Centers for Medicare & Medicaid Services, HHS § 460.150

(i) Physiological well being.
(ii) Functional status.
(iii) Cognitive ability.
(iv) Social/behavioral functioning.
(v) Quality of life of participants.

(4) Effectiveness and safety of staff-provided and contracted services, including the following:
   (i) Competency of clinical staff.
   (ii) Promptness of service delivery.
   (iii) Achievement of treatment goals and measurable outcomes.

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

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

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

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

§ 460.136 Internal quality assessment and performance improvement activities.

(a) Quality assessment and performance 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 assessment and performance 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 assessment and performance 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 assessment and performance 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 assessment and performance improvement activities, including providing information about their satisfaction with services.

§ 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 assessment and performance improvement plan.

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

§ 460.140 Additional quality assessment activities.

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

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 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 recipient. A potential PACE enrollee may be, but is not required to be, any or all of the following:

(1) Entitled to Medicare Part A.

(2) Enrolled under Medicare Part B.

(3) Eligible for Medicaid.

§460.152 Enrollment process.

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

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

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

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

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

(iv) Monthly premiums, if any.

(v) Any Medicaid spenddown obligations.

(vi) Post-eligibility treatment of income.

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

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

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

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

(1) Notify the individual in writing of the reason for the denial.

(2) Refer the individual to alternative services, as appropriate.
§ 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 recipient 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.
(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 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.
(q) The applicant’s authorization for disclosure and exchange of personal information between CMS, its agents, the State administering agency, and the PACE organization.
(r) The effective date of enrollment.
(s) The signature of the applicant or his or her designated representative and the date.
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§ 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.
(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.
(4) Stickers for the participant’s Medicare and Medicaid cards, as applicable, which indicate that he or she is a PACE participant and include the phone number of the PACE organization.
§ 460.158 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.

§ 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.

(c) Continued eligibility criteria. (i) The State administering agency, in consultation with the PACE organization, makes a determination of deemed continued eligibility based on a review of the participant’s medical record and plan of care. These criteria must be applied in reviewing the participant’s medical record and plan of care.
   (ii) The criteria used to make the determination of continued eligibility must be specified in the program agreement.

§ 460.162 Voluntary disenrollment.

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

§ 460.164 Involuntary disenrollment.

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

1. The participant fails to pay, or to make satisfactory arrangements to pay, any premium due the PACE organization after a 30-day grace period.
2. The participant engages in disruptive or threatening behavior, as described in paragraph (b) of this section.
3. 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.
4. The participant is determined to no longer meet the State Medicaid nursing facility level of care requirements and is not deemed eligible.
(5) The PACE program agreement with CMS and the State administering agency is not renewed or is terminated.

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

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

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

(2) 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.

(c) Documentation of disruptive or threatening behavior. If a PACE organization proposes to disenroll a participant who is disruptive or threatening, 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.

(d) 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.

(e) 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.

§ 460.166 Effective date of disenrollment.

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

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

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

(3) Give reasonable advance notice to the participant.

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

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

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

§ 460.168 Reinstatement in other Medicare and Medicaid programs.

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

(a) Make appropriate referrals and ensure medical records are made available to new providers in a timely manner.

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

§ 460.170 Reinstatement in PACE.

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

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

§ 460.172 Documentation of disenrollment.

A PACE organization must meet the following requirements:

(a) Have a procedure in place to document the reasons for all voluntary and involuntary disenrollments.
(b) Make documentation available for review by CMS and the State administering agency.

(c) Use the information on voluntary disenrollments in the PACE organization’s internal quality assessment and performance improvement program.

Subpart J—Payment

§ 460.180 Medicare payment to PACE organizations.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

(ii) Determine the amounts payable by those payers.

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