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

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

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

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

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

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

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

§ 460.106 Plan of care.

(a) *Basic requirement.* 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.

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

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

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

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

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

Subpart G—Participant Rights

§ 460.110 Bill of rights.

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

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

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

§ 460.112 Specific rights to which a participant is entitled.

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

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

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

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

(4) To have reasonable access to a telephone.

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

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

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

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

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

(i) 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 fur-

nish 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:

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

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

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

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

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

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

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

§ 460.114 Restraints.

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

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

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

(b) If the interdisciplinary team determines that a restraint is needed to ensure the participant's physical safety

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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