

§ 460.71

(ix) Cooperate with the competency evaluation program and direct participant care requirements specified in § 460.71.

(e) *Contracting with another entity to furnish PACE Center services.* (1) A PACE organization may only contract for PACE Center services if it is fiscally sound as defined in § 460.80(a) of this part and has demonstrated competence with the PACE model as evidenced by successful monitoring by CMS and the State administering agency.

(2) The PACE organization retains responsibility for all participants and may only contract for the PACE Center services identified in § 460.98(d).

[64 FR 66279, Nov. 24, 1999, as amended at 67 FR 61505, Oct. 1, 2002; 71 FR 71335, Dec. 8, 2006]

§ 460.71 Oversight of direct participant care.

(a) The PACE organization must ensure that all employees and contracted staff furnishing care directly to participants demonstrate the skills necessary for performance of their position.

(1) The PACE organization must provide each employee and all contracted staff with an orientation. The orientation must include at a minimum the organization's mission, philosophy, policies on participant rights, emergency plan, ethics, the PACE benefit, and any policies related to the job duties of specific staff.

(2) The PACE organization must develop a competency evaluation program that identifies those skills, knowledge, and abilities that must be demonstrated by direct participant care staff (employees and contractors).

(3) The competency program must be evidenced as completed before performing participant care and on an ongoing basis by qualified professionals.

(4) The PACE organization must designate a staff member to oversee these activities for employees and work with the PACE contractor liaison to ensure compliance by contracted staff.

(b) The PACE organization must develop a program to ensure that all staff furnishing direct participant care services meet the following requirements:

42 CFR Ch. IV (10–1–13 Edition)

(1) Comply with any State or Federal requirements for direct patient care staff in their respective settings.

(2) Comply with the requirements of § 460.68(a) regarding persons with criminal convictions.

(3) Have verified current certifications or licenses for their respective positions.

(4) Are free of communicable diseases and are up to date with immunizations before performing direct patient care.

(5) Have been oriented to the PACE program.

(6) Agree to abide by the philosophy, practices, and protocols of the PACE organization.

[67 FR 61505, Oct. 1, 2002, as amended at 71 FR 71335, Dec. 8, 2006]

§ 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 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.* (i) 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.

(ii) A PACE organization must perform the manufacturer's recommended maintenance on all equipment as indicated in the organization's written plan.

(b) *Fire safety*—(1) *General rule.* Except as otherwise provided in this section—

(i) A PACE center must meet the applicable provisions of the 2000 edition of the Life Safety Code (LSC) of the National Fire Protection Association

that apply to the type of setting in which the center is located. The Director of the Office of the Federal Register has approved the NFPA 101[®] 2000 edition of the Life Safety Code, issued January 14, 2000, for incorporation by reference in accordance with 5 U.S.C. 552(a) and 1 CFR part 51. A copy of the Code is available for inspection at the CMS Information Resource Center, 7500 Security Boulevard, Baltimore, MD or at the National Archives and Records Administration (NARA). For information on the availability of this material at NARA, call 202-741-6030, or go to:

http://www.archives.gov/federal_register/

[code_of_federal_regulations/ibr_locations.html](http://www.archives.gov/federal_register/code_of_federal_regulations/ibr_locations.html). Copies may be obtained from the National Fire Protection Association, 1 Batterymarch Park, Quincy, MA 02269. If any changes in this edition of the Code are incorporated by reference, CMS will publish notice in the FEDERAL REGISTER to announce the changes.

(ii) Chapter 19.3.6.3.2, exception number 2 of the adopted edition of the LSC does not apply to PACE centers.

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

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

(3) Beginning March 13, 2006, a PACE center must be in compliance with Chapter 9.2.9, Emergency Lighting.

(4) Beginning March 13, 2006, Chapter 19.3.6.3.2, exception number 2 does not apply to PACE centers.

(5) Notwithstanding any provisions of the 2000 edition of the Life Safety Code to the contrary, a PACE center may install alcohol-based hand rub dispensers in its facility if—

(i) Use of alcohol-based hand rub dispensers does not conflict with any State or local codes that prohibit or otherwise restrict the placement of alcohol-based hand rub dispensers in health care facilities;

(ii) The dispensers are installed in a manner that minimizes leaks and spills that could lead to falls;

(iii) The dispensers are installed in a manner that adequately protects against inappropriate access;

(iv) The dispensers are installed in accordance with chapter 18.3.2.7 or chapter 19.3.2.7 of the 2000 edition of the Life Safety Code, as amended by NFPA Temporary Interim Amendment 00-1(101), issued by the Standards Council of the National Fire Protection Association on April 15, 2004. The Director of the Office of the Federal Register has approved NFPA Temporary Interim Amendment 00-1(101) for incorporation by reference in accordance with 5 U.S.C. 552(a) and 1 CFR part 51. A copy of the amendment is available for inspection at the CMS Information Resource Center, 7500 Security Boulevard, Baltimore, MD and at the Office of the Federal Register, 800 North Capitol Street NW., Suite 700, Washington, DC. Copies may be obtained from the National Fire Protection Association, 1 Batterymarch Park, Quincy, MA 02269; and

(v) The dispensers are maintained in accordance with dispenser manufacturer guidelines.

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

§ 460.74

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.

[64 FR 66279, Nov. 24, 1999, as amended at 68 FR 1386, Jan. 10, 2003; 69 FR 49266, Aug. 11, 2004; 70 FR 15238, Mar. 25, 2005; 71 FR 55340, Sept. 22, 2006; 71 FR 71335, Dec. 8, 2006]

§ 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.

(2) Prevents and controls the transmission of disease and infection.

(c) *Contents of infection control plan.* The infection control plan must include, but is not limited to, the following:

(1) Procedures to identify, investigate, control, and prevent infections in every Pace center and in each participant's place of residence.

(2) Procedures to record any incidents of infection.

(3) Procedures to analyze the incidents of infection to identify trends and develop corrective actions related to the reduction of future incidents.

[64 FR 66279, Nov. 24, 1999, as amended at 71 FR 71334, Dec. 8, 2006]

42 CFR Ch. IV (10–1–13 Edition)

§ 460.76 Transportation services.

(a) *Safety, accessibility, and equipment.* A PACE organization's transportation services must be safe, accessible, and equipped to meet the needs of the participant population.

(b) *Maintenance of vehicles.* (1) If the PACE organization owns, rents, or leases transportation vehicles, it must maintain these vehicles in accordance with the manufacturer's recommendations.

(2) If a contractor provides transportation services, the PACE organization must ensure that the vehicles are maintained in accordance with the manufacturer's recommendations.

(c) *Communication with PACE center.* The PACE organization must ensure that transportation vehicles are equipped to communicate with the PACE center.

(d) *Training.* The PACE organization must train all transportation personnel (employees and contractors) in the following:

(1) Managing the special needs of participants.

(2) Handling emergency situations.

(e) *Changes in care plan.* As part of the interdisciplinary team process, PACE organization staff (employees and contractors) must communicate relevant changes in a participant's care plan to transportation personnel.

[64 FR 66279, Nov. 24, 1999, as amended at 71 FR 71334, Dec. 8, 2006]

§ 460.78 Dietary services.

(a) *Meal requirements.* (1) Except as specified in paragraphs (a)(2) or (a)(3) of this section, the PACE organization must ensure, through the assessment and care planning process, that each participant receives nourishing, palatable, well-balanced meals that meet the participant's daily nutritional and special dietary needs. Each meal must meet the following requirements:

(i) Be prepared by methods that conserve nutritive value, flavor, and appearance.

(ii) Be prepared in a form designed to meet individual needs.

(iii) Be prepared and served at the proper temperature.

(2) The PACE organization must provide substitute foods or nutritional