

# **Programs of All-Inclusive Care for the Elderly (PACE)**

## **Chapter 7 – Service Delivery Settings**

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## **10 - Introduction**

*(Rev. 2, Issued: 06-09-11; Effective: 06-03-11; Implementation: 06-03-11)*

The PACE organization will have a written plan and procedure specifying how the organization meets the individualized needs of each participant in all care settings 24-hours a day, every day of the year.

## **20 - PACE Center**

*(Rev. 2, Issued: 06-09-11; Effective: 06-03-11; Implementation: 06-03-11)*

### **20.1 - Physical Environment**

*(Rev. 2, Issued: 06-09-11; Effective: 06-03-11; Implementation: 06-03-11)*

The PACE organization's physical environment must be designed, constructed, equipped and maintained to provide for the physical safety of participants, personnel and caregivers, and visitors. The PACE organization is required to ensure a safe, sanitary, functional, accessible and comfortable environment for the delivery of services that protects the dignity and privacy of the participant. The PACE center must include:

- Suitable space and equipment to provide primary medical care and suitable space for treatment, restorative therapies, therapeutic recreation, socialization, dining and personal care. Examples include, but aren't limited to, food and nutritional supplement storage, meal preparation and serving and participant laundry;
- Suitable meeting space for personnel to conduct team meetings and for participants/caregivers, and visitors;
- Protecting the participant's privacy and dignity during the delivery of services.

The PACE organization must provide evidence that there are life safety code inspection results of fire marshal inspections, public health inspections, and other required state agency inspections.

The PACE organization must provide evidence of a federal Clinical Laboratory Improvement Amendment (CLIA) exemption if the center is performing waived laboratory services on site or in the home, e.g., glucose meter testing, urine testing, fecal occult blood testing, blood testing, cholesterol screening or hemoglobin or hematocrit testing.

In addition, the PACE organization must meet all applicable Federal, State, and local laws and regulations, which include the Americans with Disabilities Act and Section 504 of the Rehabilitation Act.

[42 CFR §§ 460.72(a)(1) and (2), and (b)(1); PACE State Readiness Review Guide]

## **20.2 - Frequency of Attendance at the PACE Center**

*(Rev. 2, Issued: 06-09-11; Effective: 06-03-11; Implementation: 06-03-11)*

The PACE center provides a point of service where the primary care clinic is located, where services are provided, and socialization occurs with staff that is consistent and familiar. Attendance at the center is an important aspect of the PACE model, which helps to differentiate it from home health care or institutional care.

The frequency of a participant's attendance at the center is determined by the IDT based on the needs and preferences of each participant. The PACE organization is required to maintain a written plan specifying the criteria used to determine frequency a participant attends the center. These criteria should take into account the participant's medical condition, behavioral, psychosocial and personnel care needs, caregiver support and preferences.

[42 CFR §§ 460.98(e); 460.106]

## **20.3 - Equipment**

*(Rev. 2, Issued: 06-09-11; Effective: 06-03-11; Implementation: 06-03-11)*

## **20.4 - Equipment Maintenance**

*(Rev. 2, Issued: 06-09-11; Effective: 06-03-11; Implementation: 06-03-11)*

A PACE organization must perform the manufacturer's recommended maintenance on all equipment as indicated in the manufacturer's written recommendations. This maintenance may be performed by PACE staff or contracted entities and in compliance with the contract.

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.

[42 CFR § 460.72(a)(3)]

## **20.5 - Emergency Procedures**

*(Rev. 2, Issued: 06-09-11; Effective: 06-03-11; Implementation: 06-03-11)*

The PACE organization is required to have trained personnel, drugs, and emergency equipment immediately available at every PACE center at all times to adequately support participants until Emergency Medical Services (EMS) responds to the PACE center. Each PACE center is required to have at least one staff member who has been trained in cardio-pulmonary resuscitation (CPR) and will be on site during the hours that participants are in attendance.

The minimum emergency equipment that must be on the premises and immediately available includes: portable oxygen, airways, suction, and emergency drugs.

The PACE organization must have a written plan and procedure for handling emergency situations that may arise including, but not limited to, cardiac arrest, choking and seizure activity.

In addition, the PACE center must have a documented plan to obtain Emergency Medical Services from sources outside the PACE center when needed. At least annually, a PACE organization must test, evaluate, and document the effectiveness of its emergency and disaster plans to ensure and maintain appropriate responses to the situations and needs that may arise from both medical and nonmedical emergencies.

[42 CFR § 460.72(c); 71 FR 71275 (Dec. 8, 2006)]

## **20.6 - Fire Safety**

*(Rev. 2, Issued: 06-09-11; Effective: 06-03-11; Implementation: 06-03-11)*

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. Copies of the code may be obtained from the National Fire Protection Association, 1 Batterymarch Park, Quincy, MA 02269 (<http://www.nfpa.org/index.asp?cookie%5Ftest=1>). CMS will publish any changes in the Federal Register to announce any changes in this edition.

The LSC 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 and CMS may waive specific provisions of the LSC 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 participants and staff.

Although there is specific waiver authority under the PACE statute, CMS PACE staff do not have the authority to approve waivers of the LSC. Rather, CMS staff responsible for Life Safety Code compliance would have to approve LSC waivers. Since PACE centers are often licensed as adult day health centers or clinics, they are not among the types of Medicare providers that CMS typically surveys for compliance with the LSC. As a result, CMS will accept State licensure requirements related to fire and safety as meeting the LSC.

The SAA assures that LSC requirements are met for facilities in which the PACE organization furnishes services to PACE participants in accordance with 42 CFR § 460.72(b).

CMS recognizes that the responsibility for certifying compliance with state licensure laws concerning fire safety may not be a direct function of the State Administering

Agency. For example, the clinical and building code expertise associated with this function may lend itself to a separate branch or State office.

However, CMS depends on the State Administering Agency as the single point of contact on all State-related requirements regardless of whether the functions are housed directly within the State Administering Agency. In the case of fire and safety codes imposed by State law, the State Administering Agency may find it necessary to secure appropriate documentation from the entity with jurisdiction over these areas.

Beginning March 13, 2006 a PACE center must be in compliance with the 2000 LSC Edition (Chapter 9.2.9) which states that Emergency Lighting must provide illumination for at least a 90-minute duration.

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 if:

- The 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 facilities in health care facilities;
- The dispensers are installed in such a manner that minimizes leaks and spills that could lead to falls;
- The dispensers are installed in a manner that adequately protects against inappropriate access;
- 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 National Fire Protection Association Temporary Interim Amendment; and
- The dispensers are maintained in accordance with dispenser manufacturer guidelines.

[42 CFR § 460.72(b); 71 FR 71275 (Dec. 8, 2006) and the PACE Program Agreement]

## **20.7 - Emergency and Disaster Preparedness**

*(Rev. 2, Issued: 06-09-11; Effective: 06-03-11; Implementation: 06-03-11)*

Emergencies include, but are not limited to, the following:

- Fire;
- Equipment, water or power failure;
- Care-related emergencies;

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

The PACE organization must establish, implement and maintain documented procedures to manage medical and non-medical emergencies and disasters that are likely to threaten the health and safety of participants, staff or the public. The Disaster Plan must address the organization's arrangements for emergency food, nutritional supplements and potable water supplies.

A PACE organization must provide appropriate training and periodic orientation to all employees and contracted staff and participants to ensure that all staff demonstrate a knowledge of emergency procedures, including information on what to do, where to go, and whom to contact in case of emergency.

At least annually, a PACE organization must actually test and evaluate the effectiveness of its emergency and disaster plans. Documentation must be maintained for all fire and disaster plan drills conducted by the PACE organization, along with records of all training conducted for employed and contracted staff.

[42 CFR § 460.72(c)]

## **20.8 - Participant Safety and Comfort**

*(Rev. 2, Issued: 06-09-11; Effective: 06-03-11; Implementation: 06-03-11)*

The PACE organization's physical environment must be designed, constructed, equipped and maintained to provide for the physical safety of participants, personnel caregivers, and visitors. The PACE organization is responsible for maintaining a safe, sanitary, functional, accessible and comfortable environment for the delivery of services that meet the physical needs and protects the dignity and privacy of the participant.

In order for the environment to be considered safe and comfortable, the PACE center, along with alternative care settings, must:

- Be accessible for the wheel chair bound person;
- Have entries and hallways wide enough to accommodate a stretcher;
- Ensure any handrails affixed to corridors are intact and free of splinters;
- Have a functioning call system in all bathing areas and participant toilets;
- Have water temperatures safe and comfortable;
- Have well-ventilated participant areas;

- Keep housekeeping compounds and other chemicals stored to prevent participant or visitor access;
- Be as free of accident hazards as possible;
- Be clean and pest free; and
- Be free of objectionable odors.

The PACE organization is expected to have a plan and procedure to address building security while open and after hours, including preventing participants from wandering offsite and a process for identifying participants and visitors.

[42 CFR § 460.72(a)(1); State Readiness Review Guide]

## **20.9 - Infection Control**

*(Rev. 2, Issued: 06-09-11; Effective: 06-03-11; Implementation: 06-03-11)*

The PACE organization must establish, implement, and maintain a documented infection control plan that ensures a safe and sanitary environment and prevents and controls the transmission of disease and infection. An infection control plan must include, but is not limited to: (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; and (3) procedures to analyze the incidents of infection, to identify trends and develop corrective actions related to the reduction of future incidents. PACE organizations are required to follow accepted policies and standard procedures with respect to infection control, including, at the least, the standard precautions developed by the Center for Disease Control and Prevention (CDC).

PACE organizations are expected to establish written policies and procedures for the investigation, control, and prevention of infections including:

- An OSHA Exposure Control Plan which includes the Universal Precautions and Bloodborne Pathogen exposure procedures for staff;
- Vaccinating participants and staff against diseases of particular concern for the PACE participant and the center's geographic location, e.g., influenza and pneumonia;
- Initial and ongoing health screening and vaccinations for staff and participants in accordance with OSHA regulations (staff) and CDC guidelines for tuberculosis, Hepatitis B and other communicable diseases;
- Written plans and procedures for the investigation, evaluation, resolution, and reporting of all incidences of staff and participant infection;

- Written plans and procedures for maintaining records of staff and participant infections to include post-exposure evaluation, training records, and participant and staff surveillance reports. Written plans and procedures for reporting required communicable diseases to the appropriate state and local officials;
- Plans and procedures for staff providing direct care to patients with infection(s);
- Provision of adequate facilities and supplies necessary for infection control to include:
  - Hand washing facilities and supplies;
  - Laundry facilities and supplies;
  - Isolation facilities and supplies;
- Written plans and procedures for addressing how laundry will be handled. If the service is contracted out, written agreements to comply with the requirements;
- Written plans and procedures for the ongoing monitoring of the contractual agreement provisions for laundry and waste disposal;
- Written plans and procedures for the appropriate handling and disposal of all waste products including blood and urine specimens for outside lab tests and other biohazardous wastes.

The CDC Guidelines for Environmental Infection Control in Health Care Facilities can be found at <http://www.cdc.gov/mmwr/preview/mmwrhtml/rr5210a1.htm>. The OSHA Guidelines for the handling of laundry and labeling of bio-hazardous waste can be found at [http://www.osha.gov/pls/oshaweb/owadisp.show\\_document?p\\_table=STANDARDS&p\\_id=10051#1910.1030\(d\)\(4\)\(iv\)](http://www.osha.gov/pls/oshaweb/owadisp.show_document?p_table=STANDARDS&p_id=10051#1910.1030(d)(4)(iv)). Should the State requirements be more stringent than those listed above, it is expected that the PACE organization will follow those requirements. Check with the State Administering Agency for the Guidelines for Environmental Infection Control in Health Care Facilities established by the State in which the PACE organization resides.

[42 CFR § 460.74]

### **30 - Alternative Care Settings**

*(Rev. 2, Issued: 06-09-11; Effective: 06-03-11; Implementation: 06-03-11)*

Alternative care settings are allowed when a limited number of services may be provided. An alternative care setting is a physical facility, other than the participant's place of residence, where PACE participants receive any of the required services. An adult day center used on the weekends for a blind participant is an alternate care setting.

All PACE organizations must notify CMS in writing (US mail or email) of any new arrangements being proposed whereby participants are transported from their place of residence to an alternative care setting. The arrangement minimally must describe what services will be offered, how the services will be provided, the number of participants receiving services in this setting, the location of the new setting, the staffing at the proposed new location, transportation arrangement to the new setting, Interdisciplinary team members involved, PACE Organization oversight of care provided at the new setting, and participant communication (both written and oral) considerations.

The following is an outlined procedure for the PACE organization:

- The PACE organization must notify the CMS Central Office team leader prior to opening or contracting with a provider to use an alternative care setting;
- The CMS Central Office team leader will contact the State Administering Agency to ascertain their knowledge of the new arrangement;
- The CMS Central Office team leader will schedule a conference call with your organization, the State Administering Agency and the CMS Regional Office to discuss details of the proposed arrangement;
- The CMS Central Office team leader will request additional written information from the PACE organization, if necessary, to ensure participants rights are upheld.

Additional information that may be requested:

- A listing of services offered at the alternative care setting;
- A description of the business relationship between the alternative care setting and the PACE organization;
- The location of the setting in relation to the approved service area;
- A description of staffing at the new setting;
- A description of transportation arrangements;
- A description of the interaction of interdisciplinary team members who oversee the care of participants attending the alternative care setting;
- PACE organization oversight of the alternative care setting;
- A description of how the building/space fire and safety codes meet the National Fire Protection Association 2000 guidelines;

- The proposed marketing strategy and material to be used to inform existing and new enrollees of the new setting.

[71 FR 71283 (Dec. 8, 2006); CMS Call Letter (June 23, 2004) and February 2006 Guidance]

#### **40 - Institutional Settings**

*(Rev. 2, Issued: 06-09-11; Effective: 06-03-11; Implementation: 06-03-11)*

Institutional settings include, but are not limited to, acute care hospitals, rehabilitation hospitals and distinct part rehabilitation units of acute care hospitals, psychiatric hospitals and distinct part psychiatric units of acute care hospitals, and critical access hospitals, nursing facilities and skilled nursing facilities. The PACE organization must contract only with institutional entities that meet all applicable Federal and State requirements as well as meet the Medicare or Medicaid participation requirements. There are provider specific Conditions of Participation for institutions that participate in the Medicare program. Therefore, all institutional contractors must be in compliance with their respective Conditions of Participation.

When a participant's care needs cannot be accommodated in the PACE center clinic and the organization extends its care options by contracting providers to deliver specialized services, the IDT does not "hand off" the participant's care; it expands the care team by collaborating with contracted specialists and placing participants in more appropriate healthcare settings to meet new needs. This concept is clearly supported by PACE regulations governing contracted services which require the PACE organization to maintain responsibility for the participant's care whether the care is delivered by the PACE organization or contractors. For example, when the PACE organization solicits services by a contractor or contracted facility, it must specify in the contract that the contractor furnishes only those services authorized by the PACE IDT and agrees to be accountable to the PACE organization. Or, when participants are admitted to an acute/long term/rehab facility or transferred temporarily, during that time away and upon return to program the Registered Dietician is responsible for maintaining communications as to the management of any dietary care plan changes and alters the nutrition program accordingly to keep current with the participant's health/medicinal/gastrointestinal changes.

PACE organizations cannot be reticent about exerting their contractual and regulatory authority to actively engage in the care of PACE participants placed in contracted facilities. CMS expects the PACE organization to establish a good working relationship with the contracted facility staff.

[42 CFR §§ 460.70; 460.78]

## Transmittals Issued for this Chapter

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| <a href="#">R2PACE</a> | 06/09/2011        | Initial Publication of Manual   | 06/03/2011       | NA         |
| R1_SO                  | 06/03/2011        | Initial Publication of Manual - Rescinded and replaced by Transmittal 2 | 06/03/2011       | NA         |

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