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

1. Reevaluate the participant’s plan of care.
2. Discuss any changes in the plan with the interdisciplinary team.
3. Obtain approval of the revised plan from the interdisciplinary team and the participant (or designated representative).
4. Furnish any services included in the revised plan of care as a result of a reassessment to the participant as expeditiously as the participant’s health condition requires.

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

§ 460.106 Plan of care.

(a) Basic requirement. The interdisciplinary team must promptly develop a comprehensive plan of care for each participant.

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

1. Specify the care needed to meet the participant’s medical, physical, emotional, and social needs, as identified in the initial comprehensive assessment.
2. Identify measurable outcomes to be achieved.
3. Implementation of the plan of care. The team must implement, coordinate, and monitor the plan of care whether the services are furnished by PACE employees or contractors.
4. The team must continuously monitor the participant’s health and psychosocial status, as well as the effectiveness of the plan of care, through the provision of services, informal observation, input from participants or caregivers, and communications among members of the interdisciplinary team and other providers.
5. Evaluation of plan of care. On at least a semi-annual basis, the interdisciplinary team must reevaluate the plan of care, including defined outcomes, and make changes as necessary.

Subpart G—Participant Rights

§ 460.110 Bill of rights.

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

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

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

§ 460.112 Specific rights to which a participant is entitled.

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

1. To receive comprehensive health care in a safe and clean environment and in an accessible manner.
2. To be treated with dignity and respect, be afforded privacy and confidentiality in all aspects of care, and be provided humane care.
3. Not to be required to perform services for the PACE organization.
4. To have reasonable access to a telephone.
(5) To be free from harm, including physical or mental abuse, neglect, corporal punishment, involuntary seclusion, excessive medication, and any physical or chemical restraint imposed for purposes of discipline or convenience and not required to treat the participant’s medical symptoms.

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

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

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

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

(i) Before enrollment.

(ii) At enrollment.

(iii) 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 assisted 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.

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

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

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

(3) To disenroll from the program at any time.

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

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

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

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

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

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

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

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

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

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

§ 460.118  Violation of rights.

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

§ 460.120  Grievance process.

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

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

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

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

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

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

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

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

§ 460.122 PACE organization’s appeals process.

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

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

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

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

(1) Timely preparation and processing of a written denial of coverage or payment as provided in §460.104(c)(3).
(2) How a participant files an appeal.
(3) Documentation of a participant’s appeal.
(4) Appointment of an appropriately credentialed and impartial third party who was not involved in the original action and who does not have a stake in the outcome of the appeal to review the participant’s appeal.
(5) Responses to, and resolution of, appeals as expeditiously as the participant’s health condition requires, but no later than 30 calendar days after the organization receives an appeal.
(6) Maintenance of confidentiality of appeals.

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

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

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

(1) For a Medicaid participant, continue to furnish the disputed services until issuance of the final determination if the following conditions are met:
   (i) The PACE organization is proposing to terminate or reduce services currently being furnished to the participant.
   (ii) The participant requests continuation with the understanding that he or she may be liable for the costs of the contested services if the determination is not made in his or her favor.

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

(f) Expedited appeals process. (1) A PACE organization must have an expedited appeals process for situations in which the participant believes that his or her life, health, or ability to regain or maintain maximum function could be seriously jeopardized, absent provision of the service in dispute.
(2) Except as provided in paragraph (f)(3) of this section, the PACE organization must respond to the appeal as expeditiously as the participant’s health condition requires, but no later than 72 hours after it receives the appeal.

(3) The PACE organization may extend the 72-hour timeframe by up to 14 calendar days for either of the following reasons:
   (i) The participant requests the extension.
   (ii) The organization justifies to the State administering agency the need for additional information and how the delay is in the interest of the participant.

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

(h) Determination adverse to participant. For a determination that is wholly or partially adverse to a participant, at the same time the decision is made, the PACE organization must notify the following:
   (1) CMS.
   (2) The State administering agency.
   (3) The participant.

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