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SUBCHAPTER E—PROGRAMS OF ALL-INCLUSIVE CARE FOR THE ELDERLY (PACE)

PART 460—PROGRAMS OF ALL-INCLUSIVE CARE FOR THE ELDERLY (PACE)

Subpart A—Basis, Scope, and Definitions

Sec.
460.2 Basis.
460.3 Part D program requirements.
460.4 Scope and purpose.
460.6 Definitions.

Subpart B—PACE Organization Application and Waiver Process

460.10 Purpose.
460.12 Application requirements.
460.14 [Reserved]
460.16 [Reserved]
460.18 CMS evaluation of applications.
460.19 Issuance of compliance actions for failure to comply with the terms of the PACE program agreement.
460.20 Notice of CMS determination.
460.24 Limit on number of PACE program agreements.
460.26 Submission and evaluation of waiver requests.
460.28 Notice of CMS determination on waiver requests.

Subpart C—PACE Program Agreement

460.30 Program agreement requirement.
460.32 Content and terms of PACE program agreement.
460.34 Duration of PACE program agreement.

Subpart D—Sanctions, Enforcement Actions, and Termination

460.40 Violations for which CMS may impose sanctions.
460.42 Suspension of enrollment or payment by CMS.
460.46 Civil money penalties.
460.48 Additional actions by CMS or the State.
460.50 Termination of PACE program agreement.
460.52 Transitional care during termination.
460.54 Termination procedures.
460.56 Procedures for imposing sanctions and civil money penalties.

Subpart E—PACE Administrative Requirements

460.60 PACE organizational structure.
460.62 Governing body.
460.63 Compliance oversight requirements.
460.64 Personnel qualifications.
460.66 Training.
460.68 Program integrity.
460.70 Contracted services.
460.71 Oversight of direct participant care.
460.72 Physical environment.
460.74 Infection control.
460.76 Transportation services.
460.78 Dietary services.
460.80 Fiscal soundness.
460.82 Marketing.
460.84 Emergency preparedness.
460.86 Payment to individuals and entities excluded by the OIG or included on the preclusion list.

Subpart F—PACE Services

460.90 PACE benefits under Medicare and Medicaid.
460.92 Required services.
460.94 Required services for Medicare participants.
460.96 Excluded services.
460.98 Service delivery.
460.100 Emergency care.
460.102 Interdisciplinary team.
460.104 Participant assessment.
460.106 Plan of care.

Subpart G—Participant Rights

460.110 Bill of rights.
460.112 Specific rights to which a participant is entitled.
460.114 Restraints.
460.116 Explanation of rights.
460.118 Violation of rights.
460.119 Resolution of complaints in the complaints tracking module.
460.120 Grievance process.
460.122 PACE organization's appeals process.
460.124 Additional appeal rights under Medicare or Medicaid.

Subpart H—Quality Improvement

460.130 General rule.
460.132 Quality improvement plan.
460.134 Minimum requirements for quality improvement program.
460.136 Internal quality improvement activities.
460.138 Committees with community input.

Subpart I—Participant Enrollment and Disenrollment

460.150 Eligibility to enroll in a PACE program.

460.152 Enrollment process.
460.154 Enrollment agreement.
460.156 Other enrollment procedures.
460.158 Effective date of enrollment.
460.160 Continuation of enrollment.
460.162 Voluntary disenrollment.
460.164 Involuntary disenrollment.
460.166 Disenrollment responsibilities.
460.168 Reinstatement in other Medicare and Medicaid programs.
460.170 Reinstatement in PACE.
460.172 Documentation of disenrollment.

Subpart J—Payment

460.180 Medicare payment to PACE organizations.
460.182 Medicaid payment.
460.184 Post-eligibility treatment of income.
460.186 PACE premiums.

Subpart K—Federal/State Monitoring

460.190 Monitoring during trial period.
460.192 Ongoing monitoring after trial period.
460.194 Corrective action.
460.196 Disclosure of review results.
460.198 Disclosure of compliance deficiencies.

Subpart L—Data Collection, Record Maintenance, and Reporting

460.200 Maintenance of records and reporting of data.
460.202 Participant health outcomes data.
460.204 Financial recordkeeping and reporting requirements.
460.208 Financial statements.
460.210 Medical records.

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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.

[84 FR 25671, June 3, 2019]

§ 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 19 to 30 months, as determined by CMS, but in any event will end on December 31.

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.

Service, as used in this part, means all services that could be required under §460.92, including items and drugs.

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.

[64 FR 66279, Nov. 24, 1999, as amended at 71 FR 71334, Dec. 8, 2006; 86 FR 6131, Jan. 19, 2021; 88 FR 22344, Apr. 12, 2023]

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).

[84 FR 25671, June 3, 2019]

§ 460.12 Application requirements.

(a) *Submission of application.* (1) 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 or add a PACE center site must submit to CMS a complete application in the form and manner, including timeframes for submission, specified by CMS, that describes how the entity or PACE organization meets all requirements in this part.

(2) An individual authorized to act for an entity that seeks to become a PACE organization must submit an application to qualify as a Part D sponsor in the form and manner required by CMS in accordance with 42 CFR part 423, subpart K.

(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.

(3) Any PACE application that does not include a signed and dated State assurances document that includes accurate service area information and

the physical address of the PACE center, as applicable, is considered incomplete and invalid and will not be evaluated by CMS.

(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.

[84 FR 25671, June 3, 2019, as amended at 89 FR 30843, Apr. 23, 2024; 89 FR 63828, Aug. 6, 2024]

§ 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.

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

(c) *Use of information from a current or prior PACE program agreement.* (1) If, during the 12 months preceding the deadline established by CMS for the submission of an application or submission of a response to a CMS request for additional information, a PACE organization fails to comply with the requirements of the PACE program under any current or prior PACE program agreement or fails to complete a corrective action plan during the applicable 12-month period, CMS may deny an application based on the applicant's failure to comply with the requirements of the PACE program under any current or prior PACE program agreement even if the applicant currently meets all of the requirements of this part.

(i) An applicant may be considered to have failed to comply with the requirements of the PACE program under a PACE program agreement for purposes of an application denial under paragraph (c)(1) of this section if any of the following conditions apply with respect to the applicant during the applicable 12-month review period:

(A) Was subject to the imposition of an enrollment or payment sanction under § 460.42(a) or (b) for one or more of the violations specified in § 460.40.

(B) Failed to maintain a fiscally sound operation consistent with the requirements of § 460.80(a) after the end of the trial period.

(C) Filed for or is currently in State bankruptcy proceedings.

(D) Met or exceeded 13 points for compliance actions for any one PACE program agreement.

(*1*) CMS determines the number of points accumulated during the performance period for compliance actions based on the following point values:

(*i*) Each corrective action plan issued under § 460.19(c)(3) during the performance period counts for 6 points. Corrective action requests issued under § 460.194 are not included in the point calculations.

(*ii*) Each warning letter issued under § 460.19(c)(2) during the performance period counts for 3 points.

(*iii*) Each notice of non-compliance issued under § 460.19(c)(1) during the performance period counts for 1 point.

(*2*) CMS adds all the point values for each PACE organization's program agreement to determine if the 13-point threshold described in paragraph (c)(1)(i)(D) of this section has been reached.

(ii) CMS may deny an application submitted by an organization that does not hold a PACE program agreement at the time of the submission if the applicant's parent organization or another subsidiary of the parent organization meets the criteria for denial stated in paragraph (c)(1)(i) of this section. This paragraph does not apply to a parent

organization that completed the acquisition of a subsidiary that meets the criteria for denial within the 24 months preceding the application submission deadline.

(d) If CMS has terminated a PACE program agreement under § 460.50, or did not renew a PACE program agreement, and that termination or non-renewal took effect within the 38 months preceding the submission of an initial or expansion PACE application from the same organization, CMS may deny the application based on the applicant's substantial failure to comply with the requirements of the PACE program, even if the applicant currently meets all of the requirements of this part.

[64 FR 66279, Nov. 24, 1999, as amended at 84 FR 25671, June 3, 2019; 89 FR 30843, Apr. 23, 2024]

§ 460.19 Issuance of compliance actions for failure to comply with the terms of the PACE program agreement.

(a) CMS may take compliance actions as described in paragraph (c)(1) of this section if CMS determines that the PACE organization has not complied with the terms of a current or prior PACE program agreement with CMS and a State administering agency.

(1) CMS may determine that a PACE organization is out of compliance with requirements when the organization fails to meet performance standards articulated in sections 1894 and 1934 of the Act and regulations in this chapter.

(2) If CMS has not already articulated a measure for determining non-compliance, CMS may determine that a PACE organization is out of compliance when its performance in fulfilling requirements represents an outlier relative to the performance of other PACE organizations.

(b) CMS bases its decision on whether to issue a compliance action and what level of compliance action to take on an assessment of the circumstances surrounding the non-compliance, including all of the following:

(1) The nature of the conduct.

(2) The degree of culpability of the PACE organization.

(3) The actual or potential adverse effect on beneficiaries which resulted or could have resulted from the conduct of the PACE organization.

(4) The history of prior offenses by the PACE organization or its related entities.

(5) Whether the non-compliance was self-reported.

(6) Other factors which relate to the impact of the underlying non-compliance or to the PACE organization's inadequate oversight of the operations that contributed to the non-compliance.

(c) CMS may take one of three types of compliance actions based on the nature of the non-compliance.

(1) *Notice of non-compliance.* A notice of non-compliance may be issued for any failure to comply with the requirements of the PACE organization's current or prior PACE program agreement with CMS and a State administering agency, as described in paragraph (a) of this section.

(2) *Warning letter.* A warning letter may be issued for serious and/or continued non-compliance with the requirements of the PACE organization's current or prior PACE program agreement with CMS and a State administering agency, as described in paragraph (a) of this section and as assessed in accordance with paragraph (b) of this section.

(3) *Corrective action plan.* (i) Corrective action plans are issued for particularly serious or continued non-compliance with the requirements of the PACE organization's current or prior PACE program agreement with CMS and a State administering agency, as described in paragraph (a) of this section and as assessed in accordance with paragraph (b) of this section.

(ii) CMS issues a corrective action plan if CMS determines that the PACE organization has repeated or not corrected non-compliance identified in prior compliance actions, has substantially impacted beneficiaries or the program with its non-compliance, or must implement a detailed plan to correct the underlying causes of the non-compliance.

[89 FR 30844, Apr. 23, 2024]

§ 460.20 Notice of CMS determination.

(a) *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:

(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.

(c) *Incomplete application due to the lack of required State assurances documentation.* An application that, upon submission, is determined to be incomplete under § 460.12(b)(3) is withdrawn by CMS and the applicant is notified accordingly. The applicant is not entitled to a fair hearing when CMS withdraws an incomplete application on this basis.

(d) *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.

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

(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.

(e) *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.

(f) *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.

[64 FR 66279, Nov. 24, 1999, as amended at 84 FR 25672, June 3, 2019; 89 FR 30844, Apr. 23, 2024; 89 FR 79452, Sept. 30, 2024]

§ 460.24 Limit on number of PACE program agreements.

(a) *Numerical limit.* Except as specified in paragraph (b) of this section, CMS does not permit the number of PACE organizations with which agreements are in effect under this part or under section 9412(b) of the Omnibus Budget Reconciliation Act of 1986, to exceed the following:

(1) As of August 5, 1997—40.

(2) As of each succeeding August 5, the numerical limit for the preceding year plus 20, without regard to the actual number of agreements in effect on a previous anniversary date. (For example, the limit is 60 on August 5, 1998 and 80 on August 5, 1999.)

(b) *Exception.* The numerical limit does not apply to a private, for-profit PACE organization that meets the following conditions:

(1) Is operating under a demonstration project waiver under section 1894(h) and 1934(h) of the Act.

(2) Was operating under a waiver and subsequently qualifies for PACE organization status in accordance with sections 1894(a)(3)(B)(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 onsite 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.

(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, as amended at 71 FR 71334, Dec. 8, 2006; 84 FR 25672, June 3, 2019]

§ 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.

[84 FR 25672, June 3, 2019]

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]

§ 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.

(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.

(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; 84 FR 25672, June 3, 2019]

§ 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.

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

(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.

(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.

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

(6) Misrepresents or falsifies information that is furnished—

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

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

(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.

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

(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.

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

(b) If CMS or the State administering agency makes a determination under § 460.50 that could lead to termination of a PACE program agreement, CMS may impose any of the sanctions specified at §§ 460.42 and 460.46. If CMS or the State administering agency determines that the circumstances in § 460.50(b)(1) exist, neither CMS nor the State administrating agency has to determine that the circumstances in § 460.50(b)(2) exist prior to imposing a CMP or enrollment and/or payment suspension.

[64 FR 66279, Nov. 24, 1999, as amended at 81 FR 80561, Nov. 15, 2016; 83 FR 16756, Apr. 16, 2018; 84 FR 25672, June 3, 2019; 88 FR 22345, Apr. 12, 2023]

§ 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) 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.

(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.

(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 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.

(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).

[64 FR 66279, Nov. 24, 1999, as amended at 84 FR 25672, June 3, 2019]

§ 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 phasedown 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.

§ 460.56 Procedures for imposing sanctions and civil money penalties.

CMS provides notice and a right to request a hearing according to the procedures set forth in either of the following:

(a) Section 422.756(a) and (b) of this chapter if CMS imposes a suspension of enrollment or payment under § 460.42 or § 460.48(b).

(b) Section 422.756(e)(2)(v) of this chapter if CMS imposes civil money penalties under § 460.46.

[86 FR 6132, Jan. 19, 2021]

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; 84 FR 25673, June 3, 2019]

§ 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.

(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; 84 FR 25673, June 3, 2019]

§ 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.

[84 FR 25673, June 3, 2019]

§ 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:

(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.

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

(5) Be medically cleared for communicable diseases before engaging in direct participant contact.

(i) Staff must be cleared for communicable diseases based on a physical examination performed by a licensed physician, nurse practitioner, or physician assistant acting within the scope of their authority to practice, unless—

(A) The PACE organization conducts an individual risk assessment that meets the conditions specified in paragraph (a)(5)(iii) of this section; and

(B) The results of the risk assessment indicate the individual does not require a physical examination for medical clearance.

(ii) As part of the initial physical examination, staff must be determined to be free of active Tuberculosis disease.

(iii) If the PACE organization conducts a risk assessment on an individual under paragraphs (a)(5)(i)(A) and (B) of this section—

(A) Policies and procedures for conducting a risk assessment on each individual with direct participant contact must be based on accepted professional standards of care;

(B) The PACE organization's risk assessment must identify when a physical examination is required based on the results of the assessment; and

(C) The results of the risk assessment must be reviewed by a registered nurse, physician, nurse practitioner, or physician assistant.

(D) At a minimum, the risk assessment must do both of the following:

(*1*) Assess whether staff have been exposed to or have any symptoms of the following diseases:

(*i*) COVID–19.

(*ii*) Diphtheria.

(*iii*) Influenza.

(*iv*) Measles.

(*v*) Meningitis.

(*vi*) Meningococcal Disease.

(*vii*) Mumps.

(*viii*) Pertussis.

(*ix*) Pneumococcal Disease.

(*x*) Rubella.

(*xi*) Streptococcal Infection.

(*xii*) Varicella Zoster Virus.

(*xiii*) Any other infectious diseases noted as a potential threat to public health by the CDC.

(*2*) Determine if staff are free of active Tuberculosis during the initial risk assessment.

(6) 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, as amended at 84 FR 25673, June 3, 2019; 89 FR 30844, Apr. 23, 2024]

§ 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.

[64 FR 66279, Nov. 24, 1999, as amended at 71 FR 71335, Dec. 8, 2006; 84 FR 25673, June 3, 2019]

§ 460.68 Program integrity.

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

(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;

(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;

(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

(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; 84 FR 25673, June 3, 2019]

§ 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, including, at a minimum, the medical specialties identified in paragraph (a)(1) of this section. The PACE organization does not need to have a written contract with entities that provide emergency services as described in § 460.100.

(1) At a minimum, except as noted in paragraph (a)(4) of this section, PACE organizations must have contracts in place for the following medical specialties:

(i) Anesthesiology.
(ii) Audiology.
(iii) Cardiology.
(iv) Dentistry.
(v) Dermatology.
(vi) Gastroenterology.
(vii) Gynecology.
(viii) Internal Medicine.
(ix) Nephrology.
(x) Neurosurgery.
(xi) Oncology.
(xii) Ophthalmology.
(xiii) Oral surgery.
(xiv) Orthopedic surgery.
(xv) Otorhinolaryngology.
(xvi) Palliative Medicine.
(xvii) Plastic surgery.
(xviii) Pharmacy consulting services.
(xix) Podiatry.
(xx) Psychiatry.
(xxi) Pulmonology.
(xxii) Radiology.
(xxiii) Rheumatology.
(xxiv) General Surgery.
(xxv) Thoracic and vascular surgery.
(xxvi) Urology.

(2) Contracts with medical specialists must be executed prior to enrollment of participants and must be maintained on an ongoing basis to ensure participants receive appropriate and timely access to all medically necessary care and services.

(3) A PACE organization is responsible for making all reasonable and timely attempts to contract with medical specialists. If at any time a PACE organization is unable to directly contract or maintain a contract with a specific specialty, the PACE organization must—

(i) Ensure care and services that would otherwise be provided to participants by a contracted specialist are provided and that the participant's needs are met through a different mechanism to include hospitalization; and

(ii) Promptly report the contracting issue to CMS and the State Administering Agency, including the attempts made to contract, the reason why the contract was not effectuated, and the PACE organization's plan to provide access to the necessary services.

(4) A PACE organization is not required to have a contract with a particular medical specialty if the PACE organization directly employs one or

more individuals prior to contracting who are legally authorized, and if applicable, board certified in the particular medical specialty.

(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.

(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(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; 84 FR 25673, June 3, 2019; 88 FR 22345, Apr. 12, 2023; 88 FR 34780, May 31, 2023; 90 FR 15920, Apr. 15, 2025]

§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.

(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 before engaging in direct participant contact as required under § 460.64(a)(5).

(5) Have all immunizations up to date before engaging in direct participant contact.

(6) Have been oriented to the PACE program.

(7) 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; 84 FR 25674, June 3, 2019; 89 FR 30844, Apr. 23, 2024]

§ 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; 86 FR 61618, Nov. 5, 2021; 88 FR 36510, June 5, 2023]

§ 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.

(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.

[64 FR 66279, Nov. 24, 1999, as amended at 84 FR 25674, June 3, 2019]

§ 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 every 2 years. 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.

(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.

(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 every 2 years. 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 every 2 years. 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 every 2 years.

(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 every 2 years.

(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.

(v) If the emergency preparedness policies and procedures are significantly updated, the PACE must conduct training on the updated policies and procedures.

(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;

(A) When a community-based exercise is not accessible, conduct an annual individual, facility-based functional exercise every 2 years; or

(B) 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 its next required full-scale community-based or individual, facility-based functional exercise following the onset of the emergency event.

(ii) Conduct an additional exercise every 2 years opposite the year the full-scale or functional exercise under paragraph (d)(2)(i) of this section is conducted that may include, but is not limited to the following:

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

(B) A mock disaster drill; or

(C) A tabletop exercise or workshop that is led by a facilitator and includes a group discussion, 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, as amended at 84 FR 51816, Sept. 30, 2019]

§ 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.

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

(1) All Medicare-covered services.

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

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

(b) Decisions by the interdisciplinary team to provide or deny services under paragraph (a) of this section must be based on an evaluation of the participant that takes into account:

(1) The participant's current medical, physical, emotional, and social needs; and

(2) Current clinical practice guidelines and professional standards of care applicable to the particular service.

[86 FR 6132, Jan. 19, 2021]

§ 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) 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.

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

(c) 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; 86 FR 6132, Jan. 19, 2021]

§ 460.98 Service delivery.

(a) *Access to services.* A PACE organization is responsible for providing care that meets the needs of each participant across all care settings, 24 hours a day, every day of the year, and must establish and implement a written plan to ensure that care is appropriately furnished.

(b) *Provision of services.* (1) The PACE organization must furnish comprehensive medical, health, and social services that integrate acute and long-term care. These services must be furnished in accordance with § 460.70(a).

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

(3) The PACE organization shall not discriminate against any participant in the delivery of required PACE services based on race, ethnicity, national origin, religion, sex (including sex characteristics, including intersex traits; pregnancy or related conditions; sexual orientation; gender identity; and sex stereotypes), age, mental or physical disability, or source of payment.

(4) The PACE organization must document, track and monitor the provision of services across all care settings in order to ensure the interdisciplinary team remains alert to the participant's medical, physical, emotional, and social needs regardless of whether services are formally incorporated into the participant's plan of care.

(c) *Timeframes for arranging and providing services*—(1) *Medications.* The PACE organization must arrange and schedule the dispensing of medications as expeditiously as the participant's condition requires, but no later than 24 hours after a primary care provider orders the medication.

(2) *All other services.* The PACE organization must arrange or schedule the delivery of interdisciplinary team approved services, other than medications, as identified in paragraph (c)(2)(i) of this section, as expeditiously as the participant's health condition requires, but no later than 7 calendar days after the date the interdisciplinary team or member of the interdisciplinary team first approves the service, except as identified in paragraph (c)(3) of this section.

(i) Interdisciplinary team approved services include:

(A) Services approved by the full interdisciplinary team.

(B) Services approved by a member of the interdisciplinary team.

(C) Services ordered by a member of the interdisciplinary team.

(D) Care planned services.

(ii) [Reserved]

(3) *Routine or preventative services.* Routine or preventive services are excluded from the requirement in paragraph (c)(2) of this section when all of the following requirements are met:

(i) The PACE organization documents that they were unable to schedule the appointment due to circumstances beyond the control of the PACE organization.

(ii) The participant does not have a change in status that requires the service to be provided more quickly.

(iii) The PACE organization provides the service as expeditiously as the participant's condition requires.

(4) *Providing approved services.* Services must be provided as expeditiously as the participant's health condition requires, taking into account the participant's medical, physical, social, and emotional needs.

(d) *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.

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

(4) Personal care and supportive services.

(5) Nutritional counseling.

(6) Recreational therapy.

(7) Meals.

(e) *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.

(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.

(f) *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; 84 FR 25674, June 3, 2019; 85 FR 37243, June 19, 2020; 86 FR 6132, Jan. 19, 2021; 89 FR 30845, Apr. 23, 2024; 89 FR 37692, May 6, 2024]

§ 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.

(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; 84 FR 25674, June 3, 2019]

§ 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.

(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 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.

(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.

(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 following for each participant:

(i) *Assessments and plan of care.* The initial assessment, periodic reassessments, and plan of care.

(ii) *Coordination of care.* Coordination and implementation of 24-hour care delivery that meets participant needs across all care settings, including but not limited to the following:

(A) Ordering, approving, or authorizing all necessary care.

(B) Communicating all necessary care and relevant instructions for care.

(C) Ensuring care is implemented as it was ordered, approved, or authorized by the IDT.

(D) Monitoring and evaluating the participant's condition to ensure that the care provided is effective and meets the participant's needs.

(E) Promptly modifying care when the IDT determines the participant's needs are not met in order to provide safe, appropriate, and effective care to the participant.

(iii) *Documenting recommended services.* Documenting all recommendations for care or services and the reason(s) for not approving or providing recommended care or services, if applicable, in accordance with § 460.210(b).

(iv) *Consideration of recommended services.* The interdisciplinary team must review, assess, and act on recommendations from emergency or urgent care providers, employees, and contractors, including medical specialists. Specifically, the interdisciplinary team must ensure the following requirements are met:

(A) The appropriate member(s) of the interdisciplinary team must review all recommendations from hospitals, emergency departments, and urgent care providers and determine if the recommended services are necessary to meet the participant's medical, physical, social, or emotional needs as expeditiously as the participant's health condition requires, but no later than 48 hours from the time of the participant's discharge.

(B) The appropriate member(s) of the interdisciplinary team must review all recommendations from other employees and contractors and determine if the recommended services are necessary to meet the participant's medical, physical, social, or emotional needs as expeditiously as the participant's health condition requires, but no later than 7 calendar days from the date the recommendation was made.

(C) If recommendations are authorized or approved by the interdisciplinary team or a member of the interdisciplinary team, the services must be promptly arranged and furnished under § 460.98(c).

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

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

(ii) Remaining alert to pertinent input from any individual with direct knowledge of or contact with the participant, including the following:

(A) Other team members.

(B) Participants.

(C) Caregivers.

(D) Employees.

(E) Contractors.

(F) Specialists.

(G) Designated representatives.

(iii) Documenting changes of a participant's condition in the participant's medical record consistent with documentation polices 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.

(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).

[64 FR 66279, Nov. 24, 1999, as amended at 67 FR 61506, Oct. 1, 2002; 71 FR 71334, 71336, Dec. 8, 2006; 84 FR 25674, June 3, 2019; 86 FR 6132, Jan. 21, 2021; 89 FR 30845, Apr. 23, 2024]

§ 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.

(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:

(i) Primary care provider

(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.

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

(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:

(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:

(1) Primary care provider.

(2) Registered nurse.

(3) Master's-level social worker.

(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.

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

(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.

(2) *In response to a service determination request.* In accordance with § 460.121(h), the PACE organization must conduct an in-person reassessment if it expects to deny or partially deny a service determination request, and may conduct reassessments as determined necessary for approved services.

(e) *Changes to plan of care.* When the interdisciplinary team conducts semi-annual or unscheduled reassessments, the interdisciplinary team must re-evaluate and, if necessary, revise the plan of care in accordance with § 460.106(c) following the completion of all required assessments.

(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; 84 FR 25674, June 3, 2019; 86 FR 6132, Jan. 19, 2021; 89 FR 30845, Apr. 23, 2024]

§ 460.106 Plan of care.

(a) *Definition and basic requirements*—(1) *Definition.* For purposes of this section, a ''change in participant's status'' means a major decline or improvement in a participant's status that will not normally resolve itself without further intervention by staff or by implementing standard disease-related clinical interventions, that has an impact on more than one area of the participant's health status and requires interdisciplinary team review or revision of the care plan, or both.

(2) *Basic requirements.* (i) The interdisciplinary team members specified in § 460.102(b) must develop, evaluate, and if necessary, revise a comprehensive person-centered plan of care for each participant.

(ii) Each plan of care must do all of the following:

(A) Take into consideration the most current assessment findings.

(B) Identify the services to be furnished to attain or maintain the participant's highest practicable level of well-being.

(b) *Timeframes for developing, evaluating, and revising plan of care.* (1) *Initial plan of care.* The interdisciplinary team must complete the initial plan of care within 30 calendar days of the participant's date of enrollment.

(2) *Semi-annual plan of care evaluation.* At least once every 180 calendar days from the date the latest plan of care was finalized the interdisciplinary team must complete a reevaluation of, and if necessary, revisions to each participant's plan of care.

(3) *Change in participant's status.* (i) Except as specified in paragraph (b)(3)(ii) of this section, the interdisciplinary team must complete a reevaluation of, and if necessary, revisions to a participant's plan of care within 14 calendar days after the PACE organization determines, or should have determined, that there has been a change in the participant's health or psychosocial status, or more expeditiously if the participant's condition requires.

(ii) If a participant is hospitalized within 14 calendar days of the change in participant status, the interdisciplinary team must complete a reevaluation of, and if necessary, revisions to the plan of care as expeditiously as the participant's condition requires but no later than 14 calendar days after the date of discharge from the hospital.

(c) *Content of plan of care.* At a minimum, each plan of care must meet the following requirements:

(1) Identify all of the participant's current medical, physical, emotional, and social needs, including all needs associated with chronic diseases, behavioral disorders, and psychiatric disorders that require treatment or routine monitoring. At a minimum, the care plan must address the following factors:

(i) Vision.

(ii) Hearing.

(iii) Dentition.

(iv) Skin integrity.

(v) Mobility.

(vi) Physical functioning, including activities of daily living.

(vii) Pain management.

(viii) Nutrition, including access to meals that meet the participant's daily nutritional and special dietary needs.

(ix) The participant's ability to live safely in the community, including the safety of their home environment.

(x) Home care.

(xi) Center attendance.

(xii) Transportation.

(xiii) Communication, including any identified language barriers.

(2)(i) Identify each intervention (the care and services) needed to meet each medical, physical, emotional, and social needs.

(ii) It does not have to identify the medications needed to meet the participant's needs if a comprehensive list of medications is already documented elsewhere in the medical record.

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

(4) Identify how each intervention will be implemented, including a timeframe for implementation.

(5) Identify a measurable goal for each intervention.

(6) Identify how the goal for each intervention will be evaluated to determine whether the intervention should be continued, discontinued, or modified.

(7) The participant's preferences and goals of care.

(d) *Implementation of the plan of care.* The team must continuously do all of the following:

(1) Implement, coordinate, and monitor the plan of care regardless of whether the services are furnished by PACE employees or contractors, across all care settings.

(2) Evaluate and monitor the participant's medical, physical, emotional, and social needs 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 employees or contractors.

(e) *Participant and caregiver involvement in plan of care.* (1) The interdisciplinary team must develop, evaluate, and revise each plan of care in collaboration with the participant, the participant's caregiver, or both.

(2) The interdisciplinary team must review and discuss each plan of care with the participant or the participant's caregiver or both before the plan of care is completed to ensure that there is agreement with the plan of care and that the participant's concerns are addressed.

(f) *Documentation.* The team must do all of the following:

(1) Establish and implement a process to document and maintain records related to all requirements for plans of care, in the participant's medical record.

(2) Ensure that the most recent care plan is available to all employees and contractors within the organization as needed.

[89 FR 30845, Apr. 23, 2024]

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 (including sex characteristics, including intersex traits; pregnancy or related conditions; sexual orientation; gender identity; and sex stereotypes), age, 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.

(8) To have all information regarding PACE services and treatment options explained in a culturally competent manner.

(b) *Right to treatment.* Each participant has the right to appropriate and timely treatment for their health conditions, including the right to both of the following:

(1) Receive all care and services needed to improve or maintain the participant's health condition and attain the highest practicable physical, emotional, and social well-being.

(2) Access emergency health care services when and where the need arises without prior authorization by the PACE interdisciplinary team.

(c) *Information disclosure.* Each PACE participant has the right to receive accurate, easily understood information and to receive assistance in making informed health decisions. A participant has the right to have all information in this section shared with their designated representative. 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.

(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.

(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.

(4) To contact 1–800–MEDICARE for information and assistance, including to make a complaint related to the quality of care or the delivery of a service.

(5) To be fully informed of the following, in writing, before the PACE organization implements palliative care, comfort care, or end-of-life care services:

(i) A description of the PACE organization's palliative care, comfort care, and end-of-life care services (as applicable) and how they differ from the care the participant is currently receiving.

(ii) Whether palliative care, comfort care, or end-of-life care services (as applicable) is provided in addition to or in lieu of the care the participant is currently receiving.

(iii) Identify all services that are impacted and provide a detailed explanation of how the services will be impacted if the participant or designated representative elects to initiate palliative care, comfort care, or end-of-life care, including but not limited to the following types of services.

(A) Physician services, including specialist services.

(B) Hospital services.

(C) Long-term care services.

(D) Nursing services.

(E) Social services.

(F) Dietary services.

(G) Transportation.

(H) Home care.

(I) Therapy, including physical, occupation, and speech therapy.

(J) Behavioral health.

(K) Diagnostic testing, including imaging and laboratory services.

(L) Medications.

(M) Preventative healthcare services.

(N) PACE center attendance.

(iv) The right to revoke or withdraw their consent to receive palliative, comfort, or end-of-life care at any time and for any reason, either verbally or in writing.

(d) *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 have reasonable and timely access to specialists as indicated by the participant's health condition and consistent with current clinical practice guidelines.

(4) To receive necessary care in all care settings, up to and including placement in a long-term care facility when the PACE organization can no longer provide the services necessary to maintain the participant safely in the community.

(5) 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).

(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 make health care decisions, including the right to all of the following:

(i) Have all treatment options fully explained.

(ii) Refuse any and all care and services.

(iii) Be informed of the consequences their decisions may have on their health and/or psychosocial status.

(2) To fully understand the PACE organization's palliative care, comfort care, and end-of-life care services. Specifically, the PACE organization must do all of the following before palliative care, comfort care, or end-of-life care services can be initiated:

(i) Fully explain the applicable treatment options.

(ii) Provide the participant with written information about their treatment options, in accordance with paragraph (c)(5) of this section.

(iii) Obtain written consent from the participant or designated representative prior to initiating palliative care, comfort care, or end-of-life care.

(3) 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.

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

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

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

(7) 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, requests, 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 request services from the PACE organizations, its employees, or contractors through the process described in § 460.121.

(3) 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; 84 FR 25675, June 3, 2019; 86 FR 6132, Jan. 19, 2021; 89 FR 30846, Apr. 23, 2024; 89 FR 37692, May 6, 2024; 90 FR 15920, Apr. 15, 2025]

§ 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.

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

[64 FR 66279, Nov. 24, 1999, as amended at 84 FR 25675, June 3, 2019]

§ 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.

§ 460.119 Resolution of complaints in the complaints tracking module.

The PACE organization must comply with requirements of §§ 422.125 and 422.504(a)(15) of this chapter, through the CMS complaints tracking module as defined in § 422.125(a) of this chapter, address and resolve complaints received by CMS against the PACE organization within the required timeframes. References to the MA organization or MA plan in those regulations must be read as references to the PACE organization. Nothing in this section should be construed to affect the PACE organization's obligation to resolve grievances as described in § 460.120, service determinations as described in § 460.121, or appeals as described in § 460.122.

[89 FR 30847, Apr. 23, 2024]

§ 460.120 Grievance process.

(a) *Written procedures.* A PACE organization must have a formal written process to promptly identify, document, investigate, and resolve all medical and nonmedical grievances in accordance with the requirements in this part.

(b) *Definition of grievance.* For purposes of this part, a grievance is a complaint, either oral or written, expressing dissatisfaction with service delivery or the quality of care furnished, regardless of whether remedial action is requested. Grievances may be between participants and the PACE organization or any other entity or individual through which the PACE organization provides services to the participant.

(c) *Grievance process notification to participants.* Upon enrollment, and at least annually thereafter, the PACE organization must give a participant written information on the grievance process in understandable language, including all of the following:

(1) A participant or other individual specified in paragraph (d) of this section has the right to voice grievances without discrimination or reprisal, and

without fear of discrimination or reprisal.

(2) A Medicare participant or other individual specified in paragraph (d) of this section acting on behalf of a Medicare participant has the right to file a written complaint with the quality improvement organization (QIO) with regard to Medicare covered services.

(3) The requirements under paragraphs (b) and (d) through (j) of this section.

(d) *Who can submit a grievance.* Any of the following individuals can submit a grievance:

(1) The participant.

(2) The participant's family member.

(3) The participant's designated representative.

(4) The participant's caregiver.

(e) *Methods for submitting a grievance.* (1) Any individual as permitted under paragraph (d) of this section may file a grievance with the PACE organization either orally or in writing.

(2) The PACE organization may not require a written grievance to be submitted on a specific form.

(3) A grievance may be made to any employee or contractor of the PACE organization that provides care to a participant in the participant's residence, the PACE center, or while transporting participants.

(f) *Conducting an investigation.* The PACE organization must conduct a thorough investigation of all distinct issues within the grievance when the cause of the issue is not already known.

(g) *Grievance resolution and notification timeframes.* The PACE organization must do all of the following:

(1) Take action to resolve the grievance based on the results of its investigation as expeditiously as the case requires, but no later than 30 calendar days after the date the PACE organization receives the oral or written grievance.

(2) Notify the individual who submitted the grievance of the grievance resolution as expeditiously as the case requires, but no later than 3 calendar days after the date the PACE organization resolves the grievance in accordance with paragraph (g)(1) of this section.

(h) *Grievance resolution notification.* The PACE organization must inform the individual who submitted the grievance of the resolution as follows:

(1) Either orally or in writing, based on the individual's preference for notification, except for grievances identified in paragraph (h)(3) of this section.

(2) At a minimum, oral or written notification of grievance resolutions must include the following, if applicable:

(i) A summary statement of the participant's grievance including all distinct issues.

(ii) A summary of the pertinent findings or conclusions regarding the concerns for each distinct issue that requires investigation.

(iii) For a grievance that requires corrective action, the corrective action(s) taken or to be taken by the PACE organization as a result of the grievance, and when the participant may expect corrective action(s) to occur.

(3) All grievances related to quality of care, regardless of how the grievance is filed, must be responded to in writing.

(i) The response must describe the right of a Medicare participant or other individual specified in paragraph (d) of this section acting on behalf of a Medicare participant to file a written complaint with the QIO with regard to Medicare covered services.

(ii) For any complaint submitted to a QIO, the PACE organization must cooperate with the QIO in resolving the complaint.

(4) The PACE organization may withhold notification of the grievance resolution if the individual who submitted the grievance specifically requests not to receive the notification, and the PACE organization has documented this request in writing. The PACE organization is still responsible for complying with all other requirements of this section.

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

(j) *Maintaining confidentiality of grievances.* The PACE organization must develop and implement procedures to

maintain the confidentiality of a grievance, including protecting the identity of all individuals involved in the grievance from other employees and contractors when appropriate.

(k) *Recordkeeping.* The PACE organization must establish and implement a process to document, track, and maintain records related to all processing requirements for grievances received both orally and in writing. These records, except for information deemed confidential as a part of paragraph (j) of this section, must be available to the interdisciplinary team to ensure that all members remain alert to pertinent participant information.

(l) *Analyzing grievance information.* The PACE organization must aggregate and analyze the information collected under paragraph (k) of this section for purposes of its internal quality improvement program.

[89 FR 30847, Apr. 23, 2024, as amended at 89 FR 63828, Aug. 6, 2024]

§ 460.121 Service determination process.

(a) *Written procedures.* Each PACE organization must have formal written procedures for identifying and processing service determination requests in accordance with the requirements of this Part.

(b) *What is a service determination request*—(1) *Requests that constitute a service determination request.* Except as provided in paragraph (b)(2) of this section, the following requests constitute service determination requests:

(i) A request to initiate a service.

(ii) A request to modify an existing service, including to increase, reduce, eliminate, or otherwise change a service.

(iii) A request to continue coverage of a service that the PACE organization is recommending be discontinued or reduced.

(2) *Requests that do not constitute a service determination request.* Requests to initiate, modify, or continue a service do not constitute a service determination request if the request is made prior to completing the development of the initial plan of care. For all requests identified in this section, the interdisciplinary team must—

(i) Document the request; and

(ii) Discuss the request during the care planning meeting, and either:

(A) Approve the requested service and incorporate it into the participant's initial plan of care, or

(B) Document their rationale for not approving the service in the initial plan of care.

(c) *Who can make a service determination request.* Any of the following individuals can make a service determination request:

(1) The participant.

(2) The participant's designated representative.

(3) The participant's caregiver.

(d) *Method for making a service determination request.* An individual may make a service determination request as follows:

(1) Either orally or in writing.

(2) To any employee or contractor of the PACE organization that provides direct care to a participant in the participant's residence, the PACE center, or while transporting participants.

(e) *Processing a service determination request.* (1) Except as provided in paragraph (e)(2) of this section, the PACE organization must bring a service determination request to the interdisciplinary team as expeditiously as the participant's condition requires, but no later than 3 calendar days from the time the request is made.

(2) If a member of the interdisciplinary team is able to approve the service determination request in full at the time the request is made, the PACE organization—

(i) Must fulfill all of the following:

(A) Notice of the decision to approve a service determination request requirements specified in paragraph (j)(1) of this section.

(B) Effectuation requirements specified in paragraph (k) of this section.

(C) Recordkeeping requirements specified in paragraph (m) of this section.

(ii) Is not required to process the service determination request in accordance with paragraphs (f) through (i), (j)(2), and (*l*) of this section.

(f) *Who must review a service determination request.* The full interdisciplinary team must review and discuss each service determination request and

decide to approve, deny, or partially deny the request based on that review.

(g) *Interdisciplinary team decision making.* The interdisciplinary team must consider all relevant information when evaluating a service determination request, including, but not limited to, the findings and results of any reassessments required in paragraph (h) of this section, as well as the criteria specified in §460.92(b).

(h) *Reassessments in response to a service determination request.* (1) If the interdisciplinary team expects to deny or partially deny a service determination request, the appropriate members of the interdisciplinary team, as identified by the interdisciplinary team, must conduct an in-person reassessment before the interdisciplinary team makes a final decision. The team members performing the reassessment must evaluate whether the requested service is necessary to meet the participant's medical, physical, emotional, and social needs.

(2) The interdisciplinary team may conduct a reassessment prior to approving a service determination request, either in-person or through the use of remote technology, if the team determines that a reassessment is necessary.

(i) *Notification timeframe.* Except as provided in paragraph (i)(1) of this section, when the interdisciplinary team receives a service determination request, it must make its decision and notify the participant or their designated representative of its decision as expeditiously as the participant's condition requires, but no later than 3 calendar days after the date the interdisciplinary team receives the request.

(1) *Extensions.* The interdisciplinary team may extend the timeframe for review and notification by up to 5 calendar days if either of the following occur:

(i) The participant or other requestor listed in paragraph (c)(2) or (3) of this section requests the extension.

(ii) The extension is in the participant's interest because the interdisciplinary team needs additional information from an individual not directly employed by the PACE organization that may change the interdisciplinary team's decision to deny a service. The interdisciplinary team must document the circumstances that led to the extension and demonstrate how the extension is in the participant's best interest.

(2) *Notice of extension.* When the interdisciplinary team extends the timeframe, it must notify the participant or their designated representative either orally or in writing. The notice must explain the reason(s) for the delay and must be issued as expeditiously as the participant's condition requires, but no later than 24 hours after the IDT decides to extend the timeframe.

(j) *Notification requirements*—(1) *Notice of decisions to approve a service determination request.* If the interdisciplinary team makes a determination to approve a service determination request, it must provide the participant or the designated representative either oral or written notice of the determination. Notice of any decision to approve a service determination request must explain the conditions of the approval in understandable language, including when the participant may expect to receive the approved service.

(2) *Notice of decisions to deny a service determination request.* If the interdisciplinary team decides to deny or partially deny a service, it must provide the participant or the designated representative both oral and written notice of the determination. Notice of any denial must—

(i) State the specific reason(s) for the denial, including why the service is not necessary to maintain or improve the participant's overall health status, taking into account the participant's medical, physical, emotional, and social needs, and the results of the reassessment(s) in understandable language.

(ii) Inform the participant or designated representative of his or her right to appeal the decision under §460.122.

(iii) Describe 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.

(iv) For a Medicaid participant, inform the participant of both of the following, as specified in § 460.122(e)(1):

(A) His or her right to continue receiving disputed services during the appeals process until issuance of the final determination.

(B) The conditions for continuing to receive disputed services.

(k) *Effectuation requirements.* If the interdisciplinary team approves a service determination request, in whole or in part, the PACE organization must provide the approved service as expeditiously as the participant's condition requires, taking into account the participant's medical, physical, emotional, and social needs. The interdisciplinary team must explain when the participant may expect to receive the service in accordance with paragraph (j)(1) of this section.

(l) *Effect of failure to meet the processing timeframes.* 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.

(m) *Recordkeeping.* The PACE organization must establish and implement a process to document, track, and maintain records related to all processing requirements for service determination requests received both orally and in writing. These records must be available to the interdisciplinary team to ensure that all members remain alert to pertinent participant information.

[86 FR 6132, Jan. 19, 2021, as amended at 88 FR 22345, Apr. 12, 2023; 89 FR 30848, Apr. 23, 2024]

§ 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 request to initiate, modify or continue a service must first be processed as a service determination request under § 460.121 before the PACE organization can process an appeal under this section.

(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 service determination request or request for 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 §§ 460.121(i) and (m).

(2) How a participant or their designated representative files an appeal, including procedures for accepting oral and written appeal requests.

(3) Documentation of a participant's appeal.

(4) Review of an appeal by an appropriate third party reviewer or committee. An appropriate third party reviewer or member of a review committee must be an individual who meets all of the following:

(i) Appropriately credentialed in the field(s) or discipline(s) related to the appeal.

(ii) An impartial third party who meets both of the following:

(A) Was not involved in the original action.

(B) Does not have a stake in the outcome of the appeal.

(5) The distribution of written or electronic materials to the third party reviewer or committee that, at a minimum, explain all of the following:

(i) Services must be provided in a manner consistent with the requirements in §§ 460.92 and 460.98.

(ii) The need to make decisions in a manner consistent with how determinations under section 1862(a)(1)(A) of the Act are made.

(iii) The rules in § 460.90(a) that specify that certain limitations and conditions applicable to Medicare or Medicaid or both benefits do not apply.

(6) 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.

(7) Maintenance of confidentiality of appeals.

(d) *Opportunity to submit evidence.* A PACE organization must give all parties involved in the appeal 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) *Notification.* A PACE organization must give all parties involved in the appeal appropriate written notification of the decision to approve or deny the appeal.

(1) *Notice of a favorable decision.* Notice of any favorable decision must explain the conditions of the approval in understandable language.

(2) *Notice of partially or fully adverse decisions.* (i) Notice of any denial must—

(A) State the specific reason(s) for the denial;

(B) Explain the reason(s) why the service would not improve or maintain the participant's overall health status;

(C) Inform the participant of his or her right to appeal the decision; and

(D) Describe the external appeal rights under § 460.124.

(ii) At the same time the decision is made, the PACE organization must also notify the following:

(A) CMS.

(B) The State administering agency.

(h) *Actions following a favorable decision.* 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.

(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.

[64 FR 66279, Nov. 24, 1999, as amended at 71 FR 71336, Dec. 8, 2006; 84 FR 25675, June 3, 2019; 86 FR 6134, Jan. 19, 2021]

§ 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.

(a) *Appeal rights under Medicare.* Medicare participants have the right to a reconsideration by an independent review entity.

(1) A written request for reconsideration must be filed with the independent review entity within 60 calendar days from the date of the decision by the third party reviewer under § 460.122.

(2) The independent outside entity must conduct the review as expeditiously as the participant's health condition requires but must not exceed the deadlines specified in the contract.

(3) If the independent review entity conducts a reconsideration, the parties to the reconsideration are the same parties described in § 460.122(c)(2), with the addition of the PACE organization.

(b) *Appeal rights under Medicaid.* Medicaid participants have the right to a State Fair Hearing as described in part 431, subpart E, of this chapter.

(c) *Appeal rights for dual eligible participants.* Participants who are eligible for both Medicare and Medicaid have the right to external review by means of either the Independent Review Entity described in paragraph (a) of this section or the State Fair Hearing process described in paragraph (b) of this section.

[86 FR 6134, Jan. 19, 2021]

Subpart H—Quality Improvement

§ 460.130 General rule.

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

(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.

[64 FR 66279, Nov. 24, 1999, as amended at 84 FR 25676, June 3, 2019]

§ 460.132 Quality improvement plan.

(a) *Basic rule.* 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.

[64 FR 66279, Nov. 24, 1999, as amended at 84 FR 25676, June 3, 2019]

§ 460.134 Minimum requirements for quality improvement program.

(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:

(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.

[64 FR 66279, Nov. 24, 1999, as amended at 84 FR 25676, June 3, 2019]

§ 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.

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

(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.

(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.

[64 FR 66279, Nov. 24, 1999, as amended at 84 FR 25676, June 3, 2019]

§ 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.

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

[64 FR 66279, Nov. 24, 1999, as amended at 84 FR 25676, June 3, 2019]

Subpart I—Participant Enrollment and Disenrollment

§ 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.

[64 FR 66279, Nov. 24, 1999, as amended at 84 FR 25676, June 3, 2019]

§ 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; 84 FR 25676, June 3, 2019]

§ 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; 84 FR 25676, June 3, 2019]

§ 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.

(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.

(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.

[64 FR 66279, Nov. 24, 1999, as amended at 84 FR 25676, June 3, 2019]

§ 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.

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

§ 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.

(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.

[84 FR 25676, June 3, 2019]

§ 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:

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

(2) The participant, after a 30-day grace period, fails to pay or make satisfactory arrangements to pay any applicable Medicaid spend down 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.

(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.

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

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

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

(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:

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

(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.

(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:

(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.

(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.

[64 FR 66279, Nov. 24, 1999, as amended at 84 FR 25677, June 3, 2019]

§ 460.166 Disenrollment responsibilities.

(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.

[64 FR 66279, Nov. 24, 1999, as amended at 84 FR 25676, June 3, 2019]

§ 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.

(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.

[64 FR 66279, Nov. 24, 1999, as amended at 84 FR 25677, June 3, 2019]

§ 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.

[64 FR 66279, Nov. 24, 1999, as amended at 84 FR 25677, June 3, 2019]

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 adjusts 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. The provisions of § 422.310 of this chapter apply to PACE organizations and risk adjustment data submitted by PACE organizations to CMS. In applying § 422.310 to PACE organizations and risk adjustment of payments to PACE organizations, references to MA organizations are read as references to PACE organizations. CMS ensures 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; 90 FR 15921, Apr. 15, 2025]

§ 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.

(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.

[64 FR 66279, Nov. 24, 1999, as amended at 84 FR 25677, June 3, 2019]

§ 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;

(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.

(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.

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

[64 FR 66279, Nov. 24, 1999, as amended at 84 FR 25677, June 3, 2019]

§ 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.

[64 FR 66279, Nov. 24, 1999, as amended at 84 FR 25677, June 3, 2019]

§ 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:

(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) At their discretion, CMS or the State administering agency may monitor the effectiveness of corrective actions.

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

[64 FR 66279, Nov. 24, 1999, as amended at 84 FR 25677, June 3, 2019; 89 FR 30848, Apr. 23, 2024]

§ 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.

[64 FR 66279, Nov. 24, 1999, as amended at 84 FR 25677, June 3, 2019]

§ 460.198 Disclosure of compliance deficiencies.

CMS may require a PACE organization to disclose to its PACE participants or potential PACE participants the PACE organization's performance and contract compliance deficiencies in a manner specified by CMS.

[89 FR 30848, Apr. 23, 2024]

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)(i) Participant health outcomes data.

(ii) Financial books and records.

(iii) Medical records.

(iv) Personnel records.

(2) CMS and the State administering agency must be able to obtain, examine or retrieve the information specified at paragraph (b)(1) of this section, which may include reviewing information at the PACE site or remotely. PACE organizations may also be required to upload or electronically transmit information, or send hard copies of required information by mail.

(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 do all of the following:

(1) Establish written policies and implement procedures to safeguard all data, books, and records against loss, destruction, unauthorized use, or inappropriate alteration.

(2) Maintain all written communications received in any format (for example, emails, faxes, letters, etc.) from participants or other parties in their original form when the communications relate to a participant's care, health, or safety including, but not limited to the following:

(i) Communications from the participant, his or her designated representative, a family member, a caregiver, or any other individual who provides information pertinent to a participant's, care, health, or safety.

(ii) Communications from an advocacy or governmental agency such as Adult Protective Services.

(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) Ten years from the last entry date.

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

(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.

[64 FR 66279, Nov. 24, 1999, as amended at 84 FR 25677, June 3, 2019; 86 FR 6134, Jan. 19, 2021; 88 FR 22345, Apr. 12, 2023]

§ 460.202 Participant health outcomes data.

(a) A PACE organization must establish and maintain a health information system that collects, analyzes, integrates, and reports data necessary to measure the organization's performance, including outcomes of care furnished to participants.

(b) A PACE organization must furnish data and information pertaining to its provision of participant care in the manner, and at the time intervals, specified by CMS and the State administering agency.

[64 FR 66279, Nov. 24, 1999, as amended at 89 FR 30848, April 23, 2024]

§ 460.204 Financial recordkeeping and reporting requirements.

(a) *Accurate reports.* A PACE organization must provide CMS and the State administering agency with accurate financial reports that are—

(1) Prepared using an accrual basis of accounting; and

(2) Verifiable by qualified auditors.

(b) *Accrual accounting.* A PACE organization must maintain an accrual accounting recordkeeping system that does the following:

(1) Accurately documents all financial transactions.

(2) Provides an audit trail to source documents.

(3) Generates financial statements.

(c) *Accepted reporting practices.* Except as specified under Medicare principles of reimbursement, as defined in part 413 of this chapter, a PACE organization must follow standardized definitions, accounting, statistical, and reporting practices that are widely accepted in the health care industry.

(d) *Audit or inspection.* A PACE organization must permit CMS and the State administering agency to audit or inspect any books and records of original entry that pertain to the following:

(1) Any aspect of services furnished.

(2) Reconciliation of participants' benefit liabilities.

(3) Determination of Medicare and Medicaid amounts payable.

§ 460.208 Financial statements.

(a) *General rule.* (1) Not later than 180 days after the organization's fiscal year ends, a PACE organization must submit a certified financial statement that includes appropriate footnotes.

(2) The financial statement must be certified by an independent certified public accountant.

(b) *Contents.* At a minimum, the certified financial statement must consist of the following:

(1) A certification statement.

(2) A balance sheet.

(3) A statement of revenues and expenses.

(4) A source and use of funds statement.

(c) *Quarterly financial statement*—(1) *During trial period.* A PACE organization must submit a quarterly financial statement throughout the trial period within 45 days after the last day of each quarter of the PACE organization's fiscal year.

(2) *After trial period.* If CMS or the State administering agency determines that an organization's performance requires more frequent monitoring and oversight due to concerns about fiscal soundness, CMS or the State administering agency may require a PACE organization to submit monthly or quarterly financial statements, or both.

§ 460.210 Medical records.

(a) *Maintenance of medical records.* (1) A PACE organization must maintain a single, comprehensive medical record for each participant, in accordance with accepted professional standards.

(2) The medical record for each participant must meet the following requirements:

(i) Be complete.

(ii) Accurately documented.

(iii) Readily accessible.

(iv) Systematically organized.

(v) Available to all staff.

(vi) Maintained and housed at the PACE center where the participant receives services.

(b) *Content of medical records.* At a minimum, the medical record must contain the following:

(1) Appropriate identifying information.

(2) Documentation of all services furnished, including the following:

(i) A summary of emergency care and other inpatient or long-term care services.

(ii) Services furnished by employees of the PACE center.

(iii) Services furnished by contractors and their reports.

(3) Interdisciplinary assessments, reassessments, plans of care, treatment, and progress notes that include the participant's response to treatment.

(4) All recommendations for services made by employees or contractors of the PACE organization, including specialists.

(5) If a service recommended by an employee or contractor of the PACE organization, including a specialist, is not approved or provided, the reason(s) for not approving or providing that service.

(6) Original documentation, or an unaltered electronic copy, of any written communication as described in § 460.200(d)(2) must be maintained in the participant's medical record unless the following requirements are met:

(i) The medical record contains a thorough and accurate summary of the communication including all relevant aspects of the communication,

(ii) Original documentation of the communication is maintained outside of the medical record and is accessible by employees and contractors of the PACE organization when necessary, and in accordance with § 460.200(e), and

(iii) Original documentation of the communication is available to CMS and the SAA upon request.

(7) Laboratory, radiological and other test reports.

(8) Medication records.

(9) Hospital discharge summaries, if applicable.

(10) Reports of contact with informal support (for example, caregiver, legal guardian, or next of kin).

(11) Enrollment Agreement.

(12) Physician orders.

(13) Discharge summary and disenrollment justification, if applicable.

(14) Advance directives, if applicable.

(15) A signed release permitting disclosure of personal information.

(c) *Transfer of medical records.* The organization must promptly transfer copies of medical record information between treatment facilities.

(d) *Authentication of medical records.* (1) All entries must be legible, clear, complete, and appropriately authenticated and dated.

(2) Authentication must include signatures or a secured computer entry by a unique identifier of the primary author who has reviewed and approved the entry.

[64 FR 66279, Nov. 24, 1999, as amended at 71 FR 71337, Dec. 8, 2006; 86 FR 6135, Jan. 19, 2021; 88 FR 22345, Apr. 12, 2023]