 to NFPA 101, issued October 22, 2013.

(2) [Reserved]

[64 FR 66279, Nov. 24, 1999, as amended at 68 FR 1386, Jan. 10, 2003; 69 FR 49266, Aug. 11, 2004; 70 FR 15238, Mar. 25, 2005; 71 FR 55340, Sept. 22, 2006; 71 FR 71335, Dec. 8, 2006; 81 FR 26898, May 4, 2016; 81 FR 64026, Sept. 16, 2016]

§460.74 Infection control.

(a) *Standard procedures.* The PACE organization must follow accepted policies and standard procedures with respect to infection control, including at least the standard precautions developed by the Centers for Disease Control and Prevention.

(b) *Infection control plan.* The PACE organization must establish, implement, and maintain a documented infection control plan that meets the following requirements:

(1) Ensures a safe and sanitary environment.

(2) Prevents and controls the transmission of disease and infection.

(c) *Contents of infection control plan.* The infection control plan must include, but is not limited to, the following:

(1) Procedures to identify, investigate, control, and prevent infections in every Pace center and in each participant's place of residence.

(2) Procedures to record any incidents of infection.

(3) Procedures to analyze the incidents of infection to identify trends and develop corrective actions related to the reduction of future incidents.

[64 FR 66279, Nov. 24, 1999, as amended at 71 FR 71334, Dec. 8, 2006]

§460.76 Transportation services.

(a) *Safety, accessibility, and equipment.* A PACE organization's transportation services must be safe, accessible, and equipped to meet the needs of the participant population.

(b) *Maintenance of vehicles.* (1) If the PACE organization owns, rents, or leases transportation vehicles, it must maintain these vehicles in accordance with the manufacturer's recommendations.

(2) If a contractor provides transportation services, the PACE organization must ensure that the vehicles are maintained in accordance with the manufacturer's recommendations.

(c) *Communication with PACE center.* The PACE organization must ensure that transportation vehicles are equipped to communicate with the PACE center.

(d) *Training.* The PACE organization must train all transportation personnel (employees and contractors) in the following:

- (1) Managing the special needs of participants.
- (2) Handling emergency situations.

(e) *Changes in care plan.* As part of the interdisciplinary team process, PACE organization staff (employees and contractors) must communicate relevant changes in a participant's care plan to transportation personnel.

[64 FR 66279, Nov. 24, 1999, as amended at 71 FR 71334, Dec. 8, 2006]

§460.78 Dietary services.

(a) *Meal requirements.* (1) Except as specified in paragraphs (a)(2) or (a)(3) of this section, the PACE organization must ensure, through the assessment and care planning process, that each participant receives nourishing, palatable, well-balanced meals that meet the participant's daily nutritional and special dietary needs. Each meal must meet the following requirements:

- (i) Be prepared by methods that conserve nutritive value, flavor, and appearance.
- (ii) Be prepared in a form designed to meet individual needs.
- (iii) Be prepared and served at the proper temperature.

(2) The PACE organization must provide substitute foods or nutritional supplements that meet the daily nutritional and special dietary needs of any participant who has any of the following problems:

- (i) Refuses the food served.
- (ii) Cannot tolerate the food served.
- (iii) Does not eat adequately.

(3) The PACE organization must provide nutrition support to meet the daily nutritional needs of a participant, if indicated by his or her medical condition or diagnosis. Nutrition support consists of tube feedings, total parenteral nutrition, or peripheral parenteral nutrition.

(b) *Sanitary conditions.* The PACE organization must do the following:

(1) Procure foods (including nutritional supplements and nutrition support items) from sources approved, or considered satisfactory, by Federal, State, Tribal, or local authorities with jurisdiction over the service area of the organization.

(2) Store, prepare, distribute, and serve foods (including nutritional supplements and nutrition support items) under sanitary conditions.

(3) Dispose of garbage and refuse properly.

[64 FR 66279, Nov. 24, 1999, as amended at 71 FR 71335, Dec. 8, 2006]

§460.80 Fiscal soundness.

(a) *Fiscally sound operation.* A PACE organization must have a fiscally sound operation, as demonstrated by the following:

- (1) Total assets greater than total unsubordinated liabilities.
- (2) Sufficient cash flow and adequate liquidity to meet obligations as they become due.
- (3) A net operating surplus or a financial plan for maintaining solvency that is satisfactory to CMS and the State administering agency.

(b) *Insolvency plan.* The organization must have a documented plan in the event of insolvency, approved by CMS and the State administering agency, which provides for the following:

- (1) Continuation of benefits for the duration of the period for which capitation payment has been made.
- (2) Continuation of benefits to participants who are confined in a hospital on the date of insolvency until their discharge.
- (3) Protection of participants from liability for payment of fees that are the legal obligation of the PACE organization.

(c) *Arrangements to cover expenses.* (1) A PACE organization must demonstrate that it has arrangements to cover expenses in the amount of at least the sum of the following in the event it becomes insolvent:

- (i) One month's total capitation revenue to cover expenses the month before insolvency.
 - (ii) One month's average payment to all contractors, based on the prior quarter's average payment, to cover expenses the month after the date it declares insolvency or ceases operations.
- (2) Arrangements to cover expenses may include, but are not limited to, the following:
- (i) Insolvency insurance or reinsurance.
 - (ii) Hold harmless arrangement.
 - (iii) Letters of credit, guarantees, net worth, restricted State reserves, or State law provisions.

§460.82 Marketing.

(a) *Information that a PACE organization must include in its marketing materials.* (1) A PACE organization must inform the public about its program and give prospective participants the following written information:

(i) An adequate description of the PACE organization's enrollment and disenrollment policies and requirements.

(ii) PACE enrollment procedures.

(iii) Description of benefits and services.

(iv) Premiums.

(v) Other information necessary for prospective participants to make an informed decision about enrollment.

(2) Marketing information must be free of material inaccuracies, misleading information, or misrepresentations.

(b) *Approval of marketing information.* (1) CMS must approve all marketing information before distribution by the PACE organization, including any revised or updated material.

(2) CMS reviews initial marketing information as part of an entity's application for approval as a PACE organization, and approval of the application includes approval of marketing information.

(3) Once a PACE organization is under a PACE program agreement, any revisions to existing marketing information and new information are subject to the following:

(i) *Time period for approval.* CMS approves or disapproves marketing information within 45 days after CMS receives the information from the organization.

(ii) *Deemed approval.* Marketing information is deemed approved, and the organization can distribute it, if CMS and the State administering agency do not disapprove the marketing material within the 45-day review period.

(c) *Special language requirements.* A PACE organization must furnish printed marketing materials to prospective and current participants as specified below:

(1) In English and in any other principal languages of the community, as determined by the State in which the PACE organization is located. In the absence of a State standard, a principal language of the community is any language that is spoken in the home by at least 5 percent of the individuals in the PACE organization's service area.

Deleted: In English and in any other principal languages of the community.

(2) In Braille, if necessary.

(d) *Information on restriction of services.* (1) Marketing materials must inform a potential participant that he or she must receive all needed health care, including primary care and specialist physician services (other than emergency services), from the PACE organization or from an entity authorized by the PACE organization.

(2) All marketing materials must state clearly that PACE participants may be fully and personally liable for the costs of unauthorized or out-of-PACE program agreement services.

(e) ▼

Prohibited marketing practices. A PACE organization must not use the following marketing practices, which are prohibited:

(1) Discrimination of any kind, except that marketing may be directed to individuals eligible for PACE by reason of their age.

(2) Activities that could mislead or confuse potential participants, or misrepresent the PACE organization, CMS, or the State administering agency.

(3) Gifts or payments to induce enrollment, unless the gifts are of nominal value as defined in CMS guidance, are offered to all potential enrollees without regard to whether they enroll in the PACE program, and are not in the form of cash or other monetary rebates.

(4) ▼

Marketing by any individual or entity that is directly or indirectly compensated by the PACE organization based on activities or outcomes unless the individual or entity has been appropriately trained on PACE program requirements, including but not limited to, subparts G and I of this part.

(i) PACE organizations are responsible for the activities of contracted individuals or entities who market on their behalf.

(ii) PACE organizations that choose to use contracted individuals or entities for marketing purposes must develop a method to document training has been provided.

(5) Unsolicited door-to-door marketing or other unsolicited means of direct contact, including calling or emailing a potential or current participant without the individual initiating the contact.

▼

§460.84 Emergency preparedness.

The Program for the All-Inclusive Care for the Elderly (PACE) organization must comply with all applicable Federal, State, and local emergency preparedness requirements. The PACE organization must establish and maintain an emergency preparedness program that meets the requirements of this section. The emergency preparedness program must include, but not be limited to, the following elements:

(a) *Emergency plan.* The PACE organization must develop and maintain an emergency preparedness plan that must be reviewed, and updated at least annually. The plan must do the following:

(1) Be based on and include a documented, facility-based and community-based risk assessment, utilizing an all-hazards approach.

(2) Include strategies for addressing emergency events identified by the risk assessment.

Deleted: *Prohibited marketing practices.* A PACE organization must ensure that its employees or its agents do not use prohibited marketing practices which includes the following:

Deleted: Contracting outreach efforts to individuals or organizations whose sole responsibility involves direct contact with the elderly to solicit enrollment.

Deleted: (f) *Marketing Plan.* A PACE organization must establish, implement, and maintain a documented marketing plan with measurable enrollment objectives and a system for tracking its effectiveness.

(3) Address participant population, including, but not limited to, the type of services the PACE organization has the ability to provide in an emergency; and continuity of operations, including delegations of authority and succession plans.

(4) Include a process for cooperation and collaboration with local, tribal, regional, State, and Federal emergency preparedness officials' efforts to maintain an integrated response during a disaster or emergency situation, including documentation of the PACE's efforts to contact such officials and, when applicable, of its participation in organization's collaborative and cooperative planning efforts.

(b) *Policies and procedures.* The PACE organization must develop and implement emergency preparedness policies and procedures, based on the emergency plan set forth in paragraph (a) of this section, risk assessment at paragraph (a)(1) of this section, and the communication plan at paragraph (c) of this section. The policies and procedures must address management of medical and nonmedical emergencies, including, but not limited to: Fire; equipment, power, or water failure; care-related emergencies; and natural disasters likely to threaten the health or safety of the participants, staff, or the public. Policies and procedures must be reviewed and updated at least annually. At a minimum, the policies and procedures must address the following:

(1) The provision of subsistence needs for staff and participants, whether they evacuate or shelter in place, include, but are not limited to the following:

(i) Food, water, and medical supplies.

(ii) Alternate sources of energy to maintain the following:

(A) Temperatures to protect participant health and safety and for the safe and sanitary storage of provisions.

(B) Emergency lighting.

(C) Fire detection, extinguishing, and alarm systems.

(D) Sewage and waste disposal.

(2) A system to track the location of on-duty staff and sheltered participants under the PACE center(s) care during and after an emergency. If on-duty staff and sheltered participants are relocated during the emergency, the PACE must document the specific name and location of the receiving facility or other location.

(3) Safe evacuation from the PACE center, which includes consideration of care and treatment needs of evacuees; staff responsibilities; transportation; identification of evacuation location(s); and primary and alternate means of communication with external sources of assistance.

(4) The procedures to inform State and local emergency preparedness officials about PACE participants in need of evacuation from their residences at any time due to an emergency situation based on the participant's medical and psychiatric conditions and home environment.

(5) A means to shelter in place for participants, staff, and volunteers who remain in the facility.

(6) A system of medical documentation that preserves participant information, protects confidentiality of participant information, and secures and maintains the availability of records.

(7) The use of volunteers in an emergency or other emergency staffing strategies, including the process and role for integration of State or Federally designated health care professionals to address surge needs during an emergency.

(8) The development of arrangements with other PACE organizations, PACE centers, or other providers to receive participants in the event of limitations or cessation of operations to maintain the continuity of services to PACE participants.

(9) The role of the PACE organization under a waiver declared by the Secretary, in accordance with section 1135 of the Act, in the provision of care and treatment at an alternate care site identified by emergency management officials.

(10)(i) Emergency equipment, including easily portable oxygen, airways, suction, and emergency drugs.

(ii) Staff who know how to use the equipment must be on the premises of every center at all times and be immediately available.

(iii) A documented plan to obtain emergency medical assistance from outside sources when needed.

(c) *Communication plan.* The PACE organization must develop and maintain an emergency preparedness communication plan that complies with Federal, State, and local laws and must be reviewed and updated at least annually. The communication plan must include all of the following:

(1) Names and contact information for staff; entities providing services under arrangement; participants' physicians; other PACE organizations; and volunteers.

(2) Contact information for the following:

(i) Federal, State, tribal, regional, and local emergency preparedness staff.

(ii) Other sources of assistance.

(3) Primary and alternate means for communicating with the following:

(i) PACE organization's staff.

(ii) Federal, State, tribal, regional, and local emergency management agencies.

(4) A method for sharing information and medical documentation for participants under the organization's care, as necessary, with other health care providers to maintain the continuity of care.

(5) A means, in the event of an evacuation, to release participant information as permitted under 45 CFR 164.510(b)(1)(ii).

(6) A means of providing information about the general condition and location of participants under the facility's care as permitted under 45 CFR 164.510(b)(4).

(7) A means of providing information about the PACE organization's needs, and its ability to provide assistance, to the authority having jurisdiction, the Incident Command Center, or designee.

(d) *Training and testing.* The PACE organization must develop and maintain an emergency preparedness training and testing program that is based on the emergency plan set forth in paragraph (a) of this section, risk assessment at paragraph (a)(1) of this section, policies and procedures at paragraph (b) of this section, and the communication plan at paragraph (c) of this section. The training and testing program must be reviewed and updated at least annually.

(1) *Training program.* The PACE organization must do all of the following:

(i) Initial training in emergency preparedness policies and procedures to all new and existing staff, individuals providing on-site services under arrangement, contractors, participants, and volunteers, consistent with their expected roles.

(ii) Provide emergency preparedness training at least annually.

(iii) Demonstrate staff knowledge of emergency procedures, including informing participants of what to do, where to go, and whom to contact in case of an emergency.

(iv) Maintain documentation of all training.

(2) *Testing.* The PACE organization must conduct exercises to test the emergency plan at least annually. The PACE organization must do the following:

(i) Participate in a full-scale exercise that is community-based or when a community-based exercise is not accessible, an individual, facility-based. If the PACE experiences an actual natural or man-made emergency that requires activation of the emergency plan, the PACE is exempt from engaging in a community-based or individual, facility-based full-scale exercise for 1 year following the onset of the actual event.

(ii) Conduct an additional exercise that may include, but is not limited to the following:

(A) A second full-scale exercise that is community-based or individual, facility-based.

(B) A tabletop exercise that includes a group discussion led by a facilitator, using a narrated, clinically-relevant emergency scenario, and a set of problem statements, directed messages, or prepared questions designed to challenge an emergency plan.

(iii) Analyze the PACE's response to and maintain documentation of all drills, tabletop exercises, and emergency events and revise the PACE's emergency plan, as needed.

(e) *Integrated healthcare systems.* If a PACE is part of a healthcare system consisting of multiple separately certified healthcare facilities that elects to have a unified and integrated emergency preparedness program, the PACE may choose to participate in the healthcare system's coordinated emergency preparedness program. If elected, the unified and integrated emergency preparedness program must—

(1) Demonstrate that each separately certified facility within the system actively participated in the development of the unified and integrated emergency preparedness program.

(2) Be developed and maintained in a manner that takes into account each separately certified facility's unique circumstances, participant populations, and services offered.

(3) Demonstrate that each separately certified facility is capable of actively using the unified and integrated emergency preparedness program and is in compliance with the program.

(4) Include a unified and integrated emergency plan that meets the requirements of paragraphs (a)(2), (3), and (4) of this section. The unified and integrated emergency plan must also be based on and include the following:

(i) A documented community-based risk assessment, utilizing an all-hazards approach.

(ii) A documented individual facility-based risk assessment for each separately certified facility within the health system, utilizing an all-hazards approach.

(5) Include integrated policies and procedures that meet the requirements set forth in paragraph (b) of this section, a coordinated communication plan and training and testing programs that meet the requirements of paragraphs (c) and (d) of this section, respectively.

[81 FR 64026, Sept. 16, 2016]

§460.86 Payment to individuals and entities excluded by the OIG or included on the preclusion list.

(a) A PACE organization may not pay, directly or indirectly, on any basis, for items or services (other than emergency or urgently needed services as defined in §460.100) furnished to a Medicare enrollee by any individual or entity that is excluded by the OIG or is included on the preclusion list, defined in §422.2 of this chapter.

(b) If a PACE organization receives a request for payment by, or on behalf of, an individual or entity that is excluded by the OIG or is included on the preclusion list, defined in §422.2 of this chapter, the PACE organization must notify the enrollee and the excluded individual or entity or the individual or entity that is included on the preclusion list in writing, as directed by contract or other direction provided by CMS, that payments will not be made. Payment may not be made to, or on behalf of, an individual or entity that is excluded by the OIG or is included on the preclusion list.

[83 FR 16756, Apr. 16, 2018]

Subpart F—PACE Services

§460.90 PACE benefits under Medicare and Medicaid.

If a Medicare beneficiary or Medicaid beneficiary chooses to enroll in a PACE program, the following conditions apply:

(a) Medicare and Medicaid benefit limitations and conditions relating to amount, duration, scope of services, deductibles, copayments, coinsurance, or other cost-sharing do not apply.

(b) The participant, while enrolled in a PACE program, must receive Medicare and Medicaid benefits solely through the PACE organization.

§460.92 Required services.

The PACE benefit package for all participants, regardless of the source of payment, must include the following:

(a) All Medicare-covered items and services.

(b) All Medicaid-covered items and services, as specified in the State's approved Medicaid plan.

(c) Other services determined necessary by the interdisciplinary team to improve and maintain the participant's overall health status.

[71 FR 71335, Dec. 8, 2006]

§460.94 Required services for Medicare participants.

(a) Except for Medicare requirements that are waived for the PACE program, as specified in paragraph (b) of this section, the PACE benefit package for Medicare participants must include the following services:

(1) The scope of hospital insurance benefits described in part 409 of this chapter.

(2) The scope of supplemental medical insurance benefits described in part 410 of this chapter.

(b) *Waivers of Medicare coverage requirements.* The following Medicare requirements are waived for purposes of the PACE program and do not apply:

(1) The provisions of subpart F of part 409 of this chapter that limit coverage of institutional services.

(2) The provisions of subparts G and H of part 409 of this chapter, and parts 412 through 414 of this chapter that relate to payment for benefits.

(3) The provisions of subparts D and E of part 409 of this chapter that limit coverage of extended care services or home health services.

(4) The provisions of subpart D of part 409 of this chapter that impose a 3-day prior hospitalization requirement for coverage of extended care services.

(5) Section 411.15(g) and §411.15(k) of this chapter that may prevent payment for PACE program services that are provided to PACE participants.

[64 FR 66279, Nov. 24, 1999, as amended at 71 FR 71335, Dec. 8, 2006]

§460.96 Excluded services.

The following services are excluded from coverage under PACE:

(a) Any service that is not authorized by the interdisciplinary team, even if it is a required service, unless it is an emergency service.

(b) In an inpatient facility, private room and private duty nursing services (unless medically necessary), and nonmedical items for personal convenience such as telephone charges and radio or television rental (unless specifically authorized by the interdisciplinary team as part of the participant's plan of care).

(c) Cosmetic surgery, which does not include surgery that is required for improved functioning of a malformed part of the body resulting from an accidental injury or for reconstruction following mastectomy.

(d) Experimental medical, surgical, or other health procedures.

(e) Services furnished outside of the United States, except as follows:

(1) In accordance with §424.122 and §424.124 of this chapter.

(2) As permitted under the State's approved Medicaid plan.

[64 FR 66279, Nov. 24, 1999, as amended at 71 FR 71335, Dec. 8, 2006]

§460.98 Service delivery.

(a) *Plan.* A PACE organization must establish and implement a written plan to furnish care that meets the needs of each participant in all care settings 24 hours a day, every day of the year.

(b) *Provision of services.* (1) The PACE organization must furnish comprehensive medical, health, and social services that integrate acute and long-term care.

(2) These services must be furnished in at least the PACE center, the home, and inpatient facilities.

(3) The PACE organization may not discriminate against any participant in the delivery of required PACE services based on race, ethnicity, national origin, religion, sex, age, sexual orientation, mental or physical disability, or source of payment.

(c) *Minimum services furnished at each PACE center.* At a minimum, the following services must be furnished at each PACE center:

(1) Primary care, including services furnished by a primary care provider as defined in §460.102(c) and nursing services.

(2) Social services.

Deleted: Primary care, including physician and nursing services.

(3) Restorative therapies, including physical therapy and occupational therapy.

(4) Personal care and supportive services.

(5) Nutritional counseling.

(6) Recreational therapy.

(7) Meals.

(d) PACE center operation. (1) A PACE organization must operate at least one PACE center either in, or contiguous to, its defined service area with sufficient capacity to allow routine attendance by participants.

Deleted: Pace C

(2) A PACE organization must ensure accessible and adequate services to meet the needs of its participants. If necessary, a PACE organization must increase the number of PACE centers, staff, or other PACE services.

(3) If a PACE organization operates more than one center, each PACE center must offer the full range of services and have sufficient staff to meet the needs of participants.

Deleted: Pace

(e) *Center attendance.* The frequency of a participant's attendance at a center is determined by the interdisciplinary team, based on the needs and preferences of each participant.

[64 FR 66279, Nov. 24, 1999, as amended at 71 FR 71334, 71335, Dec. 8, 2006]

§460.100 Emergency care.

(a) *Written plan.* A PACE organization must establish and maintain a written plan to handle emergency care. The plan must ensure that CMS, the State, and PACE participants are held harmless if the PACE organization does not pay for emergency services.

(b) *Emergency care.* Emergency care is appropriate when services are needed immediately because of an injury or sudden illness and the time required to reach the PACE organization or one of its contract providers, would cause risk of permanent damage to the participant's health. Emergency services include inpatient and outpatient services that meet the following requirements:

(1) Are furnished by a qualified emergency services provider, other than the PACE organization or one of its contract providers, either in or out of the PACE organization's service area.

(2) Are needed to evaluate or stabilize an emergency medical condition.

(c) An emergency medical condition means a condition manifesting itself by acute symptoms of sufficient severity (including severe pain) such that a prudent layperson, with an average knowledge of health and medicine, could reasonably expect the absence of immediate medical attention to result in the following:

(1) Serious jeopardy to the health of the participant.

(2) Serious impairment to bodily functions.

(3) Serious dysfunction of any bodily organ or part.

(d) *Explanation to participant.* The organization must ensure that the participant or caregiver, or both, understand when and how to get access to emergency services and that no prior authorization is needed.

(e) *On-call providers.* The plan must provide for the following:

(1) An on-call provider, available 24-hours per day to address participant questions about emergency services and respond to requests for authorization of urgently needed out-of-network services and post stabilization care services following emergency services.

(2) Coverage of urgently needed out-of-network and post-stabilization care services when either of the following conditions are met:

(i) The services are preapproved by the PACE organization.

(ii) The services are not preapproved by the PACE organization because the PACE organization did not respond to a request for approval within 1 hour after being contacted or cannot be contacted for approval.

(3) *Definitions.* As used in this section, the following definitions apply:

(i) Post stabilization care means services provided subsequent to an emergency that a treating physician views as medically necessary after an emergency medical condition has been stabilized. They are not emergency services, which PACE organizations are obligated to cover. Rather, they are non-emergency services that the PACE organization should approve before they are provided outside the service area.

Deleted: POs

Deleted: PO

(ii) Urgent care means the care provided to a PACE participant who is out of the PACE service area, and who believes their illness or injury is too severe to postpone treatment until they return to the service area, but their life or function is not in severe jeopardy.

[64 FR 66279, Nov. 24, 1999, as amended at 71 FR 71335, Dec. 8, 2006]

§460.102 Interdisciplinary team.

(a) *Basic requirement.* A PACE organization must meet the following requirements:

(1) Establish an interdisciplinary team composed of members that fill the roles described in paragraph (b) of this section, at each PACE center to comprehensively assess and meet the individual needs of each participant.

Deleted:

Deleted: Pace

(2) Assign each participant to an interdisciplinary team functioning at the PACE center that the participant attends.

(b) ,

Composition of interdisciplinary team. The interdisciplinary team must be composed of members qualified to fill, at minimum, the following roles, in accordance with CMS guidelines. One individual may fill two separate roles on the interdisciplinary team where the individual

Deleted: Composition of interdisciplinary team. The interdisciplinary team must be composed of at least the following members:

meets applicable state licensure requirements and is qualified to fill the two roles and able to provide appropriate care to meet the needs of participants.

- (1) Primary care provider.
- (2) Registered nurse.
- (3) Master's-level social worker.
- (4) Physical therapist.
- (5) Occupational therapist.
- (6) Recreational therapist or activity coordinator.
- (7) Dietitian.
- (8) PACE center manager.
- (9) Home care coordinator.
- (10) Personal care attendant or his or her representative.
- (11) Driver or his or her representative.

Deleted: physician

(c) Primary care provider. (1) Primary medical care must be furnished to a participant by any of the following:

- (i) A primary care physician.
- (ii) A community-based physician.
- (iii) A physician assistant who is licensed in the State and practices within his or her scope of practice as defined by State laws with regard to oversight, practice authority and prescriptive authority.
- (iv) A nurse practitioner who is licensed in the State and practices within his or her scope of practice as defined by State laws with regard to oversight, practice authority and prescriptive authority.

Deleted: (c) Primary care physician

Deleted: (1)

Deleted: Primary medical care must be furnished to a participant by a PACE primary care physician.

- (2) Each primary care provider is responsible for the following:

- (i) Managing a participant's medical situations.
- (ii) Overseeing a participant's use of medical specialists and inpatient care.

(d) *Responsibilities of interdisciplinary team.* (1) The interdisciplinary team is responsible for the initial assessment, periodic reassessments, plan of care, and coordination of 24 hour care delivery.

- (2) Each team member is responsible for the following:

Deleted: physician

(i) Regularly informing the interdisciplinary team of the medical, functional, and psychosocial condition of each participant.

(ii) Remaining alert to pertinent input from other team members, participants, and caregivers.

(iii) Documenting changes of a participant's condition in the participant's medical record consistent with documentation policies established by the medical director.

(e) Team member qualifications. The PACE organization must ensure that all members of the interdisciplinary team have appropriate licenses or certifications under State law, act within the scope of practice as defined by State laws, and meet the requirements set forth in §460.71.

Deleted: (3) The members of the interdisciplinary team must serve primarily PACE participants.

(f) Exchange of information between team members. The PACE organization must establish, implement, and maintain documented internal procedures governing the exchange of information between team members, contractors, and participants and their caregivers consistent with the requirements for confidentiality in §460.200(e).

Deleted: (e)

[64 FR 66279, Nov. 24, 1999, as amended at 67 FR 61506, Oct. 1, 2002; 71 FR 71334, 71336, Dec. 8, 2006]

§460.104 Participant assessment.

(a) ~~Initial comprehensive assessment—~~

(1) Basic requirement. The interdisciplinary team must conduct an initial in-person comprehensive assessment on each participant. The assessment must be completed in a timely manner in order to meet the requirements in paragraph (b) of this section.

Deleted: (1) *Basic requirement.* The interdisciplinary team must conduct an initial comprehensive assessment on each participant. The assessment must be completed promptly following enrollment.

(2) Members present. As part of the initial comprehensive assessment, each of the following members of the interdisciplinary team must evaluate the participant in person and develop a discipline-specific assessment of the participant's health and social status:

Deleted: (2) As part of the initial comprehensive assessment, each of the following members of the interdisciplinary team must evaluate the participant in person, at appropriate intervals, and develop a discipline-specific assessment of the participant's health and social status:

(i) Primary care ~~provider.~~

Deleted: physician

(ii) Registered nurse.

(iii) Master's-level social worker.

(iv) Physical therapist.

(v) Occupational therapist.

(vi) Recreational therapist or activity coordinator.

(vii) Dietitian.

(viii) Home care coordinator.

(3) Additional professional disciplines. At the recommendation of the interdisciplinary team, other professional disciplines (for example, speech-language pathology, dentistry, or audiology) may be included in the initial comprehensive assessment process.

Deleted: (3)

Deleted: At the recommendation of individual team members, other professional disciplines (for example, speech-language pathology, dentistry, or audiology) may be included in the comprehensive assessment process.

(4) Initial comprehensive assessment criteria. The initial in-person comprehensive assessment must at a minimum include the evaluation of:

Deleted: (4)

Deleted: *Comprehensive assessment criteria.* The comprehensive assessment must include, but is not limited to, the following:

- (i) Physical and cognitive function and ability.
- (ii) Medication use.
- (iii) Participant and caregiver preferences for care.
- (iv) Socialization and availability of family support.
- (v) Current health status and treatment needs.
- (vi) Nutritional status.
- (vii) Home environment, including home access and egress.
- (viii) Participant behavior.
- (ix) Psychosocial status.
- (x) Medical and dental status.
- (xi) Participant language.

(b) Development of plan of care. Within 30 days of the date of enrollment, the interdisciplinary team must consolidate discipline-specific assessments into a single plan of care for each participant through team discussions and consensus of the entire interdisciplinary team. In developing the plan of care:

Deleted: (b)

Deleted: *Development of plan of care.* The interdisciplinary team must promptly consolidate discipline-specific assessments into a single plan of care for each participant through discussion in team meetings and consensus of the entire interdisciplinary team. In developing the plan of care, female participants must be informed that they are entitled to choose a qualified specialist for women's health services from the PACE organization's network to furnish routine or preventive women's health services

(1) If the interdisciplinary team determines that certain services are not necessary to the care of a participant, the reasoning behind this determination must be documented in the plan of care.

(2) Female participants must be informed that they are entitled to choose a qualified specialist for women's health services from the PACE organization's network to furnish routine or preventive women's health services.

(c) Semi-annual reassessment. On at least a semi-annual basis, or more often if a participant's condition dictates, the following members of the interdisciplinary team must conduct an in-person reassessment:

Deleted: (c)

Deleted: *Periodic reassessment—(1) Semiannual reassessment.* On at least a semiannual basis, or more often if a participant's condition dictates, the following members of the interdisciplinary team must conduct an in-person reassessment:

- (1) Primary care provider.

Deleted: (i)

Deleted: physician

~~(2)~~ Registered nurse.

Deleted: (ii)

~~(3)~~ Master's-level social worker.

Deleted: (iii)

~~(4)~~ Other team members that the primary care provider, registered nurse and Master's level social worker determine are actively involved in the development or implementation of the participant's plan of care.

Deleted: (iv)

Deleted: Recreational therapist or activity coordinator.

~~(d)~~ *Unscheduled reassessments.* In addition to semiannual reassessments, unscheduled reassessments may be required based on the following:

Deleted: (v) Other team members actively involved in the development or implementation of the participant's plan of care, for example, home care coordinator, physical therapist, occupational therapist, or dietitian.¶
(2) Annual reassessment. On at least an annual basis, the following members of the interdisciplinary team must conduct an in-person reassessment:¶
 (i) Physical therapist.¶
 (ii) Occupational therapist.¶
 (iii) Dietitian.¶
 (iv) Home care coordinator.¶

~~(1)~~ *A change in participant status.* If the health or psychosocial status of a participant changes, the members of the interdisciplinary team listed in paragraph (c) of this section must conduct an in-person reassessment.

Deleted: annual and

Deleted: (1)

~~(2)~~ *At the request of the participant or designated representative.* If a participant (or his or her designated representative) believes that the participant needs to initiate, eliminate, or continue a particular service, the appropriate members of the interdisciplinary team, as identified by the interdisciplinary team, must conduct a reassessment. The interdisciplinary team member(s) may conduct the reassessment via remote technology when the interdisciplinary team determines that the use of remote technology is appropriate and the service request will likely be deemed necessary to improve or maintain the participant's overall health status and the participant or his or her designated representative agrees to the use of remote technology.

Deleted: *A change in participant status.* If the health or psychosocial status of a participant changes, the members of the interdisciplinary team, listed in paragraph (a)(2) of this section, must conduct an in-person reassessment.

~~(i)~~ *An in-person reassessment must be conducted:*

~~(A)~~ When participant or his or her designated representative declines the use of remote technology.

Deleted: (2) *At the request of the participant or designated representative.* If a participant (or his or her designated representative) believes that the participant needs to initiate, eliminate, or continue a particular service, the appropriate members of the interdisciplinary team, as identified by the interdisciplinary team, must conduct an in-person reassessment.

~~(B)~~ Before a PACE organization can deny a service request.

~~(ii)~~ The PACE organization must have explicit procedures for timely resolution of requests by a participant or his or her designated representative to initiate, eliminate, or continue a particular service.

Deleted: (i)

~~(iii)~~ Except as provided in paragraph ~~(d)(2)(iii)~~ of this section, the interdisciplinary team must notify the participant or designated representative of its decision to approve or deny the request from the participant or designated representative as expeditiously as the participant's condition requires, but no later than 72 hours after the date the interdisciplinary team receives the request for reassessment.

Commented [A1]: This cross-reference should have been changed to (d)(2)(iv).

Deleted: (ii)

~~(iv)~~ The interdisciplinary team may extend the 72-hour timeframe for notifying the participant or designated representative of its decision to approve or deny the request by no more than 5 additional days for either of the following reasons:

Deleted: (iii)

(A) The participant or designated representative requests the extension.

(B) The team documents its need for additional information and how the delay is in the interest of the participant.

(v) The PACE organization must explain any denial of a request to the participant or the participant's designated representative orally and in writing. The PACE organization must provide the specific reasons for the denial in understandable language. The PACE organization is responsible for the following:

Deleted: (iv)

(A) Informing the participant or designated representative of his or her right to appeal the decision as specified in §460.122.

(B) Describing both the standard and expedited appeals processes, including the right to, and conditions for, obtaining expedited consideration of an appeal of a denial of services as specified in §460.122.

(C) Describing the right to, and conditions for, continuation of appealed services through the period of an appeal as specified in §460.122(e).

(vi) If the interdisciplinary team fails to provide the participant with timely notice of the resolution of the request or does not furnish the services required by the revised plan of care, this failure constitutes an adverse decision, and the participant's request must be automatically processed by the PACE organization as an appeal in accordance with §460.122.

Deleted: (v)

(e) *Changes to plan of care.* Team members who conduct a reassessment must meet the following requirements:

(1) Reevaluate the participant's plan of care.

(2) Discuss any changes in the plan with the interdisciplinary team.

(3) Obtain approval of the revised plan from the interdisciplinary team and the participant (or designated representative).

(4) Furnish any services included in the revised plan of care as a result of a reassessment to the participant as expeditiously as the participant's health condition requires.

(f) *Documentation.* Interdisciplinary team members must document all assessment and reassessment information in the participant's medical record.

[64 FR 66279, Nov. 24, 1999, as amended at 71 FR 71336, Dec. 8, 2006]

§460.106 Plan of care.

(a) *Basic requirement.* Within 30 days of the date of enrollment, the interdisciplinary team members specified in §460.104(a)(2) must develop a comprehensive plan of care for each participant based on the initial comprehensive assessment findings.

Deleted: The interdisciplinary team must promptly develop a comprehensive plan of care for each participant.

(b) *Content of plan of care.* The plan of care must meet the following requirements:

(1) Specify the care needed to meet the participant's medical, physical, emotional, and social needs, as identified in the initial comprehensive assessment.

(2) Identify measurable outcomes to be achieved.

(3) Utilize the most appropriate interventions for each care need that advances the participant toward a measurable goal and outcome.

(4) Identify each intervention and how it will be implemented.

(5) Identify how each intervention will be evaluated to determine progress in reaching specified goals and desired outcomes.

(c) *Implementation of the plan of care.* (1) The team must implement, coordinate, and monitor the plan of care whether the services are furnished by PACE employees or contractors.

(2) The team must continuously monitor the participant's health and psychosocial status, as well as the effectiveness of the plan of care, through the provision of services, informal observation, input from participants or caregivers, and communications among members of the interdisciplinary team and other providers.

(d) *Evaluation of plan of care.* On at least a semi-annual basis, the interdisciplinary team must reevaluate the plan of care, including defined outcomes, and make changes as necessary.

(e) *Participant and caregiver involvement in plan of care.* The team must develop, review, and reevaluate the plan of care in collaboration with the participant or caregiver, or both, to ensure that there is agreement with the plan of care and that the participant's concerns are addressed.

(f) *Documentation.* The team must document the plan of care, and any changes made to it, in the participant's medical record.

Subpart G—Participant Rights

§460.110 Bill of rights.

(a) *Written bill of rights.* A PACE organization must have a written participant bill of rights designed to protect and promote the rights of each participant. Those rights include, at a minimum, the ones specified in §460.112.

(b) *Explanation of rights.* The organization must inform a participant upon enrollment, in writing, of his or her rights and responsibilities, and all rules and regulations governing participation.

(c) *Protection of rights.* The organization must protect and provide for the exercise of the participant's rights.

§460.112 Specific rights to which a participant is entitled.

(a) *Respect and nondiscrimination.* Each participant has the right to considerate, respectful care from all PACE employees and contractors at all times and under all circumstances. Each participant has the right not to be discriminated against in the delivery of required PACE services based on race, ethnicity, national origin, religion, sex, age, sexual orientation, mental or physical disability, or source of payment. Specifically, each participant has the right to the following:

(1) To receive comprehensive health care in a safe and clean environment and in an accessible manner.

(2) To be treated with dignity and respect, be afforded privacy and confidentiality in all aspects of care, and be provided humane care.

(3) Not to be required to perform services for the PACE organization.

(4) To have reasonable access to a telephone.

(5) To be free from harm, including physical or mental abuse, neglect, corporal punishment, involuntary seclusion, excessive medication, and any physical or chemical restraint imposed for purposes of discipline or convenience and not required to treat the participant's medical symptoms.

(6) To be encouraged and assisted to exercise rights as a participant, including the Medicare and Medicaid appeals processes as well as civil and other legal rights.

(7) To be encouraged and assisted to recommend changes in policies and services to PACE staff.

(b) *Information disclosure.* Each PACE participant has the right to receive accurate, easily understood information and to receive assistance in making informed health care decisions. Specifically, each participant has the following rights:

(1) To be fully informed in writing of the services available from the PACE organization, including identification of all services that are delivered through contracts, rather than furnished directly by the PACE organization at the following times:

(i) Prior to and upon enrollment in the PACE organization.

Deleted: Before enrollment.

(ii) At the time a participant's needs necessitate the disclosure and delivery of such information in order to allow the participant to make an informed choice.

Deleted: (ii) At enrollment.¶
(iii)

(2) To have the enrollment agreement, described in §460.154, fully explained in a manner understood by the participant.

(3) To examine, or upon reasonable request, to be helped to examine the results of the most recent review of the PACE organization conducted by CMS or the State administering agency and any plan of correction in effect.

Deleted: assisted

(c) *Choice of providers.* Each participant has the right to a choice of health care providers, within the PACE organization's network, that is sufficient to ensure access to appropriate high-quality health care. Specifically, each participant has the right to the following:

(1) To choose his or her primary care physician and specialists from within the PACE network.

(2) To request that a qualified specialist for women's health services furnish routine or preventive women's health services.

(3) To disenroll from the program at any time and have such disenrollment be effective the first day of the month following the date the PACE organization receives the participant's notice of voluntary disenrollment as set forth in §460.162(a).

Deleted: To disenroll from the program at any time.

(d) *Access to emergency services.* Each participant has the right to access emergency health care services when and where the need arises without prior authorization by the PACE interdisciplinary team.

(e) *Participation in treatment decisions.* Each participant has the right to participate fully in all decisions related to his or her treatment. A participant who is unable to participate fully in treatment decisions has the right to designate a representative. Specifically, each participant has the following rights:

(1) To have all treatment options explained in a culturally competent manner and to make health care decisions, including the right to refuse treatment, and be informed of the consequences of the decisions.

(2) To have the PACE organization explain advance directives and to establish them, if the participant so desires, in accordance with §§489.100 and 489.102 of this chapter.

(3) To be fully informed of his or her health and functional status by the interdisciplinary team.

(4) To participate in the development and implementation of the plan of care.

(5) To request a reassessment by the interdisciplinary team.

(6) To be given reasonable advance notice, in writing, of any transfer to another treatment setting and the justification for the transfer (that is, due to medical reasons or for the participant's welfare, or that of other participants). The PACE organization must document the justification in the participant's medical record.

(f) *Confidentiality of health information.* Each participant has the right to communicate with health care providers in confidence and to have the confidentiality of his or her individually identifiable health care information protected. Each participant also has the right to review and copy his or her own medical records and request amendments to those records. Specifically, each participant has the following rights:

(1) To be assured of confidential treatment of all information contained in the health record, including information contained in an automated data bank.

(2) To be assured that his or her written consent will be obtained for the release of information to persons not otherwise authorized under law to receive it.

(3) To provide written consent that limits the degree of information and the persons to whom information may be given.

(g) *Complaints and appeals.* Each participant has the right to a fair and efficient process for resolving differences with the PACE organization, including a rigorous system for internal review by the organization and an independent system of external review. Specifically, each participant has the following rights:

(1) To be encouraged and assisted to voice complaints to PACE staff and outside representatives of his or her choice, free of any restraint, interference, coercion, discrimination, or reprisal by the PACE staff.

(2) To appeal any treatment decision of the PACE organization, its employees, or contractors through the process described in §460.122.

[64 FR 66279, Nov. 24, 1999, as amended at 71 FR 71336, Dec. 8, 2006]

§460.114 Restraints.

(a) The PACE organization must limit use of restraints to the least restrictive and most effective method available. The term restraint includes either a physical restraint or a chemical restraint.

(1) A physical restraint is any manual method or physical or mechanical device, materials, or equipment attached or adjacent to the participant's body that he or she cannot easily remove that restricts freedom of movement or normal access to one's body.

(2) A chemical restraint is a medication used to control behavior or to restrict the participant's freedom of movement and is not a standard treatment for the participant's medical or psychiatric condition.

(b) If the interdisciplinary team determines that a restraint is needed to ensure the participant's physical safety or the safety of others, the use must meet the following conditions:

(1) Be imposed for a defined, limited period of time, based upon the assessed needs of the participant.

(2) Be imposed in accordance with safe and appropriate restraining techniques.

(3) Be imposed only when other less restrictive measures have been found to be ineffective to protect the participant or others from harm.

(4) Be removed or ended at the earliest possible time.

(c) The condition of the restrained participant must be continually assessed, monitored, and reevaluated.

§460.116 Explanation of rights.

(a) *Written policies.* A PACE organization must have written policies and implement procedures to ensure that the participant, his or her representative, if any, and staff understand these rights.

(b) *Explanation of rights.* The PACE organization must fully explain the rights to the participant and his or her representative, if any, at the time of enrollment in a manner understood by the participant.

(c) *Display.* The PACE organization must meet the following requirements:

(1) ~~Write the participant rights in English, and in any other principal languages of the community, as determined by the State in which the PACE organization is located. In the absence of a State standard, a principal language of the community is any language that is spoken by at least 5 percent of the individuals in the PACE organization's service area.~~**Deleted:** Write the participant rights in English and in any other principal languages of the community.

Write the participant rights in English, and in any other principal languages of the community, as determined by the State in which the PACE organization is located. In the absence of a State standard, a principal language of the community is any language that is spoken by at least 5 percent of the individuals in the PACE organization's service area.

(2) Display the PACE participant rights in a prominent place in the PACE center.

§460.118 Violation of rights.

The PACE organization must have established documented procedures to respond to and rectify a violation of a participant's rights.

§460.120 Grievance process.

For purposes of this part, a grievance is a complaint, either written or oral, expressing dissatisfaction with service delivery or the quality of care furnished.

(a) *Process to resolve grievances.* A PACE organization must have a formal written process to evaluate and resolve medical and nonmedical grievances by participants, their family members, or representatives.

(b) *Notification to participants.* Upon enrollment, and at least annually thereafter, the PACE organization must give a participant written information on the grievance process.

(c) *Minimum requirements.* At a minimum, the PACE organization's grievance process must include written procedures for the following:

- (1) How a participant files a grievance.
- (2) Documentation of a participant's grievance.
- (3) Response to, and resolution of, grievances in a timely manner.
- (4) Maintenance of confidentiality of a participant's grievance.

(d) *Continuing care during grievance process.* The PACE organization must continue to furnish all required services to the participant during the grievance process.

(e) *Explaining the grievance process.* The PACE organization must discuss with and provide to the participant in writing the specific steps, including timeframes for response, that will be taken to resolve the participant's grievance.

(f) *Analyzing grievance information.* The PACE organization must maintain, aggregate, and analyze information on grievance proceedings. This information must be used in the PACE organization's internal quality improvement program.

Deleted: quality assessment and performance improvement

§460.122 PACE organization's appeals process.

For purposes of this section, an appeal is a participant's action taken with respect to the PACE organization's noncoverage of, or nonpayment for, a service including denials, reductions, or termination of services.

(a) *PACE organization's written appeals process.* The PACE organization must have a formal written appeals process, with specified timeframes for response, to address noncoverage or nonpayment of a service.

(b) *Notification of participants.* Upon enrollment, at least annually thereafter, and whenever the interdisciplinary team denies a request for services or payment, the PACE organization must give a participant written information on the appeals process.

(c) *Minimum requirements.* At a minimum, the PACE organization's appeals process must include written procedures for the following:

(1) Timely preparation and processing of a written denial of coverage or payment as provided in ~~§460.104(d)(2)(iv)~~.

Deleted: §460.104(c)(3)

(2) How a participant files an appeal.

(3) Documentation of a participant's appeal.

(4) Appointment of an appropriately credentialed and impartial third party who was not involved in the original action and who does not have a stake in the outcome of the appeal to review the participant's appeal.

(5) Responses to, and resolution of, appeals as expeditiously as the participant's health condition requires, but no later than 30 calendar days after the organization receives an appeal.

(6) Maintenance of confidentiality of appeals.

(d) *Notification.* A PACE organization must give all parties involved in the appeal the following:

(1) Appropriate written notification.

(2) A reasonable opportunity to present evidence related to the dispute, in person, as well as in writing.

(e) *Services furnished during appeals process.* During the appeals process, the PACE organization must meet the following requirements:

(1) For a Medicaid participant, continue to furnish the disputed services until issuance of the final determination if the following conditions are met:

(i) The PACE organization is proposing to terminate or reduce services currently being furnished to the participant.

(ii) The participant requests continuation with the understanding that he or she may be liable for the costs of the contested services if the determination is not made in his or her favor.

(2) Continue to furnish to the participant all other required services, as specified in subpart F of this part.

(f) *Expedited appeals process.* (1) A PACE organization must have an expedited appeals process for situations in which the participant believes that his or her life, health, or ability to regain or maintain maximum function could be seriously jeopardized, absent provision of the service in dispute.

(2) Except as provided in paragraph (f)(3) of this section, the PACE organization must respond to the appeal as expeditiously as the participant's health condition requires, but no later than 72 hours after it receives the appeal.

(3) The PACE organization may extend the 72-hour timeframe by up to 14 calendar days for either of the following reasons:

(i) The participant requests the extension.

(ii) The organization justifies to the State administering agency the need for additional information and how the delay is in the interest of the participant.

(g) Determination in favor of participant. A PACE organization must furnish the disputed service as expeditiously as the participant's health condition requires if a determination is made in favor of the participant on appeal.

(h) Determination adverse to participant. For a determination that is wholly or partially adverse to a participant, at the same time the decision is made, the PACE organization must notify the following:

(1) CMS.

(2) The State administering agency.

(3) The participant.

(i) *Analyzing appeals information.* A PACE organization must maintain, aggregate, and analyze information on appeal proceedings and use this information in the organization's internal quality improvement program.

Deleted: assessment and performance

[64 FR 66279, Nov. 24, 1999, as amended at 71 FR 71336, Dec. 8, 2006]

§460.124 Additional appeal rights under Medicare or Medicaid.

A PACE organization must inform a participant in writing of his or her appeal rights under Medicare or Medicaid managed care, or both, assist the participant in choosing which to pursue if both are applicable, and forward the appeal to the appropriate external entity.

Subpart H—Quality Improvement

Deleted: Assessment and Performance

§460.130 General rule.

(a) A PACE organization must develop, implement, maintain, and evaluate an effective, data-driven quality improvement program.

Deleted: assessment and performance

(b) The program must reflect the full range of services furnished by the PACE organization.

(c) A PACE organization must take actions that result in improvements in its performance in all types of care.

(d) A PACE organization must meet external quality assessment and reporting requirements, as specified by CMS or the State administering agency, in accordance with §460.202.

§460.132 Quality improvement plan.

Deleted: assessment and performance

(a) *Basic rule.*

Deleted: A PACE organization must have a written quality assessment and performance improvement plan.

A PACE organization must have a written quality improvement plan that is collaborative and interdisciplinary in nature.

(b) *Annual review.* The PACE governing body must review the plan annually and revise it, if necessary.

(c) *Minimum plan requirements.* At a minimum, the plan must specify how the PACE organization proposes to meet the following requirements:

(1) Identify areas to improve or maintain the delivery of services and patient care.

(2) Develop and implement plans of action to improve or maintain quality of care.

(3) Document and disseminate to PACE staff and contractors the results from the quality improvement activities.

Deleted: assessment and performance

§460.134 Minimum requirements for quality improvement program.

Deleted: assessment and performance

(a) *Minimum program requirements.* A PACE organization's quality improvement program must include, but is not limited to, the use of objective measures to demonstrate improved performance with regard to the following:

Deleted: assessment and performance

(1) Utilization of PACE services, such as decreased inpatient hospitalizations and emergency room visits.

(2) Caregiver and participant satisfaction.

(3) Outcome measures that are derived from data collected during assessments, including data on the following:

- (i) Physiological well being.
- (ii) Functional status.
- (iii) Cognitive ability.
- (iv) Social/behavioral functioning.
- (v) Quality of life of participants.
- (4) Effectiveness and safety of staff-provided and contracted services, including the following:
 - (i) Competency of clinical staff.
 - (ii) Promptness of service delivery.
 - (iii) Achievement of treatment goals and measurable outcomes.

(5) Nonclinical areas, such as grievances and appeals, transportation services, meals, life safety, and environmental issues.

(b) *Basis for outcome measures.* Outcome measures must be based on current clinical practice guidelines and professional practice standards applicable to the care of PACE participants.

(c) *Minimum levels of performance.* The PACE organization must meet or exceed minimum levels of performance, established by CMS and the State administering agency, on standardized quality measures, such as influenza immunization rates, which are specified in the PACE program agreement.

(d) *Accuracy of data.* The PACE organization must ensure that all data used for outcome monitoring are accurate and complete.

§460.136 Internal quality improvement activities.

(a) *Quality improvement requirements.* A PACE organization must do the following:

- (1) Use a set of outcome measures to identify areas of good or problematic performance.
- (2) Take actions targeted at maintaining or improving care based on outcome measures.

(3) Incorporate actions resulting in performance improvement into standards of practice for the delivery of care and periodically track performance to ensure that any performance improvements are sustained over time.

(4) Set priorities for performance improvement, considering prevalence and severity of identified problems, and give priority to improvement activities that affect clinical outcomes.

(5) Immediately correct any identified problem that directly or potentially threatens the health and safety of a PACE participant.

Deleted: assessment and performance

Deleted: assessment and performance

(b) *Quality improvement coordinator.* A PACE organization must designate an individual to coordinate and oversee implementation of quality improvement activities.

Deleted: assessment and performance

Deleted: assessment and performance

(c) *Involvement in quality improvement activities.* (1) A PACE organization must ensure that all interdisciplinary team members, PACE staff, and contract providers are involved in the development and implementation of quality improvement activities and are aware of the results of these activities.

Deleted: assessment and performance

Deleted: assessment and performance

(2) The quality improvement coordinator must encourage a PACE participant and his or her caregivers to be involved in quality improvement activities, including providing information about their satisfaction with services.

Deleted: assessment and performance

§460.138 Committees with community input.

A PACE organization must establish one or more committees, with community input, to do the following:

(a) Evaluate data collected pertaining to quality outcome measures.

(b) Address the implementation of, and results from, the quality improvement plan.

Deleted: assessment and performance

(c) Provide input related to ethical decisionmaking, including end-of-life issues and implementation of the Patient Self-Determination Act.

Subpart I—Participant Enrollment and Disenrollment

Deleted: §460.140 Additional quality assessment activities.¶

A PACE organization must meet external quality assessment and reporting requirements, as specified by CMS or the State administering agency, in accordance with §460.202.¶

§460.150 Eligibility to enroll in a PACE program.

(a) *General rule.* To enroll in a PACE program, an individual must meet eligibility requirements specified in this section. To continue to be eligible for PACE, an individual must meet the annual recertification requirements specified in §460.160.

(b) *Basic eligibility requirements.* To be eligible to enroll in PACE, an individual must meet the following requirements:

(1) Be 55 years of age or older.

(2) Be determined by the State administering agency to need the level of care required under the State Medicaid plan for coverage of nursing facility services, which indicates that the individual's health status is comparable to the health status of individuals who have participated in the PACE demonstration waiver programs.

(3) Reside in the service area of the PACE organization.

(4) Meet any additional program specific eligibility conditions imposed under the PACE program agreement. These additional conditions may not modify the requirements of paragraph (b)(1) through (b)(3) of this section.

(c) *Other eligibility requirements.* (1) At the time of enrollment, an individual must be able to live in a community setting without jeopardizing his or her health or safety.

(2) The State administering agency criteria used to determine if an individual's health or safety would be jeopardized by living in a community setting must be specified in the program agreement.

(d) *Eligibility under Medicare and Medicaid.* Eligibility to enroll in a PACE program is not restricted to an individual who is either a Medicare beneficiary or Medicaid beneficiary. A potential PACE enrollee may be, but is not required to be, any or all of the following:

- (1) Entitled to Medicare Part A.
- (2) Enrolled under Medicare Part B.
- (3) Eligible for Medicaid.

§460.152 Enrollment process.

(a) *Intake process.* Intake is an intensive process during which PACE staff members make one or more visits to a potential participant's place of residence and the potential participant makes one or more visits to the PACE center. At a minimum, the intake process must include the following activities:

(1) The PACE staff must explain to the potential participant and his or her representative or caregiver the following information:

(i) The PACE program, using a copy of the enrollment agreement described in §460.154, specifically references the elements of the agreement including but not limited to §460.154(e), (i) through (m), and (r).

(ii) The requirement that the PACE organization would be the participant's sole service provider and clarification that the PACE organization guarantees access to services, but not to a specific provider.

(iii) A list of the employees of the PACE organization who furnish care and the most current list of contracted health care providers under §460.70(c).

- (iv) Monthly premiums, if any.
- (v) Any Medicaid spenddown obligations.
- (vi) Post-eligibility treatment of income.

(2) The potential participant must sign a release to allow the PACE organization to obtain his or her medical and financial information and eligibility status for Medicare and Medicaid.

(3) The State administering agency must assess the potential participant, including any individual who is not eligible for Medicaid, to ensure that he or she needs the level of care required under the State Medicaid plan for coverage of nursing facility services, which indicates that the individual's health status is comparable to the health status of individuals who have participated in the PACE demonstration waiver programs.

(4) PACE staff must assess the potential participant to ensure that he or she can be cared for appropriately in a community setting and that he or she meets all requirements for PACE eligibility specified in this part.

(b) *Denial of Enrollment.* If a prospective participant is denied enrollment because his or her health or safety would be jeopardized by living in a community setting, the PACE organization must meet the following requirements:

- (1) Notify the individual in writing of the reason for the denial.
- (2) Refer the individual to alternative services, as appropriate.
- (3) Maintain supporting documentation of the reason for the denial.

(4) Notify CMS and the State administering agency in the form and manner specified by CMS and make the documentation available for review.

[64 FR 66279, Nov. 24, 1999, as amended at 71 FR 71337, Dec. 8, 2006]

§460.154 Enrollment agreement.

If the potential participant meets the eligibility requirements and wants to enroll, he or she must sign an enrollment agreement which contains, at a minimum, the following information:

- (a) Applicant's name, sex, and date of birth.
- (b) Medicare beneficiary status (Part A, Part B, or both) and number, if applicable.
- (c) Medicaid beneficiary status and number, if applicable.
- (d) Other health insurance information, if applicable.
- (e) Conditions for enrollment and disenrollment in PACE.
- (f) Description of participant premiums, if any, and procedures for payment of premiums.

(g) Notification that a Medicaid participant and a participant who is eligible for both Medicare and Medicaid are not liable for any premiums, but may be liable for any applicable spenddown liability under §§435.121 and 435.831 of this chapter and any amounts due under the post-eligibility treatment of income process under §460.184.

(h) Notification that a Medicare participant may not enroll or disenroll at a Social Security office.

(i) Notification that enrollment in PACE results in disenrollment from any other Medicare or Medicaid prepayment plan or optional benefit. Electing enrollment in any other Medicare or Medicaid prepayment plan or optional benefit, including the hospice benefit, after enrolling as a PACE participant is considered a voluntary disenrollment from PACE. If a Medicaid-only or private pay participant becomes eligible for Medicare after enrollment in PACE, the participant will be disenrolled from PACE if he or she elects to obtain Medicare coverage other than from the participant's PACE organization.

(j) Information on the consequences of subsequent enrollment in other optional Medicare or Medicaid programs following disenrollment from PACE.

(k) Description of PACE services available, including all Medicare and Medicaid covered services, and how services are obtained from the PACE organization.

(l) Description of the procedures for obtaining emergency and urgently needed out-of-network services.

(m) The participant bill of rights.

(n) Information on the process for grievances and appeals and Medicare/Medicaid phone numbers for use in appeals.

(o) Notification of a participant's obligation to inform the PACE organization of a move or lengthy absence from the organization's service area.

(p) An acknowledgment by the applicant or representative that he or she understands the requirement that the PACE organization must be the applicant's sole service provider.

(q) A statement that the PACE organization has an agreement with CMS and the State administering agency that is subject to renewal on a periodic basis and, if the agreement is not renewed, the program will be terminated.

(r) The applicant's authorization for disclosure and exchange of personal information between CMS, its agents, the State administering agency, and the PACE organization.

(s) The effective date of enrollment.

(t) The signature of the applicant or his or her designated representative and the date.

[64 FR 66279, Nov. 24, 1999, as amended at 71 FR 71337, Dec. 8, 2006]

§460.156 Other enrollment procedures.

(a) *Items a PACE organization must give a participant upon enrollment.* After the participant signs the enrollment agreement, the PACE organization must give the participant the following:

(1) A copy of the enrollment agreement.

(2) A PACE membership card that indicates that he or she is a PACE participant and that includes the phone number of the PACE organization.

Deleted: A PACE membership card.

(3) Emergency information to be posted in his or her home identifying the individual as a PACE participant and explaining how to access emergency services.

(b) *Submittal of participant information to CMS and the State.* The PACE organization must submit participant information to CMS and the State administering agency, in accordance with established procedures.

Deleted: (4) Stickers for the participant's Medicare and Medicaid cards, as applicable, which indicate that he or she is a PACE participant and include the phone number of the PACE organization.¶

(c) *Changes in enrollment agreement information.* If there are changes in the enrollment agreement information at any time during the participant's enrollment, the PACE organization must meet the following requirements:

- (1) Give an updated copy of the information to the participant.
- (2) Explain the changes to the participant and his or her representative or caregiver in a manner they understand.

§460.158 Effective date of enrollment.

A participant's enrollment in the program is effective on the first day of the calendar month following the date the PACE organization receives the signed enrollment agreement.

§460.160 Continuation of enrollment.

(a) *Duration of enrollment.* Enrollment continues until the participant's death, regardless of changes in health status, unless either of the following actions occur:

- (1) The participant voluntarily disenrolls.
- (2) The participant is involuntarily disenrolled, as described in §460.164.

(b) *Annual recertification requirement.* At least annually, the State administering agency must reevaluate whether a participant needs the level of care required under the State Medicaid plan for coverage of nursing facility services.

(1) *Waiver of annual requirement.* (i) The State administering agency may permanently waive the annual recertification requirement for a participant if it determines that there is no reasonable expectation of improvement or significant change in the participant's condition because of the severity of a chronic condition or the degree of impairment of functional capacity.

(ii) The PACE organization must retain in the participant's medical record the documentation of the reason for waiving the annual recertification requirement.

(2) *Deemed continued eligibility.* If the State administering agency determines that a PACE participant no longer meets the State Medicaid nursing facility level of care requirements, the participant may be deemed to continue to be eligible for the PACE program until the next annual reevaluation, if, in the absence of continued coverage under this program, the participant reasonably would be expected to meet the nursing facility level of care requirement within the next 6 months.

(3) *Continued eligibility criteria.* (i) The State administering agency, must establish criteria to use in making the determination of "deemed continued eligibility." The State administering agency, in consultation with the PACE organization, makes a determination of deemed continued eligibility based on a review of the participant's medical record and plan of care. These criteria must be applied in reviewing the participant's medical record and plan of care.

(ii) The criteria used to make the determination of continued eligibility must be specified in the program agreement.

§460.162 Voluntary disenrollment.

(a) Effective date. A participant's voluntary disenrollment is effective on the first day of the month following the date the PACE organization receives the participant's notice of voluntary disenrollment.

Deleted: A PACE participant may voluntarily disenroll from the program without cause at any time.

(b) Reasons for voluntary disenrollment. A PACE participant may voluntarily disenroll from the program without cause at any time.

(c) Responsibilities of PACE organization. A PACE organization must ensure that its employees or contractors do not engage in any practice that would reasonably be expected to have the effect of steering or encouraging disenrollment of participants due to a change in health status.

§460.164 Involuntary disenrollment.

(a) Effective date. A participant's involuntary disenrollment occurs after the PACE organization meets the requirements set forth in this section and is effective on the first day of the next month that begins 30 days after the day the PACE organization sends notice of the disenrollment to the participant.

(b) Reasons for involuntary disenrollment. A participant may be involuntarily disenrolled for any of the following reasons:

Deleted: (a)

(a) Reasons for involuntary disenrollment. A participant may be involuntarily disenrolled for any of the following reasons:

(1) The participant, after a 30-day grace period, fails to pay, or, make satisfactory arrangements to pay, any premium due the PACE organization.

Deleted: ,

Deleted: to

Deleted: ,

Deleted: after a 30-day grace period

(2) The participant, after a 30-day grace period, fails to pay or make satisfactory arrangements to pay any applicable Medicaid spenddown liability or any amount due under the post-eligibility treatment of income process, as permitted under §§460.182 and 460.184.

(3) The participant or the participant's caregiver engages in disruptive or threatening behavior, as described in paragraph (c) of this section.

(4) The participant engages in disruptive or threatening behavior, as described in paragraph (c) of this section.

Deleted: (2)

Deleted: (b)

(5) The participant moves out of the PACE program service area or is out of the service area for more than 30 consecutive days, unless the PACE organization agrees to a longer absence due to extenuating circumstances.

Deleted: (3)

(6) The participant is determined to no longer meet the State Medicaid nursing facility level of care requirements and is not deemed eligible.

Deleted: (4)

(7) The PACE program agreement with CMS and the State administering agency is not renewed or is terminated.

Deleted: (5)

(8) The PACE organization is unable to offer health care services due to the loss of State licenses or contracts with outside providers.

Deleted: (6)

(c) Disruptive or threatening behavior. (1) For purposes of this section, a participant who engages in disruptive or threatening behavior refers to a participant who exhibits either of the following:

Deleted: (b)

(i) A participant whose behavior jeopardizes his or her health or safety, or the safety of others; or

Deleted: (1)

(ii) A participant with decision-making capacity who consistently refuses to comply with his or her individual plan of care or the terms of the PACE enrollment agreement.

Deleted: (2)

(2) For purposes of this section, a participant's caregiver who engages in disruptive or threatening behavior exhibits behavior that jeopardizes the participant's health or safety, or the safety of the caregiver or others.

(d) Documentation of disruptive or threatening behavior. If a PACE organization proposes to disenroll a participant based on the disruptive or threatening behavior of the participant or the participant's caregiver, the organization must document the following information in the participant's medical record:

Deleted: (c)

Deleted: who is disruptive or threatening

(1) The reasons for proposing to disenroll the participant.

(2) All efforts to remedy the situation.

(e) Noncompliant behavior. (1) A PACE organization may not disenroll a PACE participant on the grounds that the participant has engaged in noncompliant behavior if the behavior is related to a mental or physical condition of the participant, unless the participant's behavior jeopardizes his or her health or safety, or the safety of others.

Deleted: (d)

(2) For purposes of this section, noncompliant behavior includes repeated noncompliance with medical advice and repeated failure to keep appointments.

(f) State administering agency review and final determination. Before an involuntary disenrollment is effective, the State administering agency must review it and determine in a timely manner that the PACE organization has adequately documented acceptable grounds for disenrollment.

Deleted: (e)

§460.166 Disenrollment responsibilities.

Deleted: Effective date of disenrollment.

(a) In disenrolling a participant, the PACE organization must take the following actions:

(1) Use the most expedient process allowed under Medicare and Medicaid procedures, as set forth in the PACE program agreement.

(2) Coordinate the disenrollment date between Medicare and Medicaid (for a participant who is eligible for both Medicare and Medicaid).

(3) Give reasonable advance notice to the participant.

(b) Until the date enrollment is terminated, the following requirements must be met:

(1) PACE participants must continue to use PACE organization services and remain liable for any premiums.

(2) The PACE organization must continue to furnish all needed services.

§460.168 Reinstatement in other Medicare and Medicaid programs.

To facilitate a participant's reinstatement in other Medicare and Medicaid programs after disenrollment, the PACE organization must do the following:

(a) Make appropriate referrals and ensure medical records are made available to new providers, within 30 days.

Deleted: in a timely manner

(b) Work with CMS and the State administering agency to reinstate the participant in other Medicare and Medicaid programs for which the participant is eligible.

§460.170 Reinstatement in PACE.

(a) A previously disenrolled participant may be reinstated in a PACE program.

(b) If the reason for disenrollment is failure to pay the premium and the participant pays the premium before the effective date of disenrollment, the participant is reinstated in the PACE program with no break in coverage.

§460.172 Documentation of disenrollment.

A PACE organization must meet the following requirements:

(a) Have a procedure in place to document the reasons for all voluntary and involuntary disenrollments.

(b) Make documentation available for review by CMS and the State administering agency.

(c) Use the information on voluntary disenrollments in the PACE organization's internal quality improvement program.

Deleted: assessment and performance

Subpart J—Payment

§460.180 Medicare payment to PACE organizations.

(a) *Principle of payment.* Under a PACE program agreement, CMS makes a prospective monthly payment to the PACE organization of a capitation amount for each Medicare participant in a payment area based on the rate it pays to a Medicare Advantage organization.

(b) *Determination of rate.* (1) The PACE program agreement specifies the methodology used to calculate the monthly capitation amount applicable to a PACE organization.

(2) Except as specified in paragraph (b)(4) of this section, the monthly capitation amount is based on the Part A and Part B payment rates established for purposes of payment to Medicare Advantage organizations. As used in this section, “Medicare Advantage rates” means the Part A and Part B rates calculated by CMS for making payment to Medicare Advantage organizations under section 1853(c) of the Act.

(3) CMS will adjust the monthly capitation payment amount derived under paragraph (b)(2) of this section based on a risk adjustment that reflects the individual's health status. CMS will ensure that payments take into account the comparative frailty of PACE enrollees relative to the general Medicare population.

(4) For Medicare participants who require ESRD services, the monthly capitation amount is based on the Medicare Advantage ESRD risk adjustment model.

(5) CMS may adjust the monthly capitation amount to take into account other factors CMS determines to be appropriate.

(6) The monthly capitation payment is a fixed amount, regardless of changes in the participant's health status.

(7) The monthly capitation payment amount is an all-inclusive payment for Medicare benefits provided to participants. A PACE organization must not seek any additional payment from Medicare. The only additional payment that a PACE organization may collect from, or on behalf of, a Medicare participant for PACE services is the following:

(i) Any applicable premium amount specified in §460.186.

(ii) Any charge permitted under paragraph (d) of this section when Medicare is not the primary payer.

(iii) Any payment from the State, as specified in §460.182, for a participant who is eligible for both Medicare and Medicaid.

(iv) Payment with respect to any applicable spenddown liability under §§435.121 and 435.831 of this chapter and any amount due under the post-eligibility treatment of income process under §460.184 for a participant who is eligible for both Medicare and Medicaid.

(8) CMS computes the Medicare monthly capitation payment amount under a PACE program agreement so that the total payment level for all participants is less than the projected payment under Medicare for a comparable population not enrolled under a PACE program.

(c) *Adjustments to payments.* If the actual number of Medicare participants differs from the estimated number of participants on which the amount of the prospective monthly payment was based, CMS adjusts subsequent monthly payments to account for the difference.

(d) *Application of Medicare secondary payer provisions—(1) Basic rule.* CMS does not pay for services to the extent that Medicare is not the primary payer under part 411 of this chapter.

(2) *Responsibilities of the PACE organization.* The PACE organization must do the following:

(i) Identify payers that are primary to Medicare under part 411 of this chapter.

(ii) Determine the amounts payable by those payers.

(iii) Coordinate benefits to Medicare participants with the benefits of the primary payers.

(3) *Charges to other entities.* The PACE organization may charge other individuals or entities for PACE services covered under Medicare for which Medicare is not the primary payer, as specified in paragraphs (d)(4) and (5) of this section.

(4) *Charge to other insurers or the participant.* If a Medicare participant receives from a PACE organization covered services that are also covered under State or Federal workers' compensation, any no-fault insurance, or any liability insurance policy or plan, including a self-insured plan, the PACE organization may charge any of the following:

(i) The insurance carrier, the employer, or any other entity that is liable for payment for the services under part 411 of this chapter.

(ii) The Medicare participant, to the extent that he or she has been paid by the carrier, employer, or other entity.

(5) *Charge to group health plan (GHP) or large group health plan (LGHP).* If Medicare is not the primary payer for services that a PACE organization furnished to a Medicare participant who is covered under a GHP or LGHP, the organization may charge the following:

(i) GHP or LGHP for those services.

(ii) Medicare participant to the extent that he or she has been paid by the GHP or LGHP for those services.

[64 FR 66279, Nov. 24, 1999, as amended at 71 FR 71337, Dec. 8, 2006]

§460.182 Medicaid payment.

(a) Under a PACE program agreement, the State administering agency makes a prospective monthly payment to the PACE organization of a capitation amount for each Medicaid participant.

(b) The monthly capitation amount is negotiated between the PACE organization and the State administering agency, and the amount, or the methodology used to calculate the amount, is specified in the PACE program agreement. The amount represents the following:

(1) Is less than the amount that would otherwise have been paid under the State plan if the participants were not enrolled under the PACE program.

(2) Takes into account the comparative frailty of PACE participants.

(3) Is a fixed amount regardless of changes in the participant's health status.

(4) Can be renegotiated on an annual basis.

Deleted: The monthly capitation payment amount is negotiated between the PACE organization and the State administering agency, and specified in the PACE program agreement. The amount represents the following:

(c) The PACE organization must accept the capitation payment amount as payment in full for Medicaid participants and may not bill, charge, collect, or receive any other form of payment from the State administering agency or from, or on behalf of, the participant, except as follows:

(1) Payment with respect to any applicable spenddown liability under §§435.121 and 435.831 of this chapter and any amounts due under the post-eligibility treatment of income process under §460.184.

(2) Medicare payment received from CMS or from other payers, in accordance with §460.180(d).

(d) State procedures for the enrollment and disenrollment of participants in the State's system, including procedures for any adjustment to account for the difference between the estimated number of participants on which the prospective monthly payment was based and the actual number of participants in that month, are included in the PACE program agreement.

§460.184 Post-eligibility treatment of income.

(a) A State may provide for post-eligibility treatment of income for Medicaid participants in the same manner as a State treats post-eligibility income for individuals receiving services under a waiver under section 1915(c) of the Act.

(b) Post-eligibility treatment of income is applied as it is under a waiver of section 1915(c) of the Act, as specified in §§435.726 and 435.735 of this chapter, and section 1924 of the Act.

§460.186 PACE premiums.

The amount that a PACE organization can charge a participant as a monthly premium depends on the participant's eligibility under Medicare and Medicaid, as follows:

(a) *Medicare Parts A and B.* For a participant who is entitled to Medicare Part A, enrolled under Medicare Part B, but not eligible for Medicaid, the premium equals the Medicaid capitation amount.

(b) *Medicare Part A only.* For a participant who is entitled to Medicare Part A, not enrolled under Medicare Part B, and not eligible for Medicaid, the premium equals the Medicaid capitation amount plus the Medicare Part B capitation rate.

(c) *Medicare Part B only.* For a participant who is enrolled only under Medicare Part B and not eligible for Medicaid, the premium equals the Medicaid capitation amount plus the Medicare Part A capitation rate.

(d) *Medicaid, with or without Medicare.* A PACE organization may not charge a premium to a participant who is eligible for both Medicare and Medicaid, or who is only eligible for Medicaid.

Subpart K—Federal/State Monitoring

§460.190 Monitoring during trial period.

(a) *Trial period review.* During the trial period, CMS, in cooperation with the State administering agency, conducts comprehensive annual reviews of the operations of a PACE organization to ensure compliance with the requirements of this part.

(b) *Scope of review.* The review includes the following:

(1) An onsite visit to the PACE organization, which may include, but is not limited to, observation of program operations.

Commented [A2]: Unclear why this is not a period.

(2) Detailed analysis of the entity's substantial compliance with all significant requirements of sections 1894 and 1934 of the Act and this part, which may include review of marketing, participant services, enrollment and disenrollment, and grievances and appeals.

Deleted: the following:

Deleted: (i) Review of participants' charts.¶
(ii) Interviews with staff.¶
(iii) Interviews with participants and caregivers.¶
(iv) Interviews with contractors.¶
(v) Observation of program operations, including marketing, participant services, enrollment and disenrollment procedures, grievances, and appeals.¶

(3) A comprehensive assessment of an organization's fiscal soundness.

(4) A comprehensive assessment of the organization's capacity to furnish all PACE services to all participants.

Deleted: (2)

Deleted: (3)

(5) Any other elements that CMS or the State administering agency find necessary.

Deleted: (4)

§460.192 Ongoing monitoring after trial period.

(a) At the conclusion of the trial period, CMS, in cooperation with the State administering agency, continues to conduct reviews of a PACE organization, as appropriate, taking into account the quality of care furnished and the organization's compliance with all of the requirements of this part.

(b) CMS in cooperation with the State administering agency will conduct reviews of the operations of PACE organizations as appropriate, as determined by a risk assessment of each PACE organization which takes into account the PACE organization's performance level and compliance with the significant requirements of sections 1834 and 1934 of the Social Security Act and this part.

Deleted: Reviews include an on-site visit at least every 2 years.

§460.194 Corrective action.

(a) A PACE organization must take action to correct deficiencies identified by CMS or the State administering agency through the following:

Deleted: (a) A PACE organization must take action to correct deficiencies identified during reviews.

(1) Ongoing monitoring of the PACE organization.

(2) Reviews and audits of the PACE organization.

(3) Complaints from PACE participants or caregivers.

(4) Any other instance CMS or the State administering agency identifies programmatic deficiencies requiring correction.(b) CMS or the State administering agency monitors the effectiveness of corrective actions.

Deleted: ¶

(c) Failure to correct deficiencies may result in sanctions or termination, as specified in subpart D of this part.

§460.196 Disclosure of review results.

(a) CMS and the State administering agency promptly report the results of reviews under §§460.190 and 460.192 to the PACE organization, along with any recommendations for changes to the organization's program.

(b) CMS and the State administering agency make the results of reviews available to the public upon request.

(c) The PACE organization must post a notice of the availability of the results of the most recent review and any plans of correction or responses related to the most recent review.

(d) The PACE organization must make the review results available for examination in a place readily accessible to participants, their families, their caregivers, and their authorized representatives.

Subpart L—Data Collection, Record Maintenance, and Reporting**§460.200 Maintenance of records and reporting of data.**

(a) *General rule.* A PACE organization must collect data, maintain records, and submit reports as required by CMS and the State administering agency.

(b) *Access to data and records.* A PACE organization must allow CMS and the State administering agency access to data and records including, but not limited to, the following:

- (1) Participant health outcomes data.
- (2) Financial books and records.
- (3) Medical records.
- (4) Personnel records.

(c) *Reporting.* A PACE organization must submit to CMS and the State administering agency all reports that CMS and the State administering agency require to monitor the operation, cost, quality, and effectiveness of the program and establish payment rates.

(d) *Safeguarding data and records.* A PACE organization must establish written policies and implement procedures to safeguard all data, books, and records against loss, destruction, unauthorized use, or inappropriate alteration.

(e) *Confidentiality of health information.* A PACE organization must establish written policies and implement procedures to do the following:

(1) Safeguard the privacy of any information that identifies a particular participant. Information from, or copies of, records may be released only to authorized individuals. Original medical records are released only in accordance with Federal or State laws, court orders, or subpoenas.

- (2) Maintain complete records and relevant information in an accurate and timely manner.

(3) Grant each participant timely access, upon request, to review and copy his or her own medical records and to request amendments to those records.

(4) Abide by all Federal and State laws regarding confidentiality and disclosure for mental health records, medical records, and other participant health information.

(f) *Retention of records.* (1) A PACE organization must retain records for the longest of the following periods:

(i) The period of time specified in State law.

(ii) ~~6~~ Ten years from the last entry date.

Deleted: Six

(iii) For medical records of disenrolled participants, ~~6~~ 10 years after the date of disenrollment.

Deleted: 6

(2) If litigation, a claim, a financial management review, or an audit arising from the operation of the PACE program is started before the expiration of the retention period, specified in paragraph (f)(1) of this section, the PACE organization must retain the records until the completion of the litigation, or resolution of the claims or audit findings.

Conforming Change Made to Part D Requirements in 42 CFR Part 423

§423.4 Definitions.

The following definitions apply to this part, unless the context indicates otherwise:

Actuarial equivalence means a state of equivalent value demonstrated through the use of generally accepted actuarial principles and in accordance with section 1860D-11(c) of the Act and with CMS actuarial guidelines.

Brand name drug means a drug for which an application is approved under section 505(c) of the Federal Food, Drug, and Cosmetic Act (21 USC 355(c)), including an application referred to in section 505(b)(2) of the Federal Food, Drug and Cosmetic Act (21 USC 355(b)(2)).

Cost plan means a plan operated by a Health Maintenance Organization (HMO) or Competitive Medical Plan (CMP) in accordance with a cost-reimbursement contract under section 1876(h) of the Act.

Downstream entity means any party that enters into a written arrangement, acceptable to CMS, with persons or entities involved with the Part D benefit, below the level of the arrangement between a Part D plan sponsor (or applicant) and a first tier entity. These written arrangements continue down to the level of the ultimate provider of both health and administrative services.

Eligible fallback entity or fallback entity is defined at §423.855.

Fallback prescription drug plan is defined at §423.855.

First tier entity means any party that enters into a written arrangement, acceptable to CMS, with a Part D plan sponsor or applicant to provide administrative services or health care services for a Medicare eligible individual under Part D.

Fiscally sound operation means an operation which at least maintains a positive net worth (total assets exceed total liabilities).

Formulary means the entire list of Part D drugs covered by a Part D plan.

Full-benefit dual eligible individual has the meaning given the term at §423.772, except where otherwise provided.

Generic drug means a drug for which an application under section 505(j) of the Federal Food, Drug, and Cosmetic Act (21 USC 355(j)) is approved.

Group health plan is defined at §423.882.

Insurance risk means, for a participating pharmacy, risk of the type commonly assumed only by insurers licensed by a State and does not include payment variations designed to reflect performance-based measures of activities within the control of the pharmacy, such as formulary compliance and generic drug substitutions, nor does it include elements potentially in the control of the pharmacy (for example, labor costs or productivity).

MA stands for Medicare Advantage, which refers to the program authorized under Part C of title XVIII of the Act.

MA plan has the meaning given the term in §422.2 of this chapter.

MA-PD plan means an MA plan that provides qualified prescription drug coverage.

Medicare prescription drug account means the account created within the Federal Supplementary Medical Insurance Trust Fund for purposes of Medicare Part D.

Monthly beneficiary premium means the amount calculated under §423.286 for Part D plans other than fallback prescription drug plans, and §423.867(a) for fallback prescription drug plans.

PACE Plan means a plan offered by a PACE organization.

PACE organization is defined in §460.6 of this chapter.

Part D eligible individual means an individual who meets the requirements at §423.30(a).

Part D plan (or Medicare Part D plan) means a prescription drug plan, an MA-PD plan, a PACE Plan offering qualified prescription drug coverage, or a cost plan offering qualified prescription drug coverage.

Part D plan sponsor or Part D sponsor refers to a PDP sponsor, MA organization offering a MA-PD plan, a PACE organization offering a PACE plan including qualified prescription drug coverage, and a cost plan offering qualified prescription drug coverage.

PDP region means a prescription drug plan region as determined by CMS under §423.112.

PDP sponsor means a nongovernmental entity that is certified under this part as meeting the requirements and standards of this part that apply to entities that offer prescription drug plans. This includes fallback entities.

Pharmacist means any individual who holds a current valid license to practice pharmacy in a State or territory of the United States or the District of Columbia.

Prescription drug plan or PDP means prescription drug coverage that is offered under a policy, contract, or plan that has been approved as specified in §423.272 and that is offered by a PDP sponsor that has a contract with CMS that meets the contract requirements under subpart K of this part. This includes fallback prescription drug plans.

Related entity means any entity that is related to the Part D sponsor by common ownership or control and

- (1) Performs some of the Part D plan sponsor's management functions under contract or delegation;
- (2) Furnishes services to Medicare enrollees under an oral or written agreement; or
- (3) Leases real property or sells materials to the Part D plan sponsor at a cost of more than \$2,500 during a contract period.

Service area (Service area does not include facilities in which individuals are incarcerated.) means for—

- (1) A prescription drug plan, an area established in §423.112(a) within which access standards under §423.120(a) are met;
- (2) An MA-PD plan, an area that meets the definition of MA service area as described in §422.2 of this chapter, and within which access standards under §423.120(a) are met;
- (3) A fallback prescription drug plan, the service area described in §423.859(b);

(4) A PACE plan offering qualified prescription drug coverage, the service area described in [§460.12\(c\)](#) of this chapter; and

(5) A cost plan offering qualified prescription drug coverage, the service area defined in §417.1 of this chapter.

Subsidy-eligible individual means a full subsidy eligible individual (as defined at §423.772) or other subsidy eligible individual (as defined at §423.772).

Tiered cost-sharing means a process of grouping Part D drugs into different cost sharing levels within a Part D sponsor's formulary.

Deleted: §460.22