

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

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

(i) The participant requests the extension.

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

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

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

- (1) CMS.
- (2) The State administering agency.
- (3) The participant.

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

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

§ 460.124 Additional appeal rights under Medicare or Medicaid.

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

Subpart H—Quality Assessment and Performance Improvement

§ 460.130 General rule.

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

§ 460.132 Quality assessment and performance improvement plan.

(a) *Basic rule.* A PACE organization must have a written quality assessment and performance improvement plan.

(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 assessment and performance improvement activities.

§ 460.134 Minimum requirements for quality assessment and performance improvement program.

(a) *Minimum program requirements.* A PACE organization's quality assessment and performance 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:

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- (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 poten-

tially 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