

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

Chapter 9 – Organization’s Relationship with Health Care Providers

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(Rev. 2, Issued: 06-09-11)

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10 - Employed Direct Care Providers

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

10.1 - Requirements for Employment

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

Each member of the PACE organization's staff who has direct participant contact (employee or contractor) must:

- Have a minimum of one year of experience working with the frail or elderly population including the Primary Care Physician (PCP);
- Be medically cleared of all communicable diseases and have all immunizations up-to-date before engaging in direct participant care;
- Be legally authorized (licensed, certified or registered) to practice in the State in which they practice if the State has established requirements or they must meet the State requirements that authorize them to practice in their State; and
- Only act within the scope of his or her authority to practice;
- Meet standardized competencies for the specific position description established by the PACE organization and approved by CMS before working independently (only applies to home care aides);
- A social worker must have a master's degree in social work from an accredited school of social work.

The PACE organization must ensure that these requirements are met and, as discussed in section [10.2](#), have policies and procedures regarding these requirements.

In order to maintain compliance with program integrity the PACE organization must:

- Not employ individuals excluded from participation in the Medicare or Medicaid programs;
- Not employ individuals convicted of Medicare, Medicaid, or other health insurance, health care, or any social service program-related crimes;
- Not employ individuals convicted of physical, sexual, drug, or alcohol abuse in any capacity where such individual's contact with participants would pose a potential risk.

[42 CFR §§ 460.64(a); 460.68(a)]

10.2 - Staff and Contractor Competencies

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

In order to comply with PACE requirements, it is required that the PACE organizations have a policy and procedure in place for assuring that staff and contractors:

- Are legally authorized (licensed, certified, registered) to practice in the State in which they provide services;
- Meet State requirements that authorize them to provide services; and,
- They only act within the scope of his or her authority to practice.

The policy and procedures would also demonstrate that the PACE organization has a system for updating staff competency information, and discloses, upon request, information regarding:

- Board certification and other credentialing requirements;
- Clinical protocols;
- Medical practice guidelines, consumer satisfaction survey results; or
- The results of the organization's most recent Federal or State review.

PACE organizations may wish to refer to credentialing guidance in the Medicare Managed Care Manual for a description of one option on which to build the policy and procedure:

<http://www.cms.gov/Manuals/IOM/itemdetail.asp?filterType=none&filterByDID=-99&sortByDID=1&sortOrder=ascending&itemID=CMS019326&intNumPerPage=10>.

[42 CFR § 460.64]

10.3 - Competency Assessment

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

The PACE organization must develop a competency evaluation program to ensure all employees and contracted staff providing direct care to participants can demonstrate the skills, knowledge and abilities necessary for performance of their position. 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. The competency evaluation program must be completed by each employee prior to providing direct participant care. An employee demonstrating competence for their position is essential to ensure the delivery of safe care.

All personnel, including personal care attendants, need to meet the credentialing criteria and a standardized set of competencies for their specific position prior to their engaging in direct participant care. The PACE organization's competency evaluation program must:

- Describe the minimum skills necessary to perform each specific job;
- Describe the process for initially testing competency;
- Identify the individual(s) responsible for competency testing for employees;
- Identify the individual designated to work with the PACE contractor liaison to ensure compliance by contracted staff;
- Explain how the PACE organization will resolve competency deficiencies.

The PACE organization must conduct an annual competency review with their employees, including personal care attendants. The PACE organization's annual competency review program will:

- Describe the periodic competency review program;
- Identify who is responsible for periodic competency review;
- Explain how the PACE organization will resolve competency deficiencies.

[460 CFR § 460.66(a) and (c); 460.71(a)]

20 - Requirements for Employees and Contracted Staff

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

20.1 - Orientation and Training

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

The PACE organization is required to provide training to maintain and improve the skills and knowledge of each staff member with respect to the individual's specific duties that result in his or her continued ability to demonstrate the skills necessary for the performance of the position.

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. 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.

The PACE organization must develop a training program that will:

- Identify the person and position responsible for the overall training program;
- Describe the content of the training program including initial orientation and periodic refresher training including PACE-specific topics and position-specific topics;
- Describe the instructors, methods of teaching, methods of testing, and results of any testing (written or oral); and
- Discuss how the PACE organization will resolve knowledge deficits.

[42 CFR §§ 460.66(a), 460.71(a)(1)]

20.2 - Orientation

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

The PACE organization must provide a comprehensive orientation program to each employee and all contracted staff. Documentation of completion date(s) for each and every component of the orientation must be maintained in staff records. This orientation must be provided prior to personnel engaging in direct participant care. 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. Additionally, the orientation may include, but isn't limited to:

- Role of the team;
- Organizational Chart: who everyone is on the team and at the center;
- Standards of care and conduct;
- QI program: overview, principles, the staff role;
- List of providers;
- OSHA, standard precautions, infection reporting, waste management;
- Participant safety;
- Care of the elderly;
- Training on medical equipment used in the PACE organization;

- Body mechanics;
- Personnel policies;
- Medical documentation requirements.

[42 CFR § 460.71(a)]

20.3 - Personal Care Aide (PCA) Training

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

In addition to the general training program, the PACE organization must develop a training program for each directly employed and contracted PCA in order to establish the individual's baseline competency in furnishing personal care services and specialized skills associated with the specific care needs of individual participants. The training plan must indicate how each skill is tested to determine the PCA's initial and ongoing competency. The PACE organization must evaluate the skills of each newly hired PCA and develop a training program specific to the competencies or deficiencies that they demonstrate. PCAs must exhibit competency before performing personal care services independently. A process must be in place for monitoring ongoing competency assessments and identify the individual responsible for supervising PCAs. This training must be performed by qualified professionals. The personnel file must contain the results of any testing, both written and oral.

[42 CFR § 460.66(b) and (c)]

20.4 - All Personnel: Direct Participant Care Training

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

The PACE organization must provide ongoing training to maintain and improve the skills and knowledge of each employee and contracted staff member with respect to their specific duties in order to ensure that PACE participants receive the highest quality care possible. A PACE organization has the ultimate responsibility for all care provided to their participants and, therefore, it is in the best interest of PACE participants and the PACE organization that they provide training specific to their participant population. Ongoing in-service training for all staff will ensure that skills remain current and any detrimental practices are caught and rectified as early as possible.

Annual training must be related to specific positions which include relevant topics. Training needs to be staggered throughout the year to enable all staff to participate. The training program needs to describe plans for in-service training, the methods of teaching including handouts, pre and post test, if applicable, and the person/position conducting the training. Some PACE organizations may have the ability to use the health care facility to which they are related or they may use an outside agency for training purposes.

OSHA training must be provided on hire and is required annually, [29 CFR 1910.1030(g)(2)] by a qualified trainer. The employee cannot be given just a manual, pamphlet or policy to read. This training must be given in an interactive session with a trainer present.

[42 CFR §§ 460.66(a); 460.71]

20.5 - Immunization and Physical Health

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

The PACE regulation stipulates that the PACE organization must develop and implement an infection control plan having specific procedures to prevent, identify, investigate, and control infections. Specifically, this regulation mandates compliance with the standard precautions developed by the Center for Disease Control and Prevention (CDC). A primary standard precaution in caring for the frail elderly population is immunization of healthcare workers. The CDC strongly recommends that healthcare workers be immunized against hepatitis B virus, influenza, measles, mumps, rubella, and varicella to protect them from acquiring or transmitting these vaccine-preventable infections.

The PACE organization must also include procedures in its infection control plan to prevent healthcare workers from acquiring or transmitting tuberculosis and bloodborne pathogens. In the exposure control section of the infection control plan, the PACE organization must identify the specific job classifications that perform duties in which exposure to active tuberculosis disease or bloodborne pathogens occurs. In a typical PACE organization, most, if not all, healthcare workers deliver direct care services to participants and should be classified as at-risk for exposure to these pathogens.

Pursuant to CDC recommendations, CMS issued regulation 42 CFR § 460.64(a)(5) which states that staff having direct participant contact must be “medically cleared for communicable diseases and have all immunizations up to date before engaging in direct participant contact.” To meet this regulatory requirement, CMS expects the PACE organization to minimally take the following actions:

- Develop and implement policies and procedures to assure medical clearance during the pre-employment period. Medical clearance refers to appropriate management of:
 - Respiratory infections - appropriate precautions such as wearing face masks or other personal protective equipment (PPE) or delaying the start date for providing direct care when prospective employees present with respiratory infections (common colds, pneumonia, etc.) which are transmittable through close contact;
 - Skin infections – appropriate precautions such as requiring the covering of open and seeping lesions or delaying the start date for providing direct care when prospective employees present with skin infections (methicillin-

resistant *Staphylococcus aureus* (MRSA), varicella zoster (shingles), pediculosis (lice infestation), etc.) which are transmittable through close contact;

- Gastrointestinal infections – appropriate precautions such as delaying the start date for providing direct care when prospective employees present with gastrointestinal (GI) symptoms (vomiting or diarrhea related to acute viral hepatitis, food-borne bacterial infections, etc.) which are transmittable through close contact;
- The PACE organization must determine the methodology (medical history tool, interview by clinician, etc.) by which it will assure that participants and other healthcare workers at the facility have protection in the workplace from exposure to infectious diseases. The State Administering Agency and jurisdictional public health agency may be important resources in developing these policies and procedures;

Develop and implement policies and procedures to assure appropriate healthcare worker immunization.

Additional information on CDC recommendations for immunizations of staff can be found at the following links:

Centers for Disease Control and Prevention, Immunization of Health-Care Workers: recommendations of the Advisory Committee on Immunization Practices (ACIP) and the Hospital Infection Control Practices Advisory Committee (HICPAC). MMWR 1997;46(No. RR-18): <http://ftp.cdc.gov/pub/Publications/mmwr/rr/rr4618.pdf>.

Centers for Disease Control and Prevention, Protecting Health Care Workers: <http://www.cdc.gov/ncidod/dhqp/worker.html>.

Centers for Disease Control and Prevention, Influenza Vaccination of Health-Care Personnel: recommendations of the Healthcare Infection Control Practices Advisory Committee (HICPAC) and the Advisory Committee on Immunization Practices (ACIP): <http://www.cdc.gov/mmwr/preview/mmwrhtml/rr5502a1.htm>.

Centers for Disease Control and Prevention, Guidelines for Preventing the Transmission of *Mycobacterium tuberculosis* in Health-Care Settings, 2005. MMWR 2005;54(No. RR-17): <http://www.cdc.gov/mmwr/pdf/rr/rr5417.pdf>.

30 - Contract Providers

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

The PACE organization must develop a policy and procedure that provides for formal oversight activities such as periodic observation of service delivery, review of service

documentation, assurance of participation in refresher training, and review of applicable credentials.

[42 CFR § 460.71]

30.1 - Requirements for Written Contracts and Contract Requirements *(Rev. 2, Issued: 06-09-11; Effective: 06-03-11; Implementation: 06-03-11)*

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

Each contract needs to be in writing and contain the following information:

- Name of contractor;
- Services furnished (including work schedule if appropriate);
- Payment rate and method; and
- Terms of the contract, including the beginning and ending dates, as well as methods of extension, renegotiation, and termination.

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:

- An institutional contractor, such as a hospital or skilled nursing facility, must meet Medicare or Medicaid participation requirements;
- A practitioner or supplier must meet Medicare or Medicaid requirements applicable to the services it furnishes;
- 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; and

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

[42 CFR §§ 460.70(a), (b), (c), and (d)(1) through (4)]

30.2 - Requirements of Contract Providers and Vendors

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

In addition to the contract requirements in section [30.1](#) above, a contractor agreement must include the following written requirements for the contractor to adhere to:

- Furnish only those services authorized by the PACE IDT;
- Accept payment from the PACE organization as payment in full and not bill participants, CMS, the State Medicaid agency or private insurers;
- Hold harmless CMS, the State and PACE participants if the PACE organization cannot or will not pay for services performed by the contractor under the contract;
- Not assign the contract or delegate duties under the contract unless prior written approval is obtained from the PACE organization;
- Submit reports as required by the PACE organization;
- Agree to perform all the duties related to its position as specified in Part 460;
- Participate in IDT meetings as required;
- Agree to be accountable to the PACE organization; and
- Comply with the competency evaluation program and direct participant care requirements specified in 42 CFR § 460.71.

[42 CFR § 460.70(d)(5)]

30.3 - Requirements of Institutional Contractors, and Practitioners or Suppliers

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

Institutional providers 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 and Medicaid participation requirements. There is 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.

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

[42 CFR § 460.70]

40 - Special Rules for Emergency Care

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

Authorization is required for services a participant may need while temporarily absent from the PACE organization's service area that are not emergency services but cannot be delayed until the participant returns.

A PACE organization must establish a written plan for handling emergency health care needs. The plan must include that the participants and their caregiver know:

- When and how to access emergency services;
- That no prior approval is necessary for emergency services;
- That CMS, the State and PACE participants are held harmless for emergency services;
- That the PACE organization must provide for availability of on-call providers to address any participant questions about accessing emergency services and respond to requests for authorization of urgently needed out-of network services or post-stabilization.

Listed below are the types of services that fall under this special rule category:

- Emergency care is appropriate when services are needed immediately because of an injury or sudden illness and the time required to reach the PACE organization or a network provider would cause the risk of permanent damage to the participant's health. Thus, emergency care services include inpatient and outpatient services, furnished by a qualified emergency services provider (other than the PACE organization or one of its contract providers) either in or

out of the PACE organization's service area and that are needed to evaluate or stabilize an emergency medical condition. Emergency services that fall within this description do not require authorization by the PACE organization. Determination of the need for emergency care is dependent on the prudent layperson standard with average knowledge of health and medicine;

- Urgent care means the care provided to a PACE participant who is out of the PACE services area, and who believes their illness or injury is too severe to postpone treatment until they return to the service area, but their life or functioning is not in severe jeopardy. Participants are expected to seek prior approval from the PACE organization in order for urgent care services to be covered by the PACE organization;
- Post-stabilization care means services provided subsequent to an emergency that a treating physician views as medically necessary after an emergency medical condition has been stabilized. They are not emergency services, which PACE organizations are obligated to cover. Rather, they are non-emergency services that the PACE organization should approve before they are provided outside of the service area. Prior approval of these services is intended to ensure efficient and timely coordination of appropriate post emergency care by the IDT. In order to ensure that unforeseen circumstances do not result in delays in needed care, CMS clarified that the PACE organization must cover urgently needed out-of-network or post-stabilization care services if it does not respond to a request for approval within one hour after being contacted or cannot be contacted for approval.

[42 CFR § 460.100(b), (c), (d) and (e); 71 FR 71284 (Dec. 8, 2006)]

50 - Contracting with another Entity to Furnish PACE Center Services ***(Rev. 2, Issued: 06-09-11; Effective: 06-03-11; Implementation: 06-03-11)***

The PACE organization must meet certain criteria to contract out PACE center services. The following criteria must be included:

- Any subcontracting arrangements by the PACE center would need to be approved in writing by the PACE organization;
- The PACE organization must be fiscally sound as defined in 42 CFR § 460.80(a) and have demonstrated competence with the PACE model as evidenced by successful CMS and State onsite reviews and monitoring efforts.

The PACE organization retains responsibility for all participants and may only contract for the PACE center services identified in 42 CFR § 460.98(d) as described in detail in [Chapter 6](#), which include: primary care, social services, restorative therapies, personal care and supportive services, nutritional counseling, recreational therapy, and meals.

[42 CFR § 460.70(e)]

60 - Documenting Contractor Compliance

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

The burden of documenting contractors' compliance with applicable standards ultimately rests with the PACE organization.

It is especially important to identify specific responsibilities of a contractor. The PACE organization must develop its own procedures to ensure that the entity complies with the standards of competency and quality of care.

The PACE organization must not contract with organizations or individuals who have been excluded from the Medicare or Medicaid programs; who have been convicted of criminal offenses related to their involvement in Medicaid, Medicare, other health insurance or health care programs, or social service programs under Title XX of the Act; or for those having participant contact, who would pose a potential risk because of prior physical, sexual, drug, or alcohol abuse conviction.

The PACE organization must contract with only those entities that meet all applicable Federal and State requirements.

All employees and contractors must meet the personnel qualifications for the physician, registered nurse, social worker, physical therapist, occupational therapist, recreational therapist, dietitian and driver.

Although the PACE organization is not performing the actual compliance checks (in the case of a hospital, physician, medical equipment, or supplies), the organization must ensure that the contractor is in compliance with the written contract. The written contract must state that the contractor will meet all applicable Federal and State requirements allowing the PACE organization some flexibility in determining the organizational process that will occur to ensure their contractors meet all program requirements.

In the case of an independent contractor or provider-based organization who provides direct participant care and has not been credentialed through a Medicare or Medicaid contracting organization, the PACE organization will have to receive the same documents from the contractor as they would for an employee. If the contractor is working for the contracted organization and not independently, then the contracted organization must forward all of their staff credentials prior to performing participant care.

The PACE organization is responsible for not only ensuring the contract staff meet requirements at the onset of the contract, but on an ongoing basis. The contract organization has to have a process in place to ensure this compliance and the PACE organization has to have a process to review contract compliance. The contract organization must have a process in place to notify the PACE organization when one of their staff is out of compliance so that the PACE organization does not utilize that staff

member for participant care (in the case of a license expiring, other sanctions, or illegal activity).

[42 CFR §§ 460.64; 460.68(a); 460.70(b)(1)]

Transmittals Issued for this Chapter

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