

(iii) Establishes a process to record recusal actions on a case-by-case basis.

(iv) Establishes a process to make available to the public the general recusal restrictions and record of actions.

(3) HCFA and the State administering agency may grant a waiver if they determine the following:

(i) There is insufficient availability in the PACE organization's service area of individuals who could meet the requirement.

(ii) The proposed alternative does not adversely affect the availability of care or the quality of care that is provided to participants.

(d) *Disclosure requirements.* A PACE organization must have a formal process in place to gather information related to paragraphs (a) and (b) of this section and must be able to respond in writing to a request for information from HCFA within a reasonable amount of time.

**§ 460.70 Contracted services.**

(a) *General rule.* The PACE organization must have a written contract with each outside organization, agency, or individual that furnishes administrative or care-related services not furnished directly by the PACE organization except for emergency services as described in § 460.100.

(b) *Contract requirements.* A contract between a PACE organization and a contractor must meet the following requirements:

(1) The PACE organization must contract only with an entity that meets all applicable Federal and State requirements, including, but not limited to, the following:

(i) An organizational contractor, such as a hospital, must meet Medicare or Medicaid participation requirements.

(ii) A practitioner or supplier must meet Medicare or Medicaid requirements applicable to the services it furnishes.

(iii) A contractor must comply with the requirements of this part with respect to service delivery, participant rights, and quality assessment and performance improvement activities.

(2) A contractor must be accessible to participants, located either within or

near the PACE organization's service area.

(3) A PACE organization must designate an official liaison to coordinate activities between contractors and the organization.

(c) *List of contractors.* A current list of contractors must be on file at the PACE center and a copy must be provided to anyone upon request.

(d) *Copies of signed contracts.* The PACE organization must furnish a copy of each signed contract for inpatient care to HCFA and the State administering agency.

(e) *Content of contract.* Each contract must be in writing and include the following information:

(1) Name of contractor.

(2) Services furnished.

(3) Payment rate and method.

(4) Terms of the contract, including beginning and ending dates, methods of extension, renegotiation, and termination.

(5) Contractor agreement to do the following:

(i) Furnish only those services authorized by the PACE multidisciplinary team.

(ii) Accept payment from the PACE organization as payment in full, and not bill participants, HCFA, the State administering agency, or private insurers.

(iii) Hold harmless HCFA, the State, and PACE participants if the PACE organization does not pay for services performed by the contractor in accordance with the contract.

(iv) Not assign the contract or delegate duties under the contract unless it obtains prior written approval from the PACE organization.

(v) Submit reports required by the PACE organization.

**§ 460.72 Physical environment.**

(a) *Space and equipment—(1) Safe design.* A PACE center must meet the following requirements:

(i) Be designed, constructed, equipped, and maintained to provide for the physical safety of participants, personnel, and visitors.

(ii) Ensure a safe, sanitary, functional, accessible, and comfortable environment for the delivery of services

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that protects the dignity and privacy of the participant.

(2) *Primary care clinic.* The PACE center must include sufficient suitable space and equipment to provide primary medical care and suitable space for team meetings, treatment, therapeutic recreation, restorative therapies, socialization, personal care, and dining.

(3) *Equipment maintenance.* A PACE organization must establish, implement, and maintain a written plan to ensure that all equipment is maintained in accordance with the manufacturer's recommendations.

(b) *Fire Safety.* (1) Except as provided in paragraph (b)(2) of this section, a PACE center must meet the occupancy provisions of the 1997 edition of the Life Safety Code of the National Fire Protection Association (which is incorporated by reference) that apply to the type of setting in which the center is located. Incorporation by reference of the Life Safety Code, 1997 edition, was approved by the Director of the FEDERAL REGISTER in accordance with 5 U.S.C. 552(a) and 1 CFR part 51. The Life Safety Code is available for inspection at the Office of the Federal Register, 800 North Capitol Street, N.W., Washington, D.C. Copies of the Life Safety Code may be obtained from the National Fire Protection Code (NFPA), 1 Batterymarch Park, P.O. Box 9101, Quincy, MA 02269-9101. If any changes in the Life Safety Code, 1997 edition, are also to be incorporated by reference, notice to that effect will be published in the FEDERAL REGISTER.

(2) *Exceptions.* (i) The Life Safety Code provisions do not apply in a State in which HCFA determines that a fire and safety code imposed by State law adequately protects participants and staff.

(ii) HCFA may waive specific provisions of the Life Safety Code that, if rigidly applied, would result in unreasonable hardship on the center, but only if the waiver does not adversely affect the health and safety of the participants and staff.

(c) *Emergency and disaster preparedness—(1) Procedures.* The PACE organization must establish, implement, and maintain documented procedures to manage medical and nonmedical emer-

gencies and disasters that are likely to threaten the health or safety of the participants, staff, or the public.

(2) *Emergencies defined.* Emergencies include, but are not limited, to the following:

(i) Fire.

(ii) Equipment, water, or power failure.

(iii) Care-related emergencies.

(iv) Natural disasters likely to occur in the organization's geographic area. (An organization is not required to develop emergency plans for natural disasters that typically do not affect its geographic location.)

(3) *Emergency training.* A PACE organization must provide appropriate training and periodic orientation to all staff (employees and contractors) and participants to ensure that staff demonstrate a knowledge of emergency procedures, including informing participants what to do, where to go, and whom to contact in case of an emergency.

(4) *Availability of emergency equipment.* Emergency equipment, including easily portable oxygen, airways, suction, and emergency drugs, along with staff who know how to use the equipment, must be on the premises of every center at all times and be immediately available. The organization must have a documented plan to obtain emergency medical assistance from sources outside the center when needed.

(5) *Annual test of emergency and disaster plan.* At least annually, a PACE organization must actually test, evaluate, and document the effectiveness of its emergency and disaster plans.

§ 460.74 **Infection control.**

(a) *Standard procedures.* The PACE organization must follow accepted policies and standard procedures with respect to infection control, including at least the standard precautions developed by the Centers for Disease Control and Prevention.

(b) *Infection control plan.* The PACE organization must establish, implement, and maintain a documented infection control plan that meets the following requirements:

(1) Ensures a safe and sanitary environment.