

§ 460.70

(b) *Direct or indirect interest in contracts.* Except as provided in paragraph (c) of this section, no member of the PACE organization's governing body or any immediate family member may have a direct or indirect interest in any contract that supplies any administrative or care-related service or materials to the PACE organization.

(c) *Waiver.* (1) CMS and the State administering agency may waive the requirement in paragraph (b) of this section for PACE organizations in the following communities:

- (i) Rural.
- (ii) Tribal.
- (iii) Urban Indian.

(2) If an applicant seeking approval as a PACE organization believes a waiver under this paragraph is warranted, it must include a request for the waiver in its application that meets the following requirements:

- (i) Identifies the rural, tribal, or urban Indian community.
- (ii) Establishes recusal restrictions for each member of the PACE organization governing body or immediate family member to which the exception would apply.
- (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) CMS 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 CMS within a reasonable amount of time.

EFFECTIVE DATE NOTE: At 67 FR 61505, Oct. 1, 2002, § 460.68 was amended by revising paragraph (b), and paragraph (c) was removed and reserved, effective Oct. 31, 2002. For the con-

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venience of the user, the revised text is set forth as follows:

§ 460.68 Program integrity.

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(b) *Direct or indirect interest in contracts.* No member of the PACE organization's governing body or any immediate family member may have a direct or indirect interest in any contract that supplies any administrative or care-related service or materials to the PACE organization.

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§ 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.

Centers for Medicare & Medicaid Services, HHS

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(d) *Copies of signed contracts.* The PACE organization must furnish a copy of each signed contract for inpatient care to CMS 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, CMS, the State administering agency, or private insurers.
 - (iii) Hold harmless CMS, 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.

EFFECTIVE DATE NOTE: At 67 FR 61505, Oct. 1, 2002, in §460.70, paragraphs (b)(1)(i) and (e)(2) were revised, and paragraphs (e)(5)(vi) through (ix) and (f) were added, effective Oct. 31, 2002. For the convenience of the user, the revised and added text is set forth as follows:

§ 460.70 Contracted services.

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- (b) * * *
- (1) * * *
- (i) An institutional contractor, such as a hospital or skilled nursing facility, must meet Medicare or Medicaid participation requirements.
- * * * * *
- (e) * * *
- (1) * * *

(2) Services furnished (including work schedule if appropriate).

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- (5) * * *
- * * * * *
- (vi) Agree to perform all the duties related to its position as specified in this part.
- (vii) Participate in interdisciplinary team meeting as required.
- (viii) Agree to be accountable to the PACE organization.
- (ix) Cooperate with the competency evaluation program and direct participant care requirements specified in §460.71.
- (f) *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).

§ 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.