

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.

(a) *PACE organization's written appeals process.* The PACE organization