

(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.

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§ 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

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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 ap-

peals 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.