# PACE APPLICATION REVIEW GUIDE
# DESK REVIEW

This PACE Application Review Guide (Review Guide) has been developed solely for internal operational use by the Centers for Medicare and Medicaid Services (CMS) staff members to guide them in reviewing applications submitted by entities seeking to be approved by CMS as PACE organizations. The Review Guide is not part of the PACE regulation. CMS has made the Review Guide available only as a convenience to potential PACE applicants. The Review Guide is intended to serve as a helpful reference to clarify and inform in preparation of a PACE application to CMS. The Review Guide is not a substitute for the PACE application form itself, or for the PACE regulations at 42 C.F.R. Part 460, or for information published by CMS interpreting the PACE regulations such as manual instructions, interpretive rules, statements of policy, or guidelines of general applicability. Because this document is designed exclusively for internal operational use by CMS staff, CMS reserves the right to modify this document unilaterally at any time, and without notice to PACE applicants.

**VERSION EIGHT (b)**

MARCH 2004

Acknowledgments

The PACE Application Review Guide represents the collaborative efforts of CHPP, CMSO, OCSQ and many individuals in the Regional Offices.

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This significant amount of work by the teams was accomplished under a two-month time frame during the summer months of 2000. This project would not have been completed in such a timely manner without the dedication and time commitment of these teams.

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**CHAPTER 1 GENERAL INFORMATION AND ORGANIZATIONAL**

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| **§460.22 Service area designation**<br><br>(a) An entity must state in its application the services area it proposes for its program<br>(b) CMS, in consultation with the State administering agency, may exclude from designation an area that is already covered under another PACE program agreement to avoid unnecessary duplication of services and avoid impairing the financial and service viability of an existing program. | **Cross – Reference:**<br>§460.82 Marketing; §460.112 Specific rights to which a participant is entitled; §460.150 Eligibility to enroll<br>**Desk Review:**<br>• **Review the** State Administering Agency's **service area** approved for this PACE Organization (PO).<br>• **Review the PO's marketing materials** to include anything that describes their service area from their marketing plan to brochures and fact sheets that are given to the community and participants.<br>• **Review location of PACE center(s)** in relation to the hospital(s). This is also addressed in §460.98. | Service area: |

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| **§460.52 Transitional care during termination.**<br><br>(a) the PACE organization must develop a detailed written plan for phase-down in the event of termination, which describes how the organization plans to take the following actions:<br>(1)Inform participants, the community, CMS and the State administering agency in writing about termination and transition procedures.<br>(2) Assist participants to obtain reinstatement of conventional Medicare and Medicaid benefits.<br>(3)Transition participants' care to other providers.<br>(4)Terminate marketing and enrollment activities.<br>(b) An entity whose PACE program agreement is in the process of being terminated must provide assistance to each participant in obtaining necessary transitional care through appropriate referrals and making the participant's medical records available to new providers. | **Cross – Reference:**<br>§460.168 Reinstatement in other Medicare and Medicaid programs<br>**Desk Review:**<br>• **Review the PO's written plan** for phase down in the event of termination. Determine if the plan contains detailed procedures as specified in (a)(1)(2)(3)(4)(b) of this regulatory citation. | |

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| **§ 460.60 PACE organizational structure**<br><br>(a) A PACE organization must be, or be a distinct part of, one of the following:<br>(1) An entity of city, county, State, or Tribal government.<br>(2) A private not-for-profit entity organized for charitable purposes under section 501(c)(3) of the Internal Revenue Code of 1986. The entity may be a corporation, a subsidiary of a larger corporation, or a department of a corporation.<br>(b) *Program director.* The organization must employ, or contract with in accordance with §460.70, a program director who is responsible for oversight and administration of the entity.<br>(c) *Medical director.* The organization must employ, or contract with in accordance with § 460.70, a medical director who is responsible for the delivery of participant care, for clinical outcomes, and for the implementation, as well as oversight, of the quality | **Cross - Reference:** §460.102(f)(1)(5)<br>Interdisciplinary team<br>**Desk Review:**<br>• **Review documentation** of type of entity. Review IRS Section **501(c)(3)** tax-exempt letter to PO or parent entity. If the PO is a Catholic organization, or subsidiary or department of the Catholic organization, review "The Official Catholic Directory", published annually whereby such entities are recognized as tax-exempt under a group ruling.<br>• Review the documentation of how the PO is organized. If parent entity holds 501(c)(3), **determine relationship of parent** and PO through review of organizational chart<br>• **Review resume, position description and organizational chart** to determine if the program and medical director positions exist. In the case of a nonoperational provider, ascertain if these positions have been hired or an contractual agreement signed. If not, then the SAA will need to assure that these positons will be in place prior to the effective date of the program agreement.<br>• **Review the organizational chart.** The chart must show the PO's relationship to their board and to any parent, affiliate or subsidiary. The chart must also have the names of each leader, director, manager and the reporting relationships. | |

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| assessment and performance improvement program.<br>(d) *Organizational chart.*<br>(1) The PACE organization must have a current organizational chart showing officials in the PACE organization and relationships to any other organizational entities.<br>(2) The chart for a corporate entity must indicate the PACE organization's relationship to the corporate board and to any parent, affiliate, or subsidiary corporate entities.<br>(3) A PACE organization planning a change in organizational structure must notify CMS and the State administering agency, in writing, at least 60 days before the change takes effect.<br>(4) Changes in organizational structure must be approved in advance by CMS and the State administering agency.<br>(5) Changes in organizational structure approved by CMS and the State administering agency must be forwarded to the consumer advisory committee described in | HIPAA Privacy Compliance:<br>• Organization has appointed a privacy officer, documentation of this should be in the board minutes<br>• Privacy officer has a job description, review<br>• Verify the contact person for handling all HIPAA privacy complaints | |

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| §460.62(c) of this part for dissemination to participants as appropriate. | | |
| **§460.62 Governing body**<br><br>(a) *Governing body.* A PACE organization must be operating under the control of an identifiable governing body (for example, a board of directors) or a designated person functioning as a governing body with full legal authority and | **Cross - reference:**<br>§460.60 PACE organizational structure; §460.132 Quality assessment and improvement plan; §460.138 Committees with community input.<br>**Desk Review:**<br>• **Review PO's description of the governing body.** Does the board have governance/legal authority to operate the PO? Does it have responsibility for development of participant care and safety and personnel policies, management of all services, staff, contractors, and fiscal operations?<br>• **Review the consumer advisory committee list.** Does the committee have a participant and | |

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| responsibility for the following:<br>(1) Governance and operation of the organization.<br>(2) Development of policies consistent with the mission.<br>(3) Management and provision of all services, including the management of contractors.<br>(4) Establishment of personnel policies that address adequate notice of termination by employees or contractors with direct patient care responsibilities.<br>(5) Fiscal operations.<br>(6) Development of policies on participant health and safety, including a comprehensive, systemic operational plan to ensure the health and safety of participants.<br>(7) Quality assessment and performance improvement program<br>(b) *Community representation.* A PACE organization must ensure community | **list.** Does the committee have a participant and representatives of participants as a majority? If this is a new organization without any participants, the PO needs to explain how and when they will have this majority.<br>**NOTE TO REVIEWER:** The community representation may be on the board. The PO doesn't necessarily need to have a separate community committee. | |

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| representation on issues related to participant care. This may be achieved by having a community representative on the governing body.<br>(c) *Consumer advisory committee.* A PACE organization must establish a consumer advisory committee to provide advice to the governing body on matters of concern to participants. Participants and representatives of participants must constitute a majority of the membership of this committee. | | |

**CHAPTER 2 PACE ADMINSTRATION**

| REGULATION | REVIEWER GUIDANCE | REVIEWER NOTES |
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| **§460.64 Personnel qualifications.**<br><br>(a) *General qualification requirements.* Except as specified in paragraphs (b) and (c) of this section, each member of the staff (employee or contractor) of the PACE organization must meet the following conditions:<br>(1) Be legally authorized (currently licensed or if applicable, certified or registered) to practice in the State in which he or she performs the functions or actions.<br>(2) Only act within the scope of his or her authority to practice.<br>(b) *Federally-defined qualifications for physician.* (1) A physician must meet the qualifications and conditions in §410.20 of this chapter.<br>(2) A primary care physician must have a minimum of 1 year's experience working with a frail or elderly population.<br>(c) *Qualifications when no State licensing laws, State certification, or registration* | **Cross – Reference:**<br>§460.66 Training; §460.76 Transportation Services; §460.102 Interdisciplinary team.<br>**Desk Review:**<br>• **Identify** that the following **positions exist** either by a hiring agreement or a contract:<br>  • Physician, RN, Social Worker, PT, OT, Recreation Therapist, Dietitian, Drivers<br>• **Review the position descriptions** for the above positions to ensure that they include the qualifications required in §460.64 (**These will be found in Chapter 5).** | |

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| *requirements exist.* If there are no State licensing laws, State certification, or registration applicable to the profession, the following requirements must be met:<br>(1) *Registered Nurse.* A registered nurse must meet the following requirements:<br>(i) Be a graduate of a school of professional nursing.<br>(ii) Have a minimum of 1 years' experience working with a frail or elderly population.<br>(2) *Social worker.* A social worker must meet the following requirements:<br>(i) Have a master's degree in social work from an accredited school of social work<br>(ii) Have a minimum of 1 year's experience working with a frail or elderly population<br>(3) *Physical therapist.* A physical therapist must meet the following requirements:<br>(i) Be a graduate of a physical therapy curriculum approved by one of the following:<br>(A) The American Physical Therapy Association. | | |

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| (B) The Committee on Allied Health Education and Accreditation of the American Medical Association.<br>(C) The Council on Medical Education of the American Medical Association and the American Physical Therapy Association<br>(D) Other equivalent. organizations approved by the Secretary.<br>(ii) Have a minimum of 1 year's experience working with a frail or elderly population.<br>(4) *Occupational therapist.* An occupational therapist must meet the following requirements:<br>(i) Be a graduate of an occupational therapy curriculum accredited jointly by the Committee on Allied Health Education and Accreditation of the American Medical Association and the American Occupational Therapy Association or other equivalent organizations approved by the Secretary.<br>(ii) Be eligible for the National Registration | | |

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| Examination of the American Occupational Therapy Association.<br>(iii) Have 2 years of appropriate experience as an occupational therapist and have achieved a satisfactory grade on an proficiency examination conducted, approved, or sponsored by the U.S. Public Health Service, except that the determination of proficiency does not apply with respect to persons initially licensed by a State or seeking initial qualification as an occupational therapist after December 31, 1977.<br>(iv) Have a minimum of 1 year's experience working with a frail or elderly population.<br>(5) *Recreation therapist or activities coordinator.* A recreation therapist or activities coordinator must have 2 years experience in a social or recreational program providing and coordination services for a frail or elderly population with the last 5 years, one of | | |

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| which was full-time in a patient activities program in a health care setting.<br>(6) *Dietitian.* A dietitian must meet the following requirements:<br>(i) Have a baccalaureate or advanced degree from an accredited college with major studies in food and nutrition or dietetics.<br>(ii) Have a minimum of 1 year's experience working with a frail or elderly population.<br>(7) *Drivers.* A PACE center driver must meet the following requirements:<br>(i) Have a valid driver's license to operate a van or bus in the State of operation.<br>(ii) Be capable of, and experienced in, transporting individuals with special mobility needs. | | |

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| **460.66 Training**<br><br>(a) The PACE organization must provide training to maintain and improve the skills and knowledge of each staff member with respect to the individual's specific duties that results in his or her continued ability to demonstrate the skills necessary for the performance of the position.<br>(b) The PACE organization must develop a training program for each personal care attendant to establish the individual's competency in furnishing personal care services and specialized skills associated with specific care needs of individual participants. | **Cross – reference:**<br>§460.102 Interdisciplinary team.<br>**Desk Review:**<br>• **Review training** description. The PO should have a detailed description of their plan for initial competency testing and ongoing skills review. The plan minimally needs to address:<br>  • Minimum skills necessary to perform job (this information may be found in the position description). Every direct participant care staff member should have skills necessary to perform the job.<br>  • How does the PO know that the staff can perform what they say they can perform? Self-assessment skills list DOES NOT meet the intent of the regulation of "ability to demonstrate the skills necessary…" What process is in place to check the skills of staff initially and an ongoing basis? It may not be appropriate to "deem" staff competent solely because they have a license and practiced in a health care setting unless the PO can verify which skills are "transferable" due to knowledge of the health care setting and receiving recent documented evidence that the staff person has demonstrated those skills necessary to perform in the PACE program.<br>  • The training program should describe plans for inservices, training, methods of teaching and testing, and by whom. (NOTE: This information can be received on-site if not contained in the application). Some PO's may have the ability to use the health care facility with which they are linked.<br>• **Review the personal care attendants training program** description. The program description | |

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| | should detail the following:<br>• The skills listed that are necessary for the personal care attendant.<br>• How each of the skills listed will be tested to determine the PCA's competency.<br>• Who is responsible in the PO for determining competency of the PCA's.<br>If and when there are skills that are not observed, what criteria would have to be met? For example, The PCA has transferred to the applicant PO from another PO recently and the applicant organization could deem the PCA competent for certain skills since the settings and procedures for that particular skill are the same. Caution – deeming any staff, especially unlicensed staff is not appropriate unless the provider knows the policy and procedures that govern clinical practice at the organization that the staff is coming from, in addition to similar settings and the competency program at that organization. In those cases where a PCA is required by law to be certified, that certification does not alone ensure competency of the PCA. The PO still needs to ensure the competency level of the PCA in furnishing personal care services and other specialized skills with this frail elderly population in this particular setting utilizing the standards of care that the PO has set.<br><br>HIPAA Privacy Compliance for Education and training:<br>• The organization has a written training plan for new hires and existing staff. The training plan must include a timeline for training all existing staff.<br>• The organization has training records of | |

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| | mandatory attendance by all staff<br>• If staffs have been reassigned to new duties, he/she has been retrained in any Privacy issues that may be relevant in this new position. | |
| **§460.68 Program integrity**<br><br>(a) *Persons with criminal convictions.* A PACE organization must not employ individuals or contract with organizations or individuals –<br>(1) Who have been excluded from participation in the Medicare or Medicaid programs;<br>(2) 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<br>(3) In any capacity where an individual's contact with participants would pose a potential risk because the individual has been convicted of physical, sexual, drug, or alcohol abuse. | **Cross – Reference:**<br>§460.32 Program Agreement; §460.70 Contracted Services; §460.64 Personnel Qualifications.<br>**Desk Review:**<br>• **Review the organization's process for background checks** of individuals involved in direct contact with participants. The process needs to be defined and systematic for initial hires, ongoing and needs to include contracted staff. The PO is not responsible for completing background checks on contractors; however must ensure that the contractor/contracted organization complies with the federal regulation under Title XVIII and XIX.<br>• **Review the organization's process for** accessing the current list that CMS has for tracking excluded individuals from the Medicare/Medicaid program<br>• **Review the organization's conflict of interest process.** The policy must state/describe how conflict of interests are defined, identified and addressed for board members that may have direct or indirect interest in any contract that supplies administrative or care-related services (i.e. all leadership staff). Determine that there is a defined process not only to disclose conflicts, but also what information is reported, how the information is reported, who receives the information and how management would make decisions after a conflict is discovered. | |

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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.<br><br>(c) Reserved<br><br>(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. | | |

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| **§460.70 Contracted services.**<br><br>(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.<br>(b)*Contract requirements.* A contract between a PACE organization and a contractor must meet the following requirements: | **Cross - Reference:**<br>**§**460.40 Violations for which CMS may impose sanctions; §460.64 Personnel qualifications; §460.68 Program Integrity; §460.76 Transportation services; §460.102 Interdisciplinary team; §460.112 Specific rights to which a participant is entitled; §460.132 Quality assessment and performance improvement plan; §460.134 Minimum requirements for quality assessment and performance improvement program; §460.136 Internal quality assessment and performance improvement activities; §460.190 Monitoring during trial period.<br>**Desk Review:**<br>• **Review template of each contract** the organization has to provide administrative and care - related services. Cross reference the services delivery table to make certain all of the services that the organization state are contracted are represented by a template or executed contracted attached with the application. **NOTE TO REVIEWER: The regulation states there must be a written contract with each *outside organization.*** If the PACE organization is part of a health care system and furnishes its inpatient services through that healthcare system, this arrangement **may not** require a written contract. Although it is recommended to have a written agreement to | Contracts missing:<br><br>List areas, by contract name, not addressed in the contract: |

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| (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:<br><br>(i) An institutional contractor, such as a hospital or skilled nursing facility, must meet Medicare or Medicaid participation requirements.<br>(ii) A practitioner or supplier must meet Medicare or Medicaid requirements applicable to the services it furnishes.<br>(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.<br>(2) A contractor must be accessible to participants, located either within or near the PACE organization's service area.<br>(3) A PACE organization must designate an official liaison | provide both parties with their responsibilities, the PACE organization does not have to contract with its own organizations, *unless required by their State law or parent organization's policy.*<br>• Contract must include all the requirements set forth in this section.<br>• **Review process** organization has in place to keep a current list of contractors.<br>HIPAA compliance, "Providers to providers" for the purposes of a business associate relationship are both covered entities thus are acting on their own behalf. The use and disclosure of PHI is permitted by the HIPAA privacy rule. Providers to Providers are not considered business associates, thus no business associate agreement provisions apply here.<br><br>**EXAMPLES of Business Associate Relationships:**<br>• An organization out-sources claims processing and data warehousing;<br>• An organization has a contract with a shredding company;<br>• An organization hires a pharmacy benefits manager;<br>• An organization hires a medical transcription services firm;<br>• An organization hires a third party administrator to assist with claims processing.<br>These relationships require a Business Associate Agreement to comply with the HIPAA provisions, which are: The business associate will:<br>☐ Not use or disclose PHI other than as permitted by the agreement or required by law;<br>☐ Use appropriate safeguards to protect the | **Name of the Contractor liaison:** |

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| to coordinate activities between contractors and the organization.<br>*(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.<br>(d) C*opies of signed contracts.* The PACE organization must furnish a copy of each signed contract for inpatient care to CMS and the State administering agency.<br>(e) *Content of contract.* Each contract must be in writing and include the following information:<br>(1) Name of contractor.<br>(2) Services furnished (including work schedule if appropriate).<br>(3) Payment rate and method.<br>(4) Terms of the contract, including beginning and ending dates, methods of extension, renegotiation and termination.<br>(5) Contractor agreement to do the following:<br>(i) Furnish only those services authorized by the PACE interdisciplinary team.<br>(ii) Accept payment from the PACE Organization as payment in full, and | confidentiality of the information;<br>☐ Report to the organization any use or disclosure not permitted b the agreement<br>☐ Ensure that any of its agents or subcontractors will agree to the same restrictions and conditions as the business associate;<br>☐ Make available to the contractor any information necessary for the contractor to comply with the individual's right to access, amend and receive accounting of disclosures of their PHI;<br>☐ Make available to the secretary of the Department of Health and Human Services the business associate's internal practices, books and records relating to the use and disclosure of the PHI;<br>☐ Return or destroy the information once the contract is terminated, if feasible; if it is not possible to return or destroy the information because o other obligations or legal requirements the protections o the agreement must apply until the information is returned or destroyed, and no other uses or disclosures may be made except for the purposes that prevented the return of destruction of the information;<br>☐ Must provide that if an organization knows of a pattern of activity or practices of the business associate that is a material breach or violation of the business associate's obligation under the agreement, then the organization must take "reasonable steps" to cure the breach or end the violation. If these measures are unsuccessful, the organization must terminate the agreement if feasible. If | |

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| | not bill participants, CMS, the State administering agency, or private insurers. | this is not feasible the organization must report the violation to the Office for Civil Rights. | |
| (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. | | |
| (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 | | |

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| in §460.71.<br>(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.<br>(2) The PACE organization retains responsibility for all participants and may only contract for the PACE Center services identified in §460.98(d).<br><br>**§460.71 Oversight of direct participant care.**<br>(a) The PACE organization must ensure that all employees and contracted staff furnishing care directly to participants demonstrate the skills | | |

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| necessary for performance of their position.<br>(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.<br>(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).<br>(3) The competency program must be evidenced as completed before performing participant care and on going basis by qualified professionals.<br>(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 | | |

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| staff.<br>(b) The PACE organization must develop a program to ensure that all staff furnishing direct participant care services meet the following requirements:<br>(1) Comply with any State or Federal requirements for direct patient care staff in their respective settings.<br>(2) Comply with the requirements of §460.68(a) regarding persons with criminal convictions.<br>(3) Have verified current certifications or licenses for their respective positions.<br>(4) Are free of communicable diseases.<br>(5) Have been oriented to the PACE program.<br>(6) Agree to abide by the philosophy, practices, and protocols of the PACE organization. | **Cross-Reference:**<br>§460.64 Personnel Qualifications, §460.66 Training, §460.68 Program Integrity, §460.70 Contracted Services<br>**Desk Review:**<br>• Review the organization's description (found usually under §460.66 and §460.68) for their orientation program, initial skills testing, ongoing competency program, background checks, credential verification. The description must include both employees and contracted staff and organizations. | |
| **§460.72 Physical** | **Cross-Reference:** | |

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| **Environment.**<br><br>(a) *Space and equipment* - (1) *Safe design.* A PACE center must meet the following requirements:<br>(i) Be designed, constructed, equipped, and maintained to provide for the physical safety of participants, personnel, and visitors.<br>(ii) Ensure a safe, sanitary, functional, accessible, and comfortable environment for the delivery of services that protects the dignity and privacy of the participant.<br>*(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.<br><br>*(3) Equipment maintenance.* A PACE organization must establish, implement, and maintain a written plan to ensure that all equipment is | §460.66 Training; §460.112 Specific rights for which a participant is entitled; §460.134 Minimum requirements for quality assessment and performance improvement program.<br>**Desk Review:**<br>• **Review organization's plan** to provide required services in a safe and comfortable manner that meets the Life Safety Code requirements for occupancy.<br>• **Review the organization's plan for equipment maintenance.** The plan must:<br>  • Be written<br>  • Identify equipment<br>  • Identify how manufacturer's recommendations are going to be met<br>  • Identify the maintenance schedule<br>  • Identify who will be responsible for maintaining the equipment and record keeping<br>  • Include plans and procedures to report device related death and serious injuries to the FDA and/or the manufacturer of the equipment in accordance with the Safe Medical Devices Act of 1990<br>• **Review organization's medical and non-medical emergency plan.** The plan must include, minimally:<br>  • A plan that addresses medical and non-medical emergencies specifically at the PACE center(s) – and not the parent organization (e.g. the hospital/health care system), transporting participants and staff, at the participants home and anywhere in the service area.<br>  • Procedures to manage medical emergencies, including responding to DNR's, | |

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| maintained in accordance with the manufacturer's recommendations.<br><br>(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 1CFR 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, | or any other Advance directives, choking, chest pain, seizures, stopped breathing or cessation of heart.<br>• Procedures for the periodic examination of all emergency drugs to confirm expiration dates(s) and inventory control.<br>• Procedures for staff training on and drills for the center's emergency procedures, including the use of emergency drugs and emergency equipment.<br>• Basic Life Support certification for staff likely to provide participant care. Although all staff are not required to have CPR certification, there should always be at least one person in the building at all times that is certified. All staff should be trained in choking and first aid or emergency response.<br>• Procedures for verifying emergency drugs and emergency equipment are readily available, operating, and clean including: portable oxygen, airways, and suction equipment.<br>• Procedures to manage non-medical emergencies and any natural disasters affecting the center's geographic location including:<br>  • method of containment of fire,<br>  • evacuation plans and routes and adequate emergency lighting at exits and corridors,<br>  • power outages,<br>  • staffing in the event of a work stoppage,<br>  • problems with water supply and transfer of participants to other sites.<br>• Periodic drills<br>• Continuing care needs for participants at | |

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| are also to be incorporated by reference, notice to the effect will be published in the **Federal Register.**<br>*(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.<br>(ii) CMS 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.<br>(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.<br>*(2) Emergencies defined.* Emergencies include, but | home, what arrangements would be made to provide care in the event of inclement weather,<br>• Procedures for safe evacuation of staff, participants and visitors | |

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| are not limited, to the following:<br>(i) Fire.<br>(ii) Equipment, water, or power failure.<br>(iii) Care-related emergencies.<br>(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).<br>*(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.<br>*(4) Availability of emergency equipment.* Emergency equipment, including easily portable oxygen, airways, suction and emergency drugs, along with staff who | | |

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| 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.<br>(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.**<br><br>(a) *Standard procedures.* The PACE organization must follow accepted policies and standard procedures with respect to infection | **Cross – Reference:**<br>§460.32 Content and terms of PACE program agreement; §460.136 Internal quality assessment and performance improvement activities.<br>**Desk Review:**<br>• **Review the infection control plan.** The plan must include, minimally:<br>• Procedures for the investigation, control and prevention of staff and participant infections which includes: | |

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| control, including at least the standard precautions developed by the Centers for Disease Control and Prevention.<br>(b) *Infection control plan.* The PACE organization must establish, implement and maintain a documented infection control plan that meets the following requirements:<br>(1) Ensures a safe and sanitary environment.<br>(2) Prevents and controls the transmission of disease and infection.<br>(c) *Contents of infection control plan.* The infection control plan must include, but is not limited to, the following:<br>(1) Procedures to identify, investigate, control, and prevent infections in every center and in each participant's place of residence.<br>(2) Procedures to record any incidents of infection.<br>(3) Procedures to analyze the incidents of infection to identify trends and develop corrective actions related to the reduction of future incidents. | • Procedures for the investigation, evaluation, resolution and reporting of all incidences of staff and participant infection<br>• Procedures for maintaining records of staff and participant infections to include post-exposure evaluation, training records and participant surveillance reports<br>• Procedure for mandatory reporting of communicable diseases to the appropriate State and local officials<br>• A written OSHA Exposure Control Plan which includes the Standard Precautions and Bloodborne Pathogen exposure procedures, training and record keeping for staff (including contractors and volunteers)<br>• Vaccinating participants and staff against diseases of particular concern for the PACE participant and the center's geographic location, i.e. influenza, pneumonia, hepatitis<br>• Initial and ongoing health screening (TB) and vaccination (HBV) for staff and participants in accordance with OSHA regulations (staff) and CDC guidelines for tuberculosis, Hepatitis B and other communicable diseases<br>• Procedure for providing care to patients with infection(s)<br>• Procedures for addressing laundry handling<br>• Procedures for waste disposal to include handling and disposal of all waste products including blood and urine specimens for outside lab test and other bio-hazardous wastes<br>The actual policies do not need to accompany the application; however at least a description of the infection control plan that includes all of the areas above | |

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| | above. | |
| **§460.76 Transportation services.**<br><br>(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.<br>(b) *Maintenance of vehicles.*<br>(1) If the PACE organization owns, rents, or leases transportation vehicles, it must maintain these vehicles in accordance with the manufacturer's recommendations.<br>(2) If a contractor provides transportation services, the PACE organization must ensure that the vehicles are maintained in accordance with the manufacturer's recommendations | **Cross – Reference:**<br>**§460.66**Training; **§460.70** Contracted services; §460.102 Interdisciplinary team; §460.106Plan of care.<br>**Desk Review:**<br>• **Review description of the communication** process for the drivers to keep in contact with the center when in transit with participants<br>• **Review description of the training** that is given to the drivers and/or contracted services<br>• **Review description of** how participant status is communicated with the team | |

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| *(c) Communication with PACE center.* The PACE organization must ensure that transportation vehicles are equipped to communicate with the PACE center.<br>*(d) Training.* The PACE organization must train all transportation personnel (employees and contractors) in the following:<br>(1) Managing the special needs of participants.<br>*(2)* Handling emergency situations.<br>(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. | | |

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| **§460.78 Dietary services.**<br><br>(a) *Meal requirements.* (1) Except as specified in paragraphs (a)(2) or (a)(3) of this section, the PACE organization must provide each participant with a nourishing, palatable, well-balanced meal that meets the daily nutritional and special dietary needs of each participant. Each meal must meet the following requirements:<br>(i) Be prepared by methods that conserve nutritive value, flavor, and appearance.<br>(ii) Be prepared in a form designed to meet individual needs.<br>(iii) Be prepared and served at the proper temperature.<br>(2)The PACE organization must provide substitute foods or | **Cross – Reference:**<br>§460.72 Physical Environment; §460. 92 Required services; §460.104 Participant Assessment; §460.106 Plan of care.<br>**Desk Review:**<br>• **Review plan** for providing meals at the center and at home, if necessary.<br>• **Review plan** for providing special diets, and enteral or parenteral nutrition. | |

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| nutritional supplements that meet the daily nutritional and special dietary needs of any participant who has any of the following problems:<br>(i) Refuses the food served<br>(ii) Cannot tolerate the food served<br>(iii) Does not eat adequately<br>(3) The PACE organization must provide nutrition support to meet the daily nutritional needs of a participant, if indicated by his or her medical condition or diagnosis. Nutrition support consists of tube feedings, total parenteral nutrition, or peripheral parenteral nutrition.<br>(b) *Sanitary conditions***.** The PACE organization must do the following:<br>**(1)** Procure foods (including nutritional supplements and nutrition support items) from sources approved, or considered satisfactory, by Federal, state, Tribal, or local authorities with jurisdiction over the service area of the organization.<br>**(2)** Store, prepare, distribute, and serve foods (including nutritional supplements and | | |

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| nutrition support items) under sanitary conditions.<br>**(3)** Dispose of garbage and refuse properly. | | |

**CHAPTER 3 – FINANCIAL**

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| § **460.80 Fiscal Soundness**<br><br>(a) *Fiscally sound operation.* A PACE organization must have a fiscally sound operation, as demonstrated by the following:<br>(1)Total Assets greater than total unsubordinated liabilities.<br>(2) Sufficient cash flow and adequate liquidity to meet obligations as they become due.<br>(3) A net operating surplus or a financial plan for maintaining solvency that is satisfactory to CMS and the State Administering Agency. | **Cross-reference:** §460.62 Governing Body.<br><br>**Desk Review:**<br>• **Review the** PO's fiscal soundness by its audited and unaudited financial statements.<br>• **Review the** financial sponsor's audited statements, if applicable. (Ensure financial sponsor is in good standing with Medicare and/or Medicaid.) **Cross reference the List of Excluded Individuals and Entities (LEIE) in Chapter 2.**<br>• **Review t**he PO's Annual Report, if applicable.<br>• **Review t**he PO's prospectus, if applicable.<br>• Financial projections through break-even and one year beyond are in the application. Reports included are:<br>  • Quarterly balance sheets<br>  • Quarterly statements of revenues & expenses<br>  • Quarterly statements of cash flows<br>  • Statement & justification of assumptions including enrollment and utilization<br><br>• The PO describes state reserve and other financial requirements.<br>• Are the reserves restricted?<br><br>• **Evaluate financials and projections for**:<br>  • Are there sufficient cash reserves?<br>  • Does the PO meet State requirements?<br>• Does the PO have adequate net working capital? (1:1 current ratio or better)<br>• Are projections reasonable?<br>• Does the PO have adequate financing to break-even as projected? | *Financial Ratio Calculations*<br>Total Assets > Unsubordinated Liabilities<br><br>Cash Flow Analysis<br><br>Describe any restrictions or reserves:<br><br>Current Net Operating Surplus and/or Financial Plan (Projections) |

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| | • Is the PO able to obtain additional capital funding beyond current fiscal year if additional losses are anticipated? (Examples – open line of credit, state of parent support/funding)<br>• Do the PO's projections demonstrate adequate net worth? | |
| *(b) Insolvency Plan*<br>The organization must have a documented plan in the event of insolvency, approved by Centers for Medicare and Medicaid Services, and the State administering agency, which provides for the following:<br>(1) Continuation of benefits for the duration of the period for which capitation payment has been made.<br>(2) Continuation of benefits to participants who are confined in a hospital on the date of insolvency until their discharge.<br>(3) Protection of participants from liability for payment of fees that are the legal obligation of the PACE organization. | • **The PO has a plan for the event of insolvency plan that provides for:**<br>  • The continuation of benefits for the premium period and until discharge if in a hospital on the date of insolvency.<br>  • Protection of participants from liability for payments that are the legal obligation of the PO. | |
| *(c) Arrangements to Cover Expenses*<br>(1) A PACE Organization must demonstrate that it has arrangements to cover expenses in the amount of at | • PO has arrangements to cover expenses in the amount of at least the sum of the month before and after insolvency or insurance, hold harmless or other means that will cover expenses. | |

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| least the sum of the following in the event it becomes insolvent:<br>(i) One month's total capitation revenue to cover expenses the month before insolvency.<br>(ii) One month's average payment to all contractors, based on the prior quarter's average payment, to cover expenses the month after the date it declares insolvency or ceases operation.<br>(2) Arrangements to cover expenses may include, but are not limited to, the following:<br>(i) Insolvency insurance or reinsurance.<br>(ii) Hold harmless arrangement.<br>(iii) Letters of credit, guarantees, net worth, restricted State reserves, or State law provisions. | | Specified Arrangement: |
| **§460.204 Financial Record -** | **Cross – Reference:** §460.200 Maintenance of | |

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| **keeping and reporting requirements.**<br><br>*(a) Accurate Reports.*<br>A PACE Organization must provide CMS and the State Administering Agency with accurate financial reports that are-<br>(1) Prepared using an accrual basis of accounting; and<br>(2) Verifiable by qualified auditors<br>*(b) Accrual Accounting.*<br>A PACE Organization must maintain an accrual accounting record keeping system that does the following:<br>(1) Accurately documents all financial transactions.<br>(2) Provides and audit trail to source documents.<br>(3) Generates financial statements.<br>*(c) Accepted Reporting Practices.*<br>Except as specified under Medicare principles of reimbursement, as defined in part 413 of this chapter, a PACE Organization must follow standardized definitions, accounting, statistical, and reporting practices that are widely accepted in the health care industry. | records and reporting of data.<br><br>No desk review required | |

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| *(d) Audit or Inspection.*<br>A PACE Organization must permit CMS and the State administering agency to audit or inspect any books and records of original entry that pertain to the following:<br>(1) any aspect of services furnished<br>(2) Reconciliation of participants' benefit liabilities<br>(3) Determination of Medicare and Medicaid amounts payable.<br><br>**§460.208 Financial Statements**<br><br>*(a) General Rule.* (1) Not later than 180 days after the organization's fiscal year ends, a PACE organization's fiscal year ends, a PACE organization must submit a certified financial statement that includes appropriate footnotes.<br>(2) The financial statement must be certified by an independent certified public accountant.<br>*(b) Contents.* At a minimum, the certified financial statement must consist of the following: | | |

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| (1) a certification statement<br>(2) a balance sheet .<br>(3) a statement of revenues and expenses.<br>(4) a source and use of funds statement.<br>*(c) Quarterly financial Statement – (1)*<br>*During Trial period.* A PACE Organization must submit a quarterly financial statement throughout the trial period within 45 days after the last day of each quarter of the fiscal year.<br>(2). *After Trial Period.* If CMS or the State administering agency determines that an organization's performance requires more frequent monitoring and oversight due to concerns about fiscal soundness, CMS or the State Administering Agency may require a PACE Organization to submit monthly or quarterly financial statements, or both. | | |

**CHAPTER 4 MARKETING**

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| **§ 460.82 Marketing.**<br><br>(a) *Information that a PACE organization must include in its marketing materials.* (1) A PACE organization must inform the public about its program and give prospective participants the following written information:<br>(i) An adequate description of the PACE organization's enrollment and disenrollment policies and requirements.<br>(ii) PACE enrollment procedures.<br>(iii) Description of benefits and services.<br>(iv) Premiums<br>(v) Other information necessary for prospective participants to make an informed decision about enrollment.<br>(2) Marketing information must be free of material inaccuracies, misleading information, or misrepresentations. | **Cross-reference:** §460.110 bill of rights; §460.116 Explanation of rights; §460.120 Grievance process; §460.122 PACE organization's appeals process; §460.150 Eligibility to enroll in a PACE program; §460.154 Enrollment agreement.<br><br>***Definition of Marketing materials includes*:** **I**nformation used to inform potential participants about enrollment or re-enrollment into the program, the participant enrollment agreement, and any documents/scripts that transmit information about enrollment, disenrollment, benefits, services, referrals, etc. from the PACE organization (PO) to participants or potential participants.<br><br>**Desk Review:**<br>• Review examples of initial marketing materials to determine if they include the information listed in the regulation.<br>• Ensure that written marketing products accurately characterize the PACE model (eligibility, day center, comprehensive care from interdisciplinary team, voluntary nature of program).<br>• Review all enrollment materials for clarity, easily understood language, and to ensure that the factual information contained therein is accurate:<br>  • Focus especially on explicit language that should state that the participant could disenroll at any time, and the reasons for involuntary disenrollment.<br>  • Verify phone numbers/contact information for beneficiary access (call the number/person).<br>  • Description of benefits includes all Medicaid/Medicare services; verify if additional services are included in the | |

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| (b) A*pproval of marketing information.* (1) CMS must approve all marketing information before distribution by the PACE organization, including any revised or updated material.<br>(2) CMS reviews initial marketing information as part of an entity's application for approval as a PACE organization, and approval of the application includes approval of marketing information.<br>(3) Once a PACE organization is under a PACE program agreement, any revisions to existing marketing information and new information are subject to the following:<br>(i) *Time period for approval.* CMS approves or disapproves marketing information within 45 | benefits list.<br>• Ensure that premium information is correctly characterized.<br>• Materials clarify that individual will utilize health care via the PO unless there is an emergency.<br>• Marketing/outreach materials clarify liability to potential participants, caregivers, and other health care providers. | |

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| days after CMS receives the information from the organization.<br>(ii) *Deemed approval.* Marketing information is deemed approved, and the organization can distribute it, if CMS and the State administering agency do not disapprove the marketing material within the 45-day review period.<br>(c) *Special language requirements.* A PACE organization must furnish printed marketing materials to prospective and current participants as specified below:<br>(1) In English and in any other principal languages of the community.<br>(2) In Braille, if necessary.<br>(d) *Information on restriction of services.* (1) Marketing materials must inform a potential participant that he or she must receive all needed health care, including primary care and specialist physician services (other than emergency services), from the PACE organization or | | |

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| from an entity authorized by the PACE organization.<br>(2) All marketing materials must state clearly that PACE participants may be fully and personally liable for the costs of unauthorized or out-of-PACE program agreement services.<br>(e) *Prohibited marketing practices.* A PACE organization must ensure that its employees or its agents do not use prohibited marketing practices which includes the following:<br>(1) Discrimination of any kind, except that marketing may be directed to individuals eligible for PACE by reason of their age.<br>(2) Activities that could mislead or confuse potential participants, or misrepresent the PACE organization, CMS, or the State administering agency.<br>(3) Gifts or payments to induce enrollment.<br>(4) Contracting outreach efforts to individuals or organizations whose sole responsibility involves direct contact with the elderly to solicit enrollment. | | Contracted outreach (if applicable) entity name:<br><br>Name of enrollment broker (if applicable): |

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| (5) Unsolicited door-to-door marketing.<br>(f) *Marketing Plan.* A PACE organization must establish, implement, and maintain a documented marketing plan with measurable enrollment objectives and a system for tracking its effectiveness. | **Desk Review:**<br>• Marketing plan should be included in the application. Note projected census goals, methods for achieving them, and measurable enrollment objectives. Note that the PO has a system to track the effectiveness of its marketing activities.<br>• Compare the actual versus projected enrollment. Note capacity of day center and compare this to the projected census goals for appropriateness.<br>• Does the marketing plan in any way discriminate against populations who might reside in the service area? Is it targeted to enroll more healthy individuals?<br>• Review marketing plan and how it informs the public about the program, for example, in which media, to what geographic area, any public meetings or informational gatherings hosted by the PO | |

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| **§460.90** PACE benefits under Medicare and Medicaid.<br>If a Medicare beneficiary or Medicaid recipient chooses to enroll in a PACE program, the following conditions apply:<br>(a) Medicare and Medicaid benefit limitations and conditions relating to amount, duration, scope of services, deductibles, copayments, coinsurance, or other cost-sharing do not apply.<br>(b) The participant, while enrolled in a PACE program, must receive Medicare and Medicaid benefits solely through the PACE organization. | **Cross-reference:** §460.154 Enrollment Agreemen;, §460.82 Marketing; §460.112 Specific Rights to which a participant is entitled; and §460.32 Content and terms of PACE program agreement.<br>**NOTE TO REVIEWER:** Since this section is addressed in Chapters 4 & 8, it is not addressed as §460.90 in the application response.<br>**Desk Review:**<br>• **Review the organization's enrollment agreement**, participant rights, participant handbook, any brochures given to the public and the participants for any evidence of language regarding cost sharing for the Medicare/Medicaid eligible participant. The PO is not allowed to charge a deductible, a copay, coinsurance or premium to the dual eligible participant. If a person does not have Medicare Part A or B or Medicaid, the payment would have to be received. This however does not constitute a "cost-share".<br>**Definitions:**<br>Deductibles: are fixed dollar amounts that an individual must pay out-of-pocket before third party benefits are made available to pay health care costs.<br>Coinsurance: is a percentage of costs for a specific service, which is the responsibility of the beneficiary when a service is delivered.<br>Copayments: are fixed dollar amounts that a beneficiary must pay when he or she uses a particular service.<br>All of this language should not be in any marketing material. | |

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| §**460.92 Required services.** The PACE benefit package for all participants, regardless of the source of payment, must include the following:<br>(a) All Medicaid-covered services, as specified in the State approved Medicaid Plan.<br>(b) Interdisciplinary assessment and treatment planning.<br>(c) Primary care, including physician and nursing services.<br>(d) Social work services.<br>(e) Restorative therapies, including physical therapy, occupational therapy and speech-language pathology services.<br>(f) Personal care and supportive services.<br>(g) Nutritional counseling.<br>(h) Recreational therapy.<br>(i) Transportation.<br>(j) Meals.<br>(k) Medical specialty services – see §460.92(k) (1) - (25)..<br>(l) Laboratory tests, xray's and other diagnostic procedures.<br>(m) Drugs, biologicals<br>(n) Prosthetics, orthotics, DME, corrective vision devices, such as eye glasses and lenses, hearing aides, dentures, and repair and maintenance of these items.<br>(o) Acute inpatient care, | **Cross-reference:** as §460.90; §460.70 Contracted Services; §460.82 Marketing.<br>**Desk Review:** as §460.90, in addition:<br>• **Review the list** of required and elected services in the State Plan (provided by the RO team members)<br>• **Review the description in the application** of the interdisciplinary team functions for each of the disciplines: How are transportation, meals, medical specialty services, acute inpatient care, ER and nursing facility care provided? Does the organization have contracts in place for any of these services? **Review a template** of the contracts, when applicable, to ensure the appropriate language is contained (see regulatory language in §460.70. (Contracts are reviewed in Chapter 2). Determine if the contracted services provide access and availability throughout the designated service area.<br>• **Review the health services delivery table** to make certain all services are provided | |

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| including the following:<br>(1) Ambulance.<br>(2) Emergency room care and treatment room services.<br>(3) Semi-private room and board.<br>(4) General medical and nursing services.<br>(5) Medical surgical/intensive care/coronary care unit.<br>(6) Laboratory test, x-rays and other diagnostic procedures.<br>(7) Drugs and biologicals.<br>(8) Blood and blood derivatives.<br>(9) Surgical care, including the use of anesthesia.<br>(10) Use of oxygen.<br>(11) Physical, occupational, respiratory therapies, and speech-language pathology services.<br>(12) Social services<br>(p) Nursing facility care<br>(1) Semi-private room and board.<br>(2) Physician and skilled nursing services.<br>(3) Custodial care.<br>(4) Personal care and assistance.<br>(5) Drugs and biologicals.<br>(6) Physical, occupational, recreational therapies, and speech-language pathology, if necessary.<br>(7) Social services. | | |

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| (8) Medical supplies and appliances.<br>(q) Other services determined necessary by the interdisciplinary team to improve and maintain the participant's overall health status. | | |
| **§460.94 Required Services for Medicare participants:**<br><br>(a) Except for Medicare requirements that are waived for the PACE program, as specified in paragraph (b) of this section, the PACE benefit package for Medicare participants must include the following services:<br>(1) The scope of hospital insurance benefits described in part 409 of this chapter.<br>(2) The scope of supplemental benefits described in part 410 of this chapter.<br>(b) *Waivers of Medicare* | **Cross-reference:** §460.154 Enrollment Agreement; §460.82 Marketing; §460.112 Specific Rights to which a participant is entitled; and §460.32 Content and terms of PACE program agreement.<br>**Desk Review:**<br>• **Review the organization's enrollment agreement**, participant rights, participant handbook, any brochures given to the public and the participants for any evidence of language regarding the benefits for the Medicare/Medicaid eligible participant. (**Reviewed in Chapter 8)**<br>Make certain the participant is given information of the benefits they will be receiving while enrolled in PACE in language that is understandable to them. The information should include those Medicare and Medicaid benefits minimally, that are included in §460.92 as Required Services. | |

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| *coverage requirements.* The following Medicare requirements are waived for purposes of the PACE program and do not apply:<br>(1) The provisions of subpart F of part 409 of this chapter that limit coverage of institutional services.<br>(2) The provisions of subparts G and H of part of 409 of this chapter, and parts 412 through 414 of this chapter that relate to payment for benefits.<br>(3) The provisions of subparts D and E of part 409 of this chapter that limit coverage of extended care services or home health services.<br>(4) The provisions of subpart D of part 409 of this chapter that impose a 3-day prior hospitalization requirement for coverage of extended care services.<br>(5) Sections 411.15(g) and (k) of this chapter that may prevent payment for PACE program services to PACE participants. | | |

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| **§460.96 Excluded services.** The following services are excluded from coverage under PACE:<br>(a) Any service that is not authorized by the interdisciplinaryteam, even if it is a required service, unless it is an emergency service.<br>(b) In an inpatient facility, private room and private duty nursing, (unless medically necessary), and nonmedical items for personal convenience such as telephone charges and radio or television rental (unless specifically authorized by the interdisciplinary team as part of the participant's plan of care).<br>(c) Cosmetic surgery, which does not include surgery that is required for improved functioning of a malformed part of the body resulting from an accidental injury or for reconstruction following mastectomy.<br>(d) Experimental medical, surgical, or other health procedures.<br>(e) Services furnished outside of the United States, except | **Cross-reference:** §460.154 Enrollment Agreement; §460.82 Marketing; §460.112 Specific Rights to which a participant is entitled; and §460.32 Content and terms of PACE program agreement<br>**Desk Review:**<br>• **Review the organization's enrollment agreement**, participant rights, participant handbook, any brochures given to the public and the participants for any evidence of language of what would not be a covered service. The excluded services list should not include a covered service. (Note: Also r**eviewed in Chapter 8)** | |

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| as follows:<br>(1) In accordance with § 424.122 through 424.124 of this chapter.<br>(2) As permitted under the State's approved Medicaid plan. | | |

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| **§ 460.98 Service delivery.**<br><br>(a) *Plan.* A PACE organization must establish and implement a written plan to furnish care that meets the needs of each participant in all care settings 24 hours a day, every day of the year.<br>(b) *Provision of services.* (1) The PACE organization must furnish comprehensive medical, health and social services that integrate acute and long-term care.<br>(2) These services must be furnished in at least the PACE center, the home and inpatient facilities.<br>(3) The PACE organization may not discriminate against any participant in the delivery of required PACE services based on race, ethnicity, national origin, religion, sex, age, mental or physical disability or source of payment.<br>(c) *Minimum services furnished at each PACE center.* At a minimum, the following services | **Cross-reference:** §460.22 Service area consideration; §460.64 Personnel qualifications; §460.72 Physical Environment; §460.78 Dietary services; §460.92 Required services; §460.112 Specific rights to which a participant is entitled; §460.106 Plan of Care<br>**Desk Review:**<br>• **Review the organization's description in the application** for providing care 24 hours a day, every day of the year.<br>• **Review the organization's description** to determine how the services are integrated across all health care settings, for example coordination of care.<br>• **Review the written plan**, marketing material, organizational chart to determine if all the required services are furnished in the center, the home and inpatient facilities.<br>• **Review the map** and other accompanying materials to determine where the center(s) and health care facilities are located in the service area. Do they appear accessible and have sufficient capacity for the enrollment numbers given?<br>• **Review the organization's plan** for enrollment growth; determine if they have addressed the needs for not only space but also services and staff (this information may be found in the business, marketing or strategic plan or board meeting minutes). Note: Also r**eviewed in Chapter 4)**<br>• **Review the organization's policies** and procedures regarding what criteria are used to determine the frequency a participant would attend a center. | List the Center(s) here, by address:<br><br>List those sites that do not have the minimum services: |

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| must be furnished at each PACE center:<br>(1) Primary care, including physician and nursing services.<br>(2) Social services.<br>(3) Restorative therapies, including physical therapy and occupational therapy.<br>(4) Personal care and supportive services.<br>(5) Nutritional counseling.<br>(6) Recreational therapy.<br>(7) Meals.<br>(d) *Center operation.* (1) A PACE organization must operate at least one PACE center either in, or contiguous to, its defined service area with sufficient capacity to allow routine attendance by participants.<br>(2) A PACE organization must ensure accessible and adequate services to meet the needs of its participants. If necessary, a PACE organization must increase the number of PACE centers, staff, or other PACE services.<br>(3) If a PACE organization operates more than one center, each center must offer the full range of services and have sufficient staff to meet the needs of participants. | | |

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| (e) *Center attendance.* The frequency of a participant's attendance at a center is determined by the interdisciplinary team, based on the needs and preferences of each participant. | | |
| **§460. 100 Emergency Care**<br><br>(a) *Written plan.* A PACE organization must establish and maintain a written plan to handle emergency care. The plan must ensure that CMS, the State and PACE participants are held harmless if the PACE organization does not pay for emergency services.<br>(b) *Emergency care.* Emergency care is appropriate when services are needed immediately | **Cross-reference: §**460.110 Bill of Rights; §460.154 Enrollment Agreement<br>**Desk Review:**<br>• **Review the organization's written plan** for handling emergency care. Language must contain hold-harmless clause for CMS and the State.<br>• **Review the enrollment agreement and marketing brochure.** Make certain the PO is not requiring the participant to call the center or on-call service after hours for an emergency.<br>• **Review the organization's written plan** for handling out-of-network and urgently need services/care. | |

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| because of an injury or sudden illness and the time required to reach the PACE organization or one of its contract providers, would cause risk of permanent damage to the participant's health. Emergency services include inpatient and outpatient services that meet the following requirements:<br>(1) Are 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.<br>(2) Are needed to evaluate or stabilize an emergency medical condition.<br>(c) An emergency medical condition means a condition manifesting itself by acute symptoms of sufficient severity (including severe pain) such that a prudent layperson, with an average knowledge of health and medicine, could reasonably expect the absence of immediate medical attention to result in the following:<br>(1) Serious jeopardy to the health of the participant | • **Review any materials given to the participant/caregiver: enrollment** agreement, participant rights, handbook, brochures to determine if the prudent layperson's definition was used as it relates to the explanation given to the participant regarding when and how to get access to emergency services.<br>• **Review the organization's on-call procedure** to include any contracted services/staff, if applicable.<br>• The on-call plan must include**:**<br>  • 24 hours a day provision<br>  • urgently needed services, out of network services and post stabilization<br>  • approval process for these services<br>  • how the participant, caregiver or both know how and when to access these services | |

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| health of the participant.<br>(2) Serious impairment to bodily functions.<br>(3) Serious dysfunction of any bodily organ or part.<br>(d) *Explanation to participant.* The organization must ensure that the participant or caregiver, or both, understand when and how to get access to emergency services<br>(e) *On-call providers.* The plan must provide for the following:<br>(1) An on-call provider, available 24 hours a day to address participant questions about emergency services and respond to requests for authorization of urgently needed out-of - network services and post stabilization care services following emergency services.<br>(2) Coverage of urgently need out-of-network services and post- stabilization care services when either of the following conditions are met::<br>(i) The services are pre-approved by the organization.<br>(ii) The services are not pre- | | |

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| approved by the PACE organization because the PACE organization did not respond to a request for approval within 1 hour after being contacted or cannot be contacted for approval. | | |
| **§ 460.102 Interdisciplinary team.**<br><br>(a) *Basic requirement.* A PACE organization must meet the following requirements:<br>(1) Establish a interdisciplinary team at each center to comprehensively assess and meet the individual needs of each participant.<br>(2) Assign each participant to a interdisciplinary team functioning at the PACE center that the participant attends.<br>(b) *Composition of interdisciplinary team.* The interdisciplinary team must be composed of at least the following members:<br>(1) Primary care physician<br>(2) Registered nurse<br>(3) Social worker<br>(4) Physical therapist<br>(5) Occupational therapist<br>(6) Recreational therapist or | **Cross-reference:** §460.92 Required Services, §460.200 Maintenance of records, §460.98 Service delivery, §460.64 Personnel qualifications, §460.66 Training<br>**Desk Review:**<br>• **Review the organization's process** for assigning each participant to a interdisciplinary team functioning at the PACE center the participant attends.<br>• **Review the physician position description**. Ensure the responsibilities include managing a participant's medical situation and overseeing a participant's use of medical specialist and inpatient care.<br>• **Review the** position descriptions for the responsibilities of the interdisciplinary team. Ensure the responsibilities include initial and periodic assessments, communication of participant changes to team members, plan of care, coordination for 24-hour care delivery, and documentation requirements in the medical record. The process/description should state the timeframe for completion of each assessment and developing the plan of care. These areas will be addressed to this detail in §460.104 and 106.<br>• **Review the organization's confidentiality procedure** to ensure it addresses how the participant's medical information is handled. This | |

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| activity coordinator<br>(7) Dietitian<br>(8) PACE center manager<br>(9) Home care coordinator<br>(10) Personal care attendant or his or her representative<br>(11) Driver or his or her representative<br>*(c)Primary care physician.* (1) Primary medical care must be furnished to a participant by a PACE primary care physician.<br>(2) Each primary care physician is responsible for the following:<br>(i) Managing a participant's medical situations.<br>(ii) Overseeing a participant's use of medical specialists and inpatient care.<br>*(d) Responsibilities of interdisciplinary team.*<br>(1) The interdisciplinary team is responsible for the initial assessment, periodic reassessments, plan of care, and coordination of 24 hour care delivery.<br>(2)Each team member is responsible for the following:<br>(i) Regularly informing the interdisciplinary team of the medical, functional, | description should include all forms of communication, who has access, conditions for releasing information, who is allowed to document in the record, and how the records are safeguarded. (Note: Also r**eviewed in Chapter 10)** | |

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| and psychosocial condition of each participant.<br>(ii) Remaining alert to pertinent input from other team members, participants and caregivers.<br>(iii) Documenting changes of a participant's condition in the participant's medical record consistent with documentation policies established by the medical director.<br>(3) the members of the interdisciplinary team must serve primarily PACE participants.<br>(e) *Exchange of information between team members.* The PACE organization must establish, implement, and maintain documented internal procedures governing the exchange of information between team members, contractors, and participants and their caregivers consistent with the requirements for confidentiality in §460.200(e). | | |

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| § **460.104 Participant assessment**<br><br>(a) *Initial comprehensive assessment* – (1) *Basic requirement.* The interdisciplinary team must conduct an initial comprehensive assessment on each participant. The assessment must be completed promptly following enrollment.<br>(2) As part of the initial comprehensive assessment, each of the following members of the interdisciplinary team must evaluate the participant in person, at appropriate intervals and develop a discipline-specific assessment of the participant's health and social status:<br>(i) Primary care physician<br>(ii) Registered nurse<br>(iii) Social worker<br>(iv) Physical therapist or Occupational therapist or both<br>(v) Recreational therapist or activity coordinator<br>(vi) Dietitian<br>(vii)Home care coordinator<br>(3) At the recommendation of individual team members, other professional disciplines (for example, speech - language | **Cross-reference: §**460.92 Required Services; §460.102 Interdisciplinary team; §460.122 Appeal's process; and §460.210 Medical records.<br>**Desk Review:**<br>• **Review the organization's process** for initial assessment:<br>  • Does the process state what time frame is allowed for completing the initial assessment?<br>  • Are the minimum team members ( Primary Care Physician, RN, SW, PT/OT, Recreational Therapist, Dietitian and homecare coordinator) included in the assessment?<br>  • What information would be included in their comprehensive assessment?<br>  • The process should describe specific discipline assessment information and at what intervals these assessments are made.<br>  • What criteria are used to determine when additional disciplines (i.e. Speech, specialists) would be included in the assessment?<br>  • Does the information include at least the required elements: physical and cognitive function and ability, medication use, participant preferences for care, socialization and availability of family support, current health status and treatment needs, nutritional status, home environment, including home access and egress, participant behavior, psychosocial status, medical and dental status, participant language?<br>• **Review** any description explaining how the discipline specific assessment is consolidated. The description should state that the team meets | |

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| pathology, dentistry, or audiology) may be included in the comprehensive assessment process.<br>(4) *Comprehensive assessment criteria.* The comprehensive assessment must include, but is not limited to, the following:<br>(i) Physical and cognitive function and ability<br>(ii) Medication use<br>(iii) Participant and caregiver preferences for care<br>(iv) Socialization and availability of family support<br>(v) Current health status and treatment needs<br>(vi) Nutritional status<br>(vii)Home environment, including home access and egress<br>(viii)Participant behavior<br>(ix) Psychosocial status<br>(x) Medical and dental status<br>(xi) Participant language<br>(b) *Development of plan of care.* The interdisciplinary team must promptly consolidate discipline-specific assessments into a single plan of care for each participant through discussion in team meetings and consensus of the entire interdisciplinary | The description should state that the team meets to develop the participant plan of care. The description should include the process of incorporating the discipline specific assessments at the team meeting to develop the participant plan of care **(Note: Also reviewed in §460.106).**<br>• **Review the participant handbook, participant bill of rights and any other materials** that are given to the participant to ensure the female participants are given information about their right to choose a qualified specialist for women's health services (within the organization's network). **Cross Reference the participant's bill of rights, §460.112(c)(2) and Chapter 6**<br>• **Review the reassessment policy** (this may be one and the same with the initial assessment policy). This policy should state:<br>  • How often the reassessments are performed, what circumstances would initiate a reassessment (i.e. change in participant's condition or status)<br>  • Who performs reassessments? The reassessment policy should state that the following team members, minimally, reassess the participant twice a year: Primary care Physician, RN, SW, and Recreational therapist/activity coordinator.<br>  • How does the information compiled from the reassessment get communicated to the team?<br>  • The policy should also state that a reassessment will be performed if the health or psychosocial status of a participant changes and/or the participant believes they need to initiate, eliminate or continue a particular service (PCP, RN, SW, PT/OT, | |

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| team.<br><br>In developing the plan of care, female participants must be informed that they are entitled to choose a qualified specialist for women's health services from the PACE organization's network to furnish routine or preventive women's health services.<br>(c) *Periodic reassessment* (1) *Semiannual reassessment.* On at least a semiannual basis, or more often if a participant's condition dictates, the following members of the interdisciplinary team must conduct an in-person reassessment:<br>(i) Primary care physician<br>(ii) Registered nurse<br>(iii) Social worker<br>(iv) Recreational therapist or activity coordinator<br>(v) Other team members actively involved in the development or implementation of the participant's plan of care (for example, home care coordinator, physical therapist, occupational therapist or dietitian).<br><br>(2) *Annual reassessment.* On at least annual basis, the following members of the interdisciplinary team must | Recreational Therapist, RD, Homecare coordinator).<br>• **Review the annual assessment policy** (refer to the initial assessment policy, this information may be included as one policy). In addition to the semi-annual assessment, the following team members must conduct an in-person annual reassessment: PT/OT, Dietitian, Home care Coordinator.<br>• **Review the organization's procedure for resolving requests** in a timely manner **(Note: Also reviewed in Appeals § 460.122 and Chapter 6 of the application).** The organization's policy must state:<br>  • the team roles and functions and specific time frames for all service requests and resolution.<br>  • that the team will notify the participant of its decision to approve or deny the request within 72 hours of the date the team receives the request for reassessment. Extension of the 72 hours may be 5 days; this should be stated in the policy when only the following scenarios occur: 1). The participant requests the extension. 2).<br>  • that the team documents its need for additional information and how the delay is in the interest of the participant.<br>  • that any denial of a request must be done verbally and in writing, in an understandable language.<br>• **Review the organization's Appeal policy (Also, reviewed in Chapter 6 of the application).** The policy should clearly state how they will inform the participant's of their right to appeal the decision, describe the standard and | |

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| interdisciplinary team must conduct an in-person reassessment:<br>(i) Physical therapist or Occupational therapist, or both<br>(ii)Dietitian<br>(iii)Home care coordinator<br>(3) *Reassessment based on change in participant status or at the request of the participant or designated representative.*<br>If the health or psychosocial status of a participant changes or if a participant(or his or her designated representative) believes that the participant needs to initiate, eliminate or continue a particular service, the members of the interdisciplinary team, listed in paragraph (a)(2) of this section, must conduct an in-person reassessment (i) The PACE organization must have explicit procedures for timely resolution of requests by a participant or his or her designated representative to initiate, eliminate, or continue a particular service.<br>(ii) Except as provided in paragraph(c)(3)(iii) of this section, the interdisciplinary team must notify the participant or designated representative of its decision to approve or deny | expedited appeals process and describe the rights and conditions for the continuation of the appealed services. The policy should evidence knowledge that if the team fails to provide the participant with timely notice of the resolution or does not furnish the services required by the revised plan of care, this constitutes an adverse decision and must be processed by the organization as an appeal.<br>• **Review the** Organization's description of the requirements of a reassessment. This policy should state:<br>  • Reassessments are performed when there is a change in participant's condition or status,<br>  • To reevaluate the participants plan of care,<br>  • Discuss any changes in the plan with the team,<br>  • To obtain approval of the revised plan from the team and the participant. | |

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| the request from the participant or designated representative as expeditiously as the participant's condition requires, but no later than 72 hours after the date the interdisciplinary team receives the request for reassessment.<br>(iii) The interdisciplinary team may extend the 72-hour timeframe for notifying the participant or designated representative of its decision to approve or deny the request by no more than 5 additional days for either of the following reasons:<br>(A) The participant or designated representative request the extension<br>(B) The team documents its need for additional information and how the delay is in the interest of the participant<br>(iv) The PACE organization must explain any denial of a request to the participant or the participant's designated representative orally and in writing. The PACE organization must provide the specific reasons for the denial in understandable language.<br>(v)If the participant or designated representative is dissatisfied with the decision on | | |

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| the request, the PACE organization is responsible for the following:<br>(A) Informing the participant or designated representative of his or her right to appeal the decision as specified in §460.122.<br>(B) Describing both the standard and the expedited appeals processes, including the right to, and conditions for, obtaining expedited consideration of an appeal of a denial of services as specified in§460.122.<br>(C) Describing the right to, and conditions for, continuation of appealed services through the period of an appeal as specified in §460.122(e).<br>(D) If the interdisciplinary team fails to provide the participant with timely notice of the resolution of the request or does not furnish the services require by the revised plan of care, this failure constitutes an adverse decision, and the participant's request must be automatically processed by the PACE organization as an appeal in accordance with §460.122.<br>(d) *Changes to plan of care.* Team members who conduct a | | |

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| reassessment must meet the following requirements:<br>(1) Reevaluate the participant's plan of care.<br>(2) Discuss any changes in the plan with the interdisciplinary team.<br>(3) Obtain approval of the revised plan from the interdisciplinary team and the participant or designated representative.<br>(4) Furnish any services included the revised plan of care as a result of a reassessment to the participant as expeditiously as the participant's health condition requires.<br>(e) *Documentation.* Interdisciplinary team members must document all assessment and reassessment information in the participant's medical record. | | |

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| **§460.106 Plan of Care**<br><br>(a) *Basic requirement.*<br>The interdisciplinary team must promptly develop a comprehensive plan of care for each participant.<br>(b) *Content of plan of care.*<br>The plan of care must meet the following requirements:<br>(1) Specify the care needed to meet the participant's medical, physical, emotional, and social needs, as identified in the initial comprehensive assessment.<br>(2) Identify measurable outcomes to be achieved.<br>*(c) Implementation of the plan of care.* (1) The team must implement, coordinate, and monitor the plan of care whether the services are furnished by PACE employees or contractors.<br>(2) The team must continuously monitor the participant's health and psychosocial status, as well as the effectiveness of the plan of care, through the provision of services, informal observation, input from participants or caregivers, and communications among members of the interdisciplinary | **Cross-reference: §**460.102 Interdisciplinary Team; §460.104. Participant assessment.<br>**Desk Review:**<br>• Review the sample plan of care to determine whether the organization has a written format to document the participant's plan of care.<br>• Review the organization's description sent with the application of the care planning process to include how the participant is a part of the development of their own plan of care, coordination of care and monitoring the plan of care for effectiveness. Is the plan of care reviewed at least every 6 months? | |

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| team and other providers.<br>(d) *Evaluation of plan of care.* On at least a semi-annual basis, the interdisciplinary team must reevaluate the plan of care, including defined outcomes and make changes as necessary.<br>(e) *Participant and caregiver involvement in plan of care.* The team must develop, review, and reevaluate the plan of care in collaboration with the participant or caregiver, or both, to ensure that there is agreement with the plan of care and the participant's concerns are addressed.<br>(f) *Documentation.* The team must document the plan of care, and any changes made to it, in the participant's medical record. | | |

**CHAPTER 6 PARTICIPANT RIGHTS**

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| § **460.110 Bill of rights.**<br><br>(a) *Written bill of rights*. A PACE organization must have a written participant bill of rights designed to protect and promote the rights of each participant. Those rights include, at a minimum, the ones specified in § 460.112.<br>(b) *Explanation of rights*. The organization must inform a participant upon enrollment, in writing, of his or her rights and responsibilities, and all rules and regulations governing participation.<br>(c) *Protection of rights.* The organization must protect and provide for the exercise of the participant's rights. | **Cross-reference:**<br>§460.154 Enrollment Agreement<br>**Review § 460.110 and §460.112 together**<br>**Desk Review:**<br>• **Review written bill of rights** to ensure that all rights identified at §460.112 at a minimum are included and are tailored to the specific PO and its potential participant market (including plain English or language of primary audience if non-English speaking).<br>• **Review process described in the application** to determine if the organization has described:<br>  • Specific participant responsibilities and rules and regulations governing participation (e.g., compliance with treatment regimen, behavior/conduct, etc)<br>  • The nature of the document presenting the rights and responsibilities (handbook, separate sheet, etc): clarity, accuracy, sufficiency of info<br>  • The time frame for discussing with and presenting the written rights document to the participant, including approaches to ascertain and assure participant understands the rights and responsibilities. | List all rights that have been omitted or are unclear: |

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| **§ 460.112 Specific rights to which a Participant is entitled.**<br>*(a) Respect and nondiscrimination.* Each participant has the right to considerate, respectful care from all PACE employees and contractors at all times and under all circumstances. Each participant has the right not to be discriminated against in the delivery of required PACE services based on race, ethnicity, national origin, religion, sex, age, mental or physical disability, or source of payment. Specifically, each participant has the right to the following:<br>(1) To receive comprehensive health care in a safe and clean environment and in an accessible manner.<br>(2) To be treated with dignity and respect, be afforded privacy and confidentiality in all aspects of care, and be provided humane care.<br>(3) Not to be | **Desk Review:**<br>**Review the process to determine if the organization has described:**<br>• The nature and location of the documentation required to substantiate presentation and discussion of rights, etc<br>• Whether the PO has designated who (e.g. by position or specific names) is responsible for presenting rights to the participant (and family/care giver) and for ensuring that the participant understands the rights (including use of interpreter when necessary)<br>• How the PO will promote the exercise of rights (e.g., voting, autonomy, making choices, voicing suggestions and concerns, participating in care planning decisions, etc)<br>• How both the PO and participant are to proceed if the participant believes his/her rights have been abridged.<br>**Review the Enrollment agreement** to determine if the agreement includes the complete and current copy of the bill of rights. (Refer §460.154, Chapter 8)<br><br>HIPAA Privacy Compliance:<br>The organization has a separate authorization form that is separate from a release form. An authorization is used when someone asks for a non-permitted use of Protected Health Information (PHI). The authorization must contain all the HIPAA privacy elements required for an authorization that is not included in a HIPAA release form. If required | |

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| required to perform services for the PACE organization.<br>(4) To have reasonable access to a telephone.<br>(5) To be free from harm, including physical or mental abuse, neglect, corporal punishment, involuntary seclusion, excessive medication, and any physical or chemical restraint imposed for purposes of discipline or convenience and not required to treat the participant's medical symptoms.<br>(6) To be encouraged and assisted to exercise rights as a participant, including the Medicare and Medicaid appeals processes as well as civil and other legal rights.<br>(7) To be encouraged and assisted to recommend changes in policies and services to PACE staff.<br>*(b) Information disclosure*. Each PACE participant has | elements are missing form the authorization template then the request for the PHI must be denied (by the organization or the participant)<br>☐ The authorization is written in plain language (it is easy to read and is understandable)<br>☐ A copy of the authorization must be provided the individual<br>☐ The authorization describes in detail the PHI that is being required (for example: lab reports, MRI of "event date")<br>☐ The authorization states each purpose of the requested PHI<br>☐ The authorization states who (the name of organization, or a person at the organization) is permitted to make the requested use of disclosure of the PHI<br>☐ The authorization states to whom (the name of the person or the organization and address) the PHI may be disclosed<br>☐ The authorization includes an expiration date or expiration event, which has not yet passes<br>☐ The authorization says that the individual patient or member who signed the authorization has the right to revoke the authorization at any time in writing<br>☐ The authorization describes the exceptions to the individual patient or member revocation right (for example, if the authorization has already been replied upon, or the authorization was obtained as a condition of getting insurance and insurance law gives the right to contest the claim)<br>☐ The authorization describes how the individual patient or member may revoke the authorization<br>☐ The authorization states that the PHI, once | |

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| Each PACE participant has the right to receive accurate, easily understood information and to receive assistance in making informed health care decisions. Specifically, each participant has the following rights:<br>(1) To be fully informed in writing of the services available from the PACE organization, including identification of all services that are delivered through contracts, rather than furnished directly by the PACE organization at the following times:<br>(i) Before enrollment.<br>(ii) At enrollment.<br>(iii) When there is a change in services.<br>(2) To have the enrollment agreement, described in §460.154, fully explained in a manner understood by the participant.<br>(3) To examine, or upon reasonable request, to be assisted | disclosed to others, may be redisclosed to other individuals or organizations that are not subject to the HIPAA privacy requirements and may no longer be protected by the HIPAA privacy standards.<br>☐ The authorization states the ability of inability to condition treatment, payment, enrollment or eligibility for benefits on the authorization<br>☐ The authorization is signed by the individual patient or member or their personal representative, and describes the personal representatives authority to act for the individual<br>☐ The authorization is dated<br><br>**HIPAA Privacy Individual Rights**<br>The HIPAA privacy regulation establishes a number of patient rights regarding their PHI. The rights include:<br>1. Notice of privacy practices<br>2. Privacy compliant<br>3. Right to request restrictions<br>4. Confidential communications<br>5. Right to access and copy PHI<br>6. Right to request an amendment<br>7. Right to an accounting of disclosures<br><br>These individual rights coupled with the authorization gives patients control over their PHI.<br><br>**EXCEPTIONS:** Individuals may not have access to their PHI if it is:<br>• In psychotherapy notes<br>• Information collected an developed for use in a civil, criminal or administrative action or proceeding | |

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| to examine the results of the most recent review of the PACE organization conducted by CMS or the State administering agency and any plan of correction in effect.<br>*(c) Choice of providers*. Each participant has the right to a choice of health care providers, within the PACE organization's network, that is sufficient to ensure access to appropriate high-quality health care. Specifically, each participant has the right to the following:<br>(1) To choose his or her primary care physician and specialists from within the PACE network.<br>(2) To request that a qualified specialist for women's health services furnish routine or preventive women's health services.<br>(3) To disenroll from the program at any time.<br>*(d) Access to emergency services.* Each participant has the right to access emergency health care services when and | • PHI that relates to the CLIA of 1998 if CLIA would prohibit individual access.<br>• If the individual or another may be at risk or in danger.<br>• The organization may charge a reasonable fee for copying of their records. The fees for the copies must be cost-based. The request for access and copying must be honored within 30 days.<br>• The organization must also have evidence of:<br>  • Notice of privacy practices document<br>  • Process for the plain language requirement for the notice of privacy practices document<br>  • Contract providers evidence acknowledgement of the notice of privacy practice and a good faith effort when the provider will not acknowledge by signature<br>  • Policies and/or procedures and/or process for the individual right of requesting a restriction<br>  • Policies and/or procedures and/or process for agreement of objection for facility directory<br>  • Policies and/or procedures and/or process for involvement in care (this should be evident everywhere in PACE through the IDT)<br>  • Policies and/or procedures and/or process for notification purposes<br>  • Policies and/or procedures and/or process for confidential communications of PHI (cross reference to §460.200)<br>  • Policies and/or procedures and/or process for the individual right to request access to PHI | |

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| where the need arises without prior authorization by the PACE interdisciplinary team.<br>*(e) Participation in treatment decisions.* Each participant has the right to participate fully in all decisions related to his or her treatment. A participant who is unable to participate fully in treatment decisions has the right to designate a representative. Specifically, each participant has the following rights:<br>(1) To have all treatment options explained in a culturally competent manner and to make health care decisions, including the right to refuse treatment, and be informed of the consequences of the decisions.<br>(2) To have the PACE organization explain advance directives and to establish them, if the participant so desires, in accordance with §§489.100 and §489.102 of this chapter.<br>(3) To be fully | • Policies and/or procedures and/or process for the individual right to request amendment to PHI<br>• Policies and/or procedures and/or process for the individual right to a right of accounting of disclosures of PHI | |

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| informed of his or her health and functional status by the interdisciplinary team.<br>(4) To participate in the development and implementation of the plan of care.<br>(5) To request a reassessment by the interdisciplinary team.<br>(6) To be given reasonable advance notice, in writing, of any transfer to another treatment setting and the justification for the transfer (that is, due to medical reasons or for the participant's welfare, or that of other participants). The PACE organization must document the justification in the participant's medical record.<br>*(f) Confidentiality of health information.* Each participant has the right to communicate with health care providers in confidence and to have the confidentiality of his or her individually identifiable health care information protected. | | |

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| Each participant also has the right to review and copy his or her own medical records and request amendments to those records. Specifically, each participant has the following rights:<br>(1) To be assured of confidential treatment of all information contained in the health record, including information contained in an automated data bank.<br>(2) To be assured that his or her written consent will be obtained for the release of information to persons not otherwise authorized under law to receive it.<br>(3) To provide written consent that limits the degree of information and the persons to whom information may be given.<br>(g) *Complaints and appeals.* Each participant has the right to a fair and efficient process for resolving differences with the PACE organization, including a rigorous system for internal | | |

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| review by the organization and an independent system of external review. Specifically, each participant has the following rights:<br>(1) To be encouraged and assisted to voice complaints to PACE staff and outside representatives of his or her choice, free of any restraint, interference, coercion, discrimination, or reprisal by the PACE staff.<br>(2) To appeal any treatment decision of the PACE organization, its employees, or contractors through the process described in §460.122 [42 CFR]. | | |

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| **§ 460.114 Restraints.**<br>(a) The PACE organization must limit use of restraints to the least restrictive and most effective method available. The term restraint includes either a physical restraint or a chemical restraint.<br>(1) A physical restraint is any manual method or physical or mechanical device, materials, or equipment attached or adjacent to the participant's body that he or she cannot easily remove that restricts freedom of movement or normal access to one's body.<br>(2) A chemical restraint is a medication used to control behavior or to restrict the participant's freedom of movement and is not a standard treatment for the participant's medical or psychiatric condition.<br>(b) If the interdisciplinary team determines that a restraint is needed to ensure the participant's physical safety or the safety of others, the use must meet the following conditions:<br>(1) Be imposed for a defined, limited period of time, based upon the assessed | **Cross - reference**: § 460.66 Training; §460.104 Assessment; §460.106 Plan of Care; §460.112(a)(5) Rights, abuse, neglect, restraints.<br><br>The PO must develop policies, which define whether and how the organization plans to incorporate the use of restraints (chemical and physical) into its treatment options. The policies must address each aspect specifically identified in §460.112(a), and §460.114.<br>**Desk review:**<br>**review written policies and procedures governing restraint use.** The policy and procedure should include:<br>• Circumstances for which restraints may be used<br>• Requirements for documentation regarding restraints, e.g.:<br>o symptoms which lead to consideration of use of restraints,<br>o less restrictive approaches used and evaluation of the participant's response to those approaches and<br>o specific goals to be achieved by use of the restraint.<br>• Definition and examples of restraints which the organization will allow (Some examples of physical restraints include: geri-chairs, lap buddy, seat-wedges, tray tables on wheelchair or geri-chair, vests, seat belts, Merry walkers, etc. when used to restrict a participant's freedom of movement or access to his/her body. Chemical restraints include the use of medications, such as: female hormones, psychoactive medications not being used as a standard treatment for the | |

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| needs of the participant.<br>(2) Be imposed in accordance with safe and appropriate restraining techniques.<br>(3) Be imposed only when other less restrictive measures have been found to be ineffective to protect the participant or others from harm.<br>(4) Be removed or ended at the earliest possible time.<br>(c) The condition of the restrained participant must be continually assessed, monitored, and reevaluated. | medical or documented psychiatric condition, etc. to control behavior or restrict a participant's freedom of movement.<br>**Review staff training** regarding:<br>• use of any type of restraint,<br>• hazards associated with use (including physical hand or body holds, etc.),<br>• requirements for monitoring,<br>• care of participants while in restraints, e.g., release, exercise, positioning and repositioning,<br>• alternate approaches,<br>• reduction or elimination of restraint use once imposed, potential for abuse or neglect, being alert to circumstances in the home which may represent the use of restraints for punishment (e.g., using a restraint to tie the participant to the toilet because the participant has soiled), etc.<br>• Staff responsible for assessing the need for restraints<br>• Incorporating use of restraints into plan of care | |
| **§ 460.116 Explanation of rights.**<br>(a) *Written policies.* A PACE organization must have written policies and implement procedures to ensure that the participant, his or her representative, if any, and staff understand these rights.<br>(b) *Explanation of rights*. The PACE organization | **Cross-reference:**<br>§460.110 and §460.112; §460.154 Enrollment Agreement.<br>**Desk Review:**<br>• **Review written bill of rights** to ensure that all rights identified at §460.112 at a minimum are included and are tailored to the specific PO and its potential Participant market (including plain English or language of primary audience if non-English speaking).<br>• **Review the process** to determine if the | |

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| must fully explain the rights to the participant and his or her representative, if any, at the time of enrollment in a manner understood by the participant.<br>(c) *Display*. The PACE organization must meet the following requirements:<br>(1) Write the participant rights in English and in any other principal languages of the community.<br>(2) Display the participant rights in a prominent place in the PACE center. | organization has described:<br>• Specific participant responsibilities and rules and regulations governing participation (e.g., compliance with treatment regimen, behavior/conduct, etc)<br>• The nature of the document presenting the rights and responsibilities (handbook, separate sheet, etc): clarity, accuracy, sufficiency of info<br>• The time frame for discussing with and presenting the written rights document to the participant, including approaches to ascertain and assure participant understands the rights and responsibilities.<br>• The nature and location of documentation required to substantiate presentation and discussion of rights, etc<br>• Whether the PO has designated who (e.g. by position or specific names) is responsible for presenting rights to the participant (and family/care giver) and for ensuring that the participant understands the rights (including use of interpreter when necessary)<br>• How the PO will promote the exercise of rights (e.g., voting, autonomy, making choices, voicing suggestions and concerns, participating in care planning decisions, etc)<br>• How both the PO and Participant are to proceed if the participant believes his/her rights have been abridged.<br><br>Review the Enrollment agreement to determine if the agreement includes the complete and current copy of the bill of rights. (Refer to §460.154)<br>**On-Site Review:** | |

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| | • **Review policy and procedure** manuals dealing with informing participants/representatives of their rights<br>• **Review policies and procedures** manuals for training staff, including contracted staff, to understand the participant rights and how to report violations.<br>• Determine if PO has an ongoing education for both participants and staff regarding participant rights.<br>• Determine whether materials are available in appropriate languages and that staff communicates to participants in their primary language.<br>• Determine if dealing with violations includes incorporating issues into the quality assessment program.<br>• View the display of the Bill Of Participation Rights; bulletin boards (centrally located readable height and font).<br>• Determine if the participants are treated in a manner consistent with the Bill of Rights. | |
| **§ 460.118 Violation of rights.**<br>The PACE organization must have established documented procedures to respond to and rectify a violation of a participant's rights. | **Cross – Reference: §**460.120.<br>No desk review required | |

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| **§ 460.120 Grievance process.**<br>For purposes of this part, a grievance is a complaint, either written or oral, expressing dissatisfaction with service delivery or the quality of care furnished.<br>(a) *Process to resolve grievances.* A PACE organization must have a formal written process to evaluate and resolve medical and nonmedical grievances by participants, their family members, or representatives.<br>(b) *Notification to participants*. Upon enrollment, and at least annually thereafter, the PACE organization must give a participant written information on the grievance process.<br>(c) *Minimum requirements.* At a minimum, the PACE organization's grievance process must include written procedures for the following:<br>(1) How a participant files a grievance.<br>(2) Documentation of a participant's grievance.<br>(3) Response to, and resolution of, grievances in a timely manner.<br>(4) Maintenance of | **Desk review:**<br>• Review procedures for confidentiality of grievances & appeals (refer to §460.110).<br>• **Ensure the process** for grievances have been established and include the requirements of §460.120(c),(d),(e), and (f) and policies and procedures for appeals (including expedited appeals) have been established and include the requirements of §460.122. **The process should include** who is responsible:<br>o for initiating the response or follow up with the participant with regard to the grievance or appeal,<br>o for determining whether the complaint is medical in nature,<br>o for coordinating with the departments involved, etc.<br>• Ensure the process explains how the PO proceeds if written or oral complaint involves both a grievance and an appeal.<br>• Ensure the **processes define** how the grievances and appeals are tracked and analyzed and how data regarding care issues are incorporated into the quality assessment and performance improvement program.<br>• Ensure the **procedures include** annually providing participant with up-to-date grievance & appeal information.<br>• Ascertain if the PO is appropriately determining whether a complaint is a grievance (e.g., adequacy of the facility, quality of care, timeliness of transport, waiting times for clinicians, etc) or an appeal (e.g., payment or denial of services). | |

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| confidentiality of a participant's grievance.<br>(d) *Continuing care during grievance process.* The PACE organization must continue to furnish all required services to the participant during the grievance process.<br>(e) *Explaining the grievance process.* The PACE organization must discuss with and provide to the participant in writing the specific steps, including timeframes for response that will be taken to resolve the participant's grievance.<br>(f) *Analyzing grievance information*. The PACE organization must maintain, aggregate, and analyze information on grievance proceedings. This information must be used in the PACE organization's internal quality assessment and performance improvement program. | • **Review phone and grievance/appeals logs** to determine if the PO has addressed complaints received and incorporated them into the grievance or appeals process.<br>• **Select medical records** to correspond with a sample of participants who filed a grievance/appeal to ascertain whether the PO has continued to furnish services, as appropriate.<br>• **Review the QAPI program** to determine how the analysis of grievance/appeals is incorporated into the program.<br>• During the **on-site observation** and interviews be sensitive to whether staff inappropriately use the nature or content of any grievances/appeals during participant interaction or during staff interaction when in the presence of participants or visitors.<br>• Ascertain whether **grievance/appeal records** are secured to prevent unauthorized access.<br>• Ascertain whether staff records have documentation of training in the POs procedures and policy regarding grievances and appeals.<br>**Interview:**<br>• Participant or Family or Representative.<br>o Interview probes:<br>o General-Knowledge of process to file a complaint/grievance/appeal<br>o If participant or family has lodged grievance/appeal, effect on care and treatment by staff and/or other participants; resolution of complaint/appeal; receipt of notification about process and | |

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| | timeframes<br>• Conduct interviews with a variety of staff, depending upon findings from the policies and procedures, observation, and file reviews and information from the participants and families. Interview, e.g.,<br>• Program Director.<br>• Social Worker.<br>• Direct care staff.<br>• Personnel assigned to analyze data.<br>o Interview Probes:<br>o Knowledge of complaints/grievance and appeals processes and differences, including training within last year;<br>o Mechanism to assure participants and families understand rights and processes with regard to grievances and appeals upon enrollment, annually, and when changes are made;<br>o Trends in the past year;<br>o How findings have been incorporated into QAPI and what effect have these changes made – any improvements? | |

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| **§ 460.122 PACE Organization's appeals Process.**<br>For purposes of this section, an appeal is a participant's action taken with respect to the PACE organization's noncoverage of, or nonpayment for, a service.<br>(a) *PACE organization's written appeals process.* The PACE organization must have a formal written appeals process, with specified timeframes for response, to address noncoverage or nonpayment of a service.<br>(b) *Notification of participants*. Upon enrollment, at least annually thereafter, and whenever the interdisciplinary team denies a request for services or payment, the PACE organization must give a participant written information on the appeals process.<br>(c) *Minimum requirements*. At a minimum, the PACE organization's appeals process must include written procedures for the following:<br>(1) Timely preparation and processing of a written denial of coverage or payment | **Cross – Reference:** §460.120 Grievance process<br>**Desk Review:**<br>**Some of this review might already have been addressed in §460.120 appeals.**<br>• Review procedures for confidentiality of grievances & appeals (refer to §460.110).<br>• **Ensure written policy and procedures** for grievances have been established and include the requirements of §460.120(c),(d),(e), and (f) and policies and procedures for appeals (including expedited appeals) have been established and include the requirements of §460.122. **The P and P include** who is responsible:<br>o for initiating the response or follow up with the participant with regard to the grievance or appeal,<br>o for determining whether the complaint is medical in nature,<br>o for coordinating with the departments involved, etc.<br>• Ensure **P and P** explain how the PO proceeds if written or oral complaint involves both a grievance and an appeal.<br>• Ensure the **processes define** how the grievances and appeals are tracked and analyzed and how data regarding care issues is incorporated into the quality assessment and performance improvement program.<br>• Ensure the **procedures include** annually providing participant with up-to-date grievance & appeal information.<br>• **Review the organization's description in the application.** Does the organization analyze grievance and appeals in the | |

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| as provided in §460.104(c)(3).<br>(2) How a participant files an appeal.<br>(3) Documentation of a participant's appeal.<br>(4) Appointment of an appropriately credentialed and impartial third party who was not involved in the original action and who does not have a stake in the outcome of the appeal to review the participant's appeal.<br>(5) Responses to, and resolution of, appeals as expeditiously as the participant's health condition requires, but no later than 30 calendar days after the organization receives an appeal.<br>(6) Maintenance of confidentiality of appeals.<br>(d) *Notification.* A PACE organization must give all parties involved in the appeal the following:<br>(1) Appropriate written notification.<br>(2) A reasonable opportunity to present evidence related to the dispute, in person, as well as in writing.<br>(e) *Services furnished during appeals process*. During the appeals process, the PACE | aggregate? | |

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| organization must meet the following requirements:<br>(1) For a Medicaid participant, continue to furnish the disputed services until issuance of the final determination if the following conditions are met:<br>(i) The PACE organization is proposing to terminate or reduce services currently being furnished to the participant.<br>(ii) The participant requests continuation with the understanding that he or she may be liable for the costs of the contested services if the determination is not made in his or her favor.<br>(2) Continue to furnish to the participant all other required services, as specified in subpart F of this part.<br>(f) *Expedited appeals process*. (1) A PACE organization must have an expedited appeals process for situations in which the participant believes that his or her life, health, or ability to regain maximum function would be seriously jeopardized, absent provision of the service in dispute.<br>(2) Except as provided | | |

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| in paragraph (f)(3) of this section, the PACE organization must respond to the appeal as expeditiously as the participant's health condition requires, but no later than 72 hours after it receives the appeal.<br>(3) The PACE organization may extend the 72-hour timeframe by up to 14 calendar days for either of the following reasons:<br>(i) The participant requests the extension.<br>(ii) The organization justifies to the State administering agency the need for additional information and how the delay is in the interest of the participant.<br>(g) *Determination in favor of participant.* A PACE organization must furnish the disputed service as expeditiously as the participant's health condition requires if a determination is made in favor of the participant on appeal.<br>(h) *Determination adverse to participant.* For a determination that is wholly or partially adverse to a participant, at the same time the decision is made, the PACE | | |

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| organization must notify the following:<br>(1) CMS.<br>(2) The State administering agency.<br>(3) The participant.<br>(i) *Analyzing appeals information*. A PACE organization must maintain, aggregate, and analyze information on appeal proceedings and use this information in the organization's internal quality assessment and performance improvement program. | | |
| § **460.124 Additional appeal rights under Medicare or Medicaid.**<br>A PACE organization must inform a participant in writing of his or her appeal rights under Medicare or Medicaid managed care, or both, assist the participant in choosing which to pursue if both are applicable, and forward the appeal to the appropriate external entity. | No desk review required | |

**CHAPTER 7 QUALITY ASSESSMENT AND PERFORMANCE IMPROVEMENT**

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| **§460.130 General rule:**<br><br>(a) A PACE organization must develop, implement, maintain, and evaluate an effective, data-driven quality assessment and performance improvement program.<br>(b) The program must reflect the full range of services furnished by the PACE organization.<br>(c) A PACE organization must take actions that result in improvements in its performance in all types of care. | **Cross-reference**: § 460.32Program Agreement; §460.132 QAPI plan.<br>The QAPI plan should be included in the application. A description of the levels of performance required by CMS on standard quality measures will be attached to the final program agreement.<br>**Desk Review:**<br>• **Review the written QAPI program** to determine if it includes at least the following elements:<br>  • How it is developed<br>  • Who and how it is evaluated<br>  • PACE services covered in the QAPI<br>  • How corrective actions are implemented to improve performance<br>• **Review the medical director's position description** to determine if there is oversight of the QAPI program, as regulated in § 460.60(c). | |

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| **§460.132 Quality assessment and performance improvement plan.**<br>*(a) Basic rule.* A PACE organization must have a written quality assessment and performance improvement plan.<br>*(b) Annual review:* The PACE governing body must review the plan annually and revise it, if necessary.<br>*(c) Minimum plan requirements.* At a minimum, the plan must specify how the PACE organization proposes to meet the following requirements:<br>(1) Identify areas to improve or maintain the delivery of services and patient care.<br>(2) Develop and implement plans of action to improve or maintain quality of care.<br>Document and disseminate to PACE staff and contractors the results from the quality assessment and performance improvement activities. | **Cross-reference**: §460.62 Governing body; §460.202 Participant Health Outcomes Data.<br>**Desk Review:**<br>• **Review the QAPI plan** to verify that all of the elements are described:<br>• a methodology to identify areas to improve or to maintain the delivery of services & participant care;<br>• a methodology to implement QAPI plan to improve/maintain quality of care;<br>• a procedure to document and inform PACE staff & contractors of QAPI results (QAPI reports, newsletters/publications, QA manual & QA committee meeting minutes); and<br>• complies with the Bill of Participant Rights in regard to confidentiality of data in the medical record.<br>• determine if the governing body has reviewed the QAPI program during the prior year, if applicable and made revisions, if necessary. | |

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| **§ 460.134 Minimum requirements for quality assessment and performance improvement program.**<br>(a) *Minimum program requirements.* A PACE organization's quality assessment and performance improvement program must include, but is not limited to, the use of objective measures to demonstrate improved performance with regard to the following:<br>(1) Utilization of PACE services, such as decreased inpatient hospitalization and emergency room visits.<br>(2) Care giver and participant satisfaction.<br>(3) Outcome measures that are derived from data collected during assessments, including data on the following:<br>(i) Physiological well being.<br>(ii) Functional status.<br>(iii) Cognitive ability.<br>(iv) Social/behavioral functioning.<br>(v) Quality of life of participants.<br>(4) Effectiveness and safety of staff- provided and contracted services, including the | **Cross-reference:** § 460.112Specific rights to which a participant is entitled; §460.104 Participant assessment.<br><br>**Desk Review:**<br>• **Review QAPI plan** to verify it contains the minimum requirements. | |

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| following:<br>(i) Competency of clinical staff.<br>(ii) Promptness of service delivery.<br>(iii) Achievement of treatment goals and measurable outcomes.<br>(5) Non-clinical areas, such as grievances and appeals, transportation services, meals, life safety, and environmental issues.<br>(b) *Basis for outcome measures*. Outcomes must be based on current clinical practice guidelines and professional practice standards applicable to the standards to the care of the PACE participants.<br>*(c) Minimum levels of performance.*<br>The PACE organization must meet or exceed minimum levels of performance established by CMS and the State administering agency, or standardized quality measures such as influenza immunization rates, which are specified in the PACE agreement.<br>(d) *Accuracy of data*.<br>The PACE organization must ensure that all data used for outcome monitoring are accurate and complete. | | |

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| **§460.136 Internal quality assessment and performance improvement activities.**<br><br>*(a) Quality assessment and performance improvement requirements.* A PACE organization must do the following:<br>(1) Use a set of outcome measures to identify areas of good or problematic performance.<br>(2) Take actions targeted at maintaining or improving care based on outcome measures.<br>**(3)** Incorporate actions resulting in performance improvement into standards of practice for the delivery of care and periodically track performance to ensure that any performance improvements are sustained over time.<br>(4) Set priorities for performance improvement, considering prevalence and severity of identified problems, and give priority to improvement activities that affect clinical outcomes.<br>(5) Immediately correct any identified problem that | **Cross-reference:** §460.32Content and terms of PACE agreement, §460.62 Governing body, §460.72Physical environment, §460.74Infection control, §460.103Interdisciplinaryteam.<br>**Desk Review:**<br>• **Review the QAPI program** for regulatory requirements met | |

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| directly or potentially threatens the health and safety of a PACE participant.<br>*(b) Quality assessment and performance improvement coordinator.* A PACE organization must designate an individual to coordinate and oversee implementation of quality assessment and performance improvement activities.<br>*(c) Involvement in quality assessment and performance improvement activities.* (1) A PACE organization must ensure that all interdisciplinary team members, PACE staff, and contract providers are involved in the development and implementation of quality assessment and performance improvement activities and are aware of the results of these activities.<br>(2)The quality improvement coordinator must encourage a PACE participant and his or her caregivers to be involved in quality assessment and performance improvement activities, including providing | | |

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| information about their satisfaction with services. | | |
| **§ 460.138 Committees with community input.**<br>A PACE organization must establish one or more committees, with community input, to do the following:<br>a) Evaluate data collected pertaining to quality outcome measures.<br>b) Address the implementation of, and results from, the quality assessment and performance improvement plan.<br>c) Provide input related to ethical decision making, including end-of-life issues and implementation of the Patient Self-Determination Act. | **Cross-reference:** § 460.32(9)(10)Program agreement, § 460.62(b)Governing body, Subpart G - Participant rights § 460.110 & §460.112.<br>**Desk Review:**<br>• **Review Committee membership lists** that are included in the application. Is there an established committee with community representatives? (**Contained in Chapter 1)**<br>• Community representations in the committee to ensure that issues related to participants' care are addressed. § 460.62(b)<br>• **Review QAPI plan** determine there are mechanisms in place to ensure the committee functions, the functions are delineated to include how input is received, where the information goes and how information regarding data collected are addressed with this committee.<br>• **Review process** set up by the organization to handle end-of-life and Self-Determination issues. | |

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| §**460.140 Additional quality assessment activities.**<br><br>A PACE organization must meet external quality assessment and reporting requirements, as specified by CMS or the State administering agency, in accordance with §460.202. | **Cross reference:** §460.130, §460.132, §460.134,-QAPI, §460.202 Participant health outcomes data.<br>**Desk Review:**<br>• Review the plan against minimum data elements needed to sustain the Organization's performance.<br>  • Verify that Industry standard codes (ICD-9, CPT, DRG, etc.) are utilized. The PACE Organization must ensure that service data are collected in standardized formats to the extent feasible and appropriate. Verify that non-standard coding, unique to the PACE Organization are fully documented, approved and utilized consistently throughout the organization (including the data submitted by contractors).<br>The Health Insurance Portability and Accountability Act of 1996 includes data standardization language. This requirement is effective October 2003. The organization must have a plan for privacy and transmission and code sets.<br><br>Standard formats are needed to assure that data elements are reported uniformly by all Providers, and that reports from multiple sources are comparable and can be reliably merged into more comprehensive reports.<br><br>A PACE Organization may have systems that are not fully automated. It is important to review these manual systems and determine the reliability and validity of the data.. It is equally important to assess how this data is integrated into the whole.<br>  • Example: The PACE Organization must track the frequency of participant's attendance at a center, to ensure that the | |

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| | participant's needs and wants are being meet. How is this information being gathered, analyzed and integrated with other participant outcome data?<br>• **Review the PACE Organization's** standards for all data entry processes, as well as the procedures for assessing and assuring compliance with them.<br>• Review procedures and standards that document manual processes for the collection of data.<br>• Review procedures for the review of medical records.<br>  • The PO must ensure that data abstracted from medical records is reliable and accurately recorded. (see attached sample of an abstraction tool).<br>• **Review information** on the type of software utilized by the program to integrate data from all components of its system.<br>• **Review the organization's plan** for the collection of, at a minimum, the following types of data: enrollee and provider characteristics; services furnished to enrollees; data as needed to guide the selection of performance improvement projects and to meet data collection requirements for performance improvement projects. | |

**CHAPTER 8 PARTICIPANT ENROLLMENT AND DISENROLLMENT**

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| **§ 460.150 Eligibility to enroll in a PACE program.**<br>(a) *General rule.* To enroll in a PACE program, an individual must meet eligibility requirements specified in the section. To continue to be eligible for PACE, an individual must meet the annual recertification requirements specified in §460.160.<br>(b) *Basic eligibility requirements.* To be eligible to enroll in PACE, an individual must meet the following requirements:<br>1) Be 55 years of age or older.<br>2) Be determined by the State administering agency to need the level of care required under the State Medicaid plan for coverage of nursing facility services, which indicates that the individual's health status is comparable to the health status of individuals who have participated in the PACE demonstration waiver programs.<br>3) Reside in the service area of the PACE organization.<br>4) Meet any additional program specific eligibility conditions imposed under the PACE program agreement. These | **Cross-reference**: §460.82 Marketing<br>**Desk Review:**<br>• Verify that the application specifies regulatory requirements and through what processes the PACE Organization (PO) verifies that each are met:<br>  • Verify the age eligibility.<br>  • Verify enrollment process, center staff time and participant census if the PO is accepting other participants in the same center as PACE participants (THIS MAY BE IN CHAPTER 1 OR 2 OF THE APPLICATION)<br>  • Verify the private pay premium collection process<br>  • Who performs the level of care determination—the State agency, or a designated physician from the PO? How is conflict of interest avoided?<br>• If applicable, ensure that any specific eligibility conditions meet all regulatory requirements.<br>• Determine if criteria for verifying health and safety are adequate. Ensure that it is specified in the program agreement.<br>• The application adequately describes how items in the regulation under this section are communicated to potential participants<br>• Review the enrollment process.<br>  • Who goes to the participant's place of residence? Is this part of the health and safety assessment?<br>  • What occurs when the participant visits the PACE center?<br>• **Review form letters** and useful documentation | |

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| additional conditions may not modify the requirements of paragraph (b)(1) through (b)3) of this section.<br>(c) *Other eligibility requirements.* (1) At the time of enrollment, an individual must be able to live in a community setting without jeopardizing his or her health or safety.<br>*(2)* The criteria used to determine if an individual's health or safety would be jeopardized by living in a community setting must be specified in the program agreement.<br>(d) E*ligibility under Medicare and Medicaid.* Eligibility to enroll in a PACE program is not restricted to an individual who is either a Medicare beneficiary or Medicaid recipient. A potential PACE enrollee may be, but is not required to be, any or all of the following:<br>(1) Entitled to Medicare Part A.<br>(2) Enrolled under Medicare Part B.<br>(3) Eligible for Medicaid. | that is given to participants (cross – reference to the Marketing section §460.82). | |

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| **§ 460.152 Enrollment process**.<br>(a) *Intake process.* Intake is an intensive process during which PACE staff members make one of more visits to a potential participant's place of residence and the potential participant makes one or more visits to the PACE center. At a minimum, the intake process must include the following activities:<br>(1) The PACE staff must explain to the potential participant and his or her representative or caregiver the following information:<br>(i) The PACE program, using a copy of the enrollment agreement described in § 460.154, specifically references the elements of the agreement including but not limited to § 460.154(e), (i) through (m), and (r).<br>(ii) The requirement that the PACE organization would be the participant's sole service provider and clarification that the PACE organization | **Desk Review:**<br>• Ensure that the application explains how the PO addresses items 1-4 in the regulation and includes in the documents part form letters utilized.<br>• Does the **referral process** include adequate follow-up and connection to another provider/case manager for assistance?<br>• Are CMS and the State Administering Agency (SAA) notified electronically or otherwise?<br><br>Enrollment Agreement must be included in Documents section of the application.<br>• Determine if enrollment agreement and member handbook meet requirements in the regulation. If not, request a mark-up of revisions and **verify onsite** those revisions have been made and that version is being utilized.<br><br>• Verify the PO can provide Hospice-like care (i.e. end of life care), however, a participant cannot utilize services from the Hospice benefit while enrolled in PACE.<br>• **Cross reference to "services"** section (Chapter 2) of review guide | |

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| guarantees access to services, but not to a specific provider<br>(iii) A list of the employees of the PACE organization who furnish care and the most current list of contracted health care providers under § 460.70(c).<br>(iv) Monthly premiums, if any.<br>(v) Any Medicaid spenddown obligations.<br>(2) The potential participant must sign a release to allow the PACE organization to obtain his or her medical and financial information and eligibility status for Medicare and Medicaid.<br>(3) The State administering agency must assess the potential participant, including any individual who is not eligible for Medicaid, to ensure that he or she needs the level of care required under the State Medicaid plan for coverage of nursing facility services, which indicates that the individual's health status is comparable to the health status of individuals who | | |

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| have participated in the PACE demonstration waiver programs.<br>(4) PACE staff must assess the potential participant to ensure that he or she can be cared for appropriately in a community setting and that he or she meets all requirements for PACE eligibility specified in this part.<br>(b) *Denial of Enrollment.* If a prospective participant is denied enrollment because his or her health or safety would be jeopardized by living in a community setting, the PACE organization must meet the following requirements:<br>1) Notify the individual in writing of the reason for the denial.<br>2) Refer the individual to alternative services, as appropriate.<br>3) Maintain supporting documentation of the reason for the denial.<br>4) Notify CMS and the State administering agency and make the documentation available for review. | | |

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| **§ 460.154 Enrollment agreement.**<br>If the potential participant meets the eligibility requirements and wants to enroll, he or she must sign an enrollment agreement which contains, at a minimum, the following information:<br>(a) Applicant's name, sex, and date of birth.<br>(b) Medicare beneficiary status (Part A, Part B, or both) and number, if applicable.<br>(c) Medicaid recipient status and number, if applicable.<br>(d) Other health insurance information, if applicable.<br>(e) Conditions for enrollment and disenrollment in PACE.<br>(f) Description of participant premiums, if any, and procedures for payment of premiums.<br>(g) Notification that a Medicaid participant and a participant who is eligible for both Medicare and Medicaid are not liable for any premiums, but may be liable for any applicable spenddown liability under §§435.121 and 435.831 and any amounts due under the post-eligibility treatment of income process under § 460.184.<br>(h) Notification that a Medicare | | |

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| participant may not disenroll from PACE at a social security office.<br>(i) Notification that enrollment in PACE results in disenrollment from any other Medicare or Medicaid prepayment plan or optional benefit. Electing enrollment in any other Medicare or Medicaid prepayment plan or optional benefit, including the hospice benefit, after enrolling as a PACE participant is considered a voluntary disenrollment from PACE.<br>(j) Information on the consequences of subsequent enrollment in other optional Medicare or Medicaid programs following disenrollment from PACE.<br>(k) Description of PACE services available, including all Medicare and Medicaid covered services, and how services are obtained from the PACE organization.<br>(l) Description of the procedures for obtaining emergency and urgently needed out-of-network services.<br>(m) The participant bill of rights.<br>(n) Information on the process for grievances and appeals and | | |

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| Medicare/Medicaid phone numbers for use in appeals.<br>(o) Notification of a participant's obligation to inform the PACE organization of a move or lengthy absence from the organization's service area.<br>(p) An acknowledgment by the applicant or representative that he or she understands the requirement that the PACE organization must be the applicant's sole service provider.<br>(q) A statement that the PACE organization has an agreement with CMS and the State administering agency that is subject to renewal on a periodic basis and, if the agreement is not renewed, the program will be terminated.<br>(r) The applicant's authorization for disclosure and exchange of personal information between CMS, its agents, the State administering agency, and the PACE organization.<br>(s) The effective date of enrollment.<br>(t) The applicant's signature and the date. | | |

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| **§ 460.156 Other enrollment procedures.**<br>(a) *Items a PACE organization must give a participant upon enrollment.* After the participant signs the enrollment agreement, the PACE organization must give the participant the following:<br>1) A copy of the enrollment agreement.<br>2) A PACE membership card.<br>3) Emergency information to be posted in his or her home identifying the individual as a PACE participant and explaining how to access emergency services.<br>4) Stickers for the participant's Medicare and Medicaid cards, as applicable, which indicate that he or she is a PACE participant and include the phone number of the PACE organization.<br>(b)*Submittal of participant information to CMS and the State*. The PACE organization must submit participant information to CMS and the State administering agency, in accordance with established procedures.<br>(c)*Changes in enrollment agreement information.* If there are changes in the enrollment | | |

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| agreement information at any time during the participant's enrollment, the PACE organization must meet the following requirements:<br>1) Give an updated copy of the information to the participant.<br>2) Explain the changes to the participant and his or her representative or caregiver in a manner they understand. | | |
| **§ 460.158 Effective date of enrollment.**<br>A participant's enrollment in the program is effective on the first day of the calendar month following the date the PACE organization receives the signed enrollment agreement. | Effective date of enrollment.<br>**Desk Review: none required** | |
| **§ 460.160 Continuation of enrollment.**<br>(a) *Duration of enrollment.*<br>Enrollment continues until the participant's death, regardless of changes in health status, unless either of the following actions occur:<br>1) The participant voluntarily | **Desk Review: none required** | |

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| disenrolls.<br>2) The participant is involuntarily disenrolled, as described in § 460.164.<br>(b) *Annual recertification requirement*. At least annually, the State administering agency must reevaluate whether a participant needs the level of care required under the State Medicaid plan for coverage of nursing facility services.<br>(1) *Waiver of annual requirement.*<br>(i) The State Administering Agency may permanently waive the annual recertification requirement for a participant if it determines that there is no reasonable expectation of improvement or significant change in the participant's condition because of the severity of a chronic condition or the degree of impairment of functional capacity.<br>(ii) The PACE organization must retain in the participant's medical record the documentation of the reason for waiving the annual recertification requirement.<br>(2) *Deemed continued eligibility.* If the State administering agency determines that a PACE | | |

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| participant no longer meets the State Medicaid nursing facility level of care requirements, the participant may be deemed to continue to be eligible for the PACE program until the next annual reevaluation, if, in the absence of continued coverage under this program, the participant reasonably would be expected to meet the nursing facility level of care requirement within the next 6 months.<br>(3) *Continued eligibility criteria.*<br>(i)The State administering agency, in consultation with the PACE organization, makes a determination of continued eligibility based on a review of the participant's medical record and plan of care.<br>(ii) The criteria used to make the determination of continued eligibility must be specified in the program agreement.<br><br>**§ 460.162 Voluntary disenrollment.** A PACE participant may voluntarily disenroll from the program without cause at any time. | **Cross – reference:** §460.152 Enrollment process; §460.154 Enrollment agreement<br>**Desk Review:**<br>• **Review the process for participant voluntary disenrollment.** The policy should state that participants may voluntarily disenroll without cause at any time. Is the disenrollment process burdensome for the participant? Will it occur in a timely manner? Is the process for notifying CMS and the State done electronically or manually? | |

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| **§ 460.164 Involuntary disenrollment.**<br>(a) *Reasons for involuntary disenrollment***.** A participant may be involuntarily disenrolled for any of the following reasons:<br>1) The participant fails to pay, or to make satisfactory arrangements to pay, any premium due the PACE organization after a 30-day grace period.<br>2) The participant engages in disruptive or threatening behavior, as described in paragraph (b) of this section.<br>3) The participant moves out of the PACE program service area or is out of the service area for more than 30 consecutive days, unless the PACE organization agrees to a longer absence due to extenuating circumstances.<br>4) The participant is determined to no longer meet the State Medicaid nursing facility level of care requirements and is not deemed eligible.<br>5) The PACE program agreement with CMS and the State administering agency is not renewed or is terminated.<br>6) The PACE organization is unable to offer health care services due to the loss of State licenses or contracts with | **Desk Review:**<br>• **Review the PO's reasons** for involuntary disenrollment and match items 1-6 in the regulation.<br>• Ensure that adequate safeguards for participants are in place to protect the rights of beneficiaries in these circumstances.<br>• **Verify in the application and Onsite** that the process involves the participant and applicable caregivers and participation of the inter-disciplinary team. | |

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| outside providers.<br>(b)*Disruptive or threatening behavior*. A participant who engages in disruptive or threatening behavior refers to a participant who exihibits either of the following:<br>1) A participant whose behavior jeopardizes his or her health or safety, or the safety of others; or<br>2) A participant With decision-making capacity who consistently refuses to comply with his or her individual plan of care or the terms of the PACE enrollment agreement.<br>(c) *Documentation of disruptive or threatening behavior*. If a PACE organization proposes to disenroll a participant who is disruptive or threatening, the organization must document the following information in the participant's medical record:<br>1) The reasons for proposing to disenroll the participant.<br>2) All efforts to remedy the situation.<br>(d) *Noncompliant behavior*. (1) A PACE organization may not disenroll a PACE participant on the grounds that the participant has engaged in noncompliant behavior if the behavior is related to a mental or physical | | |

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| condition of the participant, unless the participant's behavior jeopardizes his or her health or safety, or the safety of others.<br>(2) For purposes of this section, noncompliant *behavior* includes repeated noncompliance with medical advice and repeated failure to keep appointments.<br>(e) *State administering agency review and final determination.* Before an involuntary disenrollment is effective, the State administering agency must review it and determine in a timely manner that the PACE organization has adequately documented acceptable grounds for disenrollment. | | |

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| **§ 460.166 Effective date of disenrollment**.<br>(a) In disenrolling a participant, the PACE organization must take the following actions:<br>1) Use the most expedient process allowed under Medicare and Medicaid procedures, as set forth in the PACE program agreement.<br>2) Coordinate the disenrollment date between Medicare and Medicaid (for a participant who is eligible for both Medicare and Medicaid).<br>3) Give reasonable advance notice to the participant.<br>(b)Until the date enrollment is terminated, the following requirements must be met:<br>(1) PACE participants must continue to use PACE organization services and remain liable for any premiums.<br>(2) The PACE organization must continue to furnish all needed services. | **Desk Review:**<br>• Ensure that the application adequately describes the referral process, that a designated party is named to provide medical follow-up in regard to participant care, and that a process is in place to work with the SAA and CMS to ensure that the beneficiaries' care is covered. | |

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| **§ 460.168 Reinstatement in other Medicare and Medicaid programs.** To facilitate a participant's reinstatement in other Medicare and Medicaid programs after disenrollment, the PACE organization must do the following:<br>(a) Make appropriate referrals and ensure medical records are made available to new providers in a timely manner.<br>(b )Work with CMS and State Administering Agency to reinstate the participant in other Medicare and Medicaid programs for which the participant is eligible.<br><br>**§460.170 Reinstatement in PACE.**<br>(a) A previously disenrolled participant may be reinstated in a PACE program.<br>(b) If the reason for disenrollment is failure to pay the premium and the participant pays the premium before the effective date of disenrollment, the participant is reinstated in the PACE program with no break in coverage. | **Desk Review:**<br>• Review the policy and procedure for documentation of disenrollments:<br>  • How are disenrollments documented?<br>  • (Cross reference to QAPI). For quality assessment/performance improvement: How frequently does the information get communicated/transmitted to the QA dept., in what form, and how is the information utilized? | |

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| **§ 460.172 Documentation of disenrollment**.<br>A PACE organization must meet the following requirements:<br>(a) Have a procedure in place to document the reasons for all voluntary and involuntary disenrollments.<br>(b) Make documentation available for review by CMS and the State administering agency.<br>(c) Use the information on voluntary disenrollments in the PACE organization's internal quality assessment and performance improvement program. | | |

**CHAPTER 9 PAYMENT**

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| **§460.180 Medicare payment to PACE organizations:**<br><br>(d) *Application to Medicare secondary payer provisions*<br>*(1) Basic Rule.* – CMS does not pay for services to the extent that Medicare is not the primary payer under part 411 of this chapter.<br>*(2) Responsibilities of the PACE Organization.* The PACE Organization must do the following:<br>(i) Identify payers that are primary to Medicare under part 411 of the chapter.<br>(ii) Determine the amounts payable by those payers.<br>(iii) Coordinate benefits to Medicare participants with the benefits of primary payers.<br>*(3) Charges to other entities.* The PACE Organization may charge other individuals or entities for PACE services covered under Medicare for which Medicare is not the primary payer, as specified in (d)(4) and (5) of this section.<br>*(4) Charge to other insurers of the participant.* If a Medicare | **Cross-reference: None**<br><br>**Desk Review:**<br>The following required materials have been submitted with the PACE application. Are all of the forms completed and signed and dated by the responsible parties?<br>• Payment Information Form<br>• Medicare Contractor Data<br>**CO Medicare team leader:** Examine the forms in the application to make certain they are complete.<br><br>• Does the PO have systems/procedures to implement under the Medicare Secondary Payor provisions and Medicaid Third Party Liability?<br><br>• Does the PO have systems/procedures to avoid duplicate payment of health care services? | |

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| participant receives from a PACE organization covered services that are also covered under State or Federal Workers compensation, any no-fault insurance, or any liability insurance policy or plan, including a self-insured plan, the PO may charge any of the following:<br>(i)The insurance carrier, the employer, or any other entity that is liable for payment for the services under part 411 of this chapter.<br>(ii)The Medicare participant, to the extent that he or she has been paid by the carrier, employer, or other entity.<br>(5) *Charge to group health plan (GHP) or large group health (LGHP).* If Medicare is not the primary payer for services that a PACE Organization furnished to a Medicare participant who is covered under a GHP or LGHP, the organization may charge the following:<br>(i) GHP or LGHP for those services.<br>(ii) Medicare participant to the extent that he or she has been paid by the GHP or LGHP for those services. | | |

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| **§460.182 Medicaid Payment.**<br>(a) Under a PACE program agreement, the State administering agency makes a prospective monthly payment to the PACE Organization of a capitation amount for each Medicaid participant.<br>(b)The monthly capitation payment amount is negotiated between the PACE organization and the State administering agency, and specified in the PACE program agreement. The amount represents the following:<br>(1) Is less than the amount that would otherwise have been paid under the State plan if the participants were not enrolled under the PACE program.<br>(2) Takes into account the comparative frailty of PACE participants.<br>(3) Is a fixed amount regardless of changes in the participant's health status.<br>(4) Can be renegotiated on an annual basis.<br>(c)The PACE Organization must accept the capitation payment amount as payment in full for Medicaid participants and may not bill, charge, collect, or receive any other form of payment from the State | The UPL checklist will serve as a guide for this review:<br>**Desk Review:**<br>• The methodology for the Medicaid payment rate will be included in the State Plan Amendment. The Regional Office will review this methodology.<br>• The actual Medicaid capitation rates for this PO are included with the application.<br>• These capitation rates correspond with the methodology included in the State Plan Amendment. | |

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| administering agency or from, or on behalf of the participant, except as follows:<br>(1) Payment with respect to any applicable spenddown liability and any amounts due under the post-eligibility treatment of income process under §460.184.<br>(2) Medicare payment received from CMS or from other payers in accordance with §460.180(d).<br>(d) State procedures for the enrollment and disenrollment of participants in the States system, including procedures for any adjustment to account for the difference between the estimated number of participants on which the prospective monthly payment was based and the actual number of participants in the month, are included in the PACE program agreement. | The State's procedures will be included in the Program Agreement | |

**CHAPTER 10 DATA COLLECTION, RECORD MAINTENANCE AND REPORTING**

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| **§ 460.200 Maintenance of records and reporting of data**<br><br>(a) *General rule.* A PACE organization must collect data, maintain records, and submit reports as required by CMS and the State administering agency.<br>*(b)Access to data and records.* A PACE organization must allow CMS and the State administering agency access to data and records including, but not limited to, the following:<br>(1) Participant health outcomes data<br>(2) Financial books and records<br>(3) Medical records<br>(4) Personnel records<br>*(c) Reporting.* A PACE organization must submit to CMS and the State Administering Agency all reports that CMS and the State Administering Agency require to monitor the operation, cost, quality, and | **Cross-reference: §**460. 32 Content and terms of PACE program agreement; §460.68 Program Integrity; §460.72 Physical Environment; §460.80 Fiscal Soundness; §460.122 Appeal's process; §460.134 Minimum requirements for quality assessment and performance improvement program; §460.190 Monitoring during trial period; §460.202 Participant health outcomes; §460. 210 Medical Records.<br>**Desk Review:**<br>• **Review the PO's description** to collect data, maintain records and submit reports as required by CMS and the State: The description should include:<br>  • Who has access to data and records to include:<br>  • Participant health outcomes data<br>  • Financial books and records<br>  • Medical records<br>  • Personnel records<br>• **Review the PO's written policy** on safeguarding all data. A POLICY is required by regulation. The policy must have the following elements:<br>  • How all data, books and records are safeguarded against loss and to prevent unauthorized use (for example: having a check-out and in system when personnel are reviewing or auditing records in the PACE center, prohibiting any original record from leaving the center without the Director's written approval, securing all records in a cabinet after hours or when the center is not opened); | |

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| effectiveness of the program and establish payment rates.<br>(d) *Safeguarding data and records.* A PACE Organization must establish written policies and implement procedures to safeguard all data, books, and records against loss, destruction, unauthorized use, or inappropriate alteration.<br>(e) *Confidentiality of health information.* A PACE Organization must establish written policies and implement procedures to do the following:<br>(1) Safeguard the privacy of any information that identifies a particular participant. Information from or copies of records may be released only to authorized individuals. Original medical records are released only in accordance with Federal or State laws, court orders or subpoenas.<br>(2) Maintain complete records and relevant information in an accurate and timely manner.<br>(3)Grant each participant timely access, upon request, to review and copy his or her own medical records and to request | • How all data and records are held confidential (for example: training all staff how to keep participant information private when they are outside the center, inside the center in a common area that others can over-hear a conversation; posting medical information on a public bulletin board where those, other then the team have access; what information, under what circumstances and who needs to approve transmitting medical information by fax (consider State law that may prohibit fax of certain diagnoses – mental health, substance abuse and HIV status under any circumstance);<br>• How data and records are protected from destruction (for example: by placing the records in a fire proof or retardant cabinet and file when not reviewing; keeping the data off the floors to prevent destruction from water damage or flood; not allowing staff to document or review a record or data while eating or in a kitchen area, which is also a consideration for confidentiality; daily and weekly back up of all computer data; maintenance of computer data to decrease the chance of corrupt and lost data)<br>• Under what circumstances would an original record by allowed to be released from the center<br>• What procedures are in place to maintain the accuracy of records, and what are the timeframes to complete medical documentation in the participant record<br>• How does the PO assure the filing is up to date so the record can be complete and up to date for anyone needing to access that information | |

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| amendments to those records<br>(4) Abide by all Federal and State laws regarding confidentiality and disclosure for mental health records, medical records and other participant health information<br>(f) *Retention of records.* (1) A PACE Organization must retain records for the longest of the following periods:<br>(i) The period of time specified in State law.<br>(ii) Six years from the last entry date.<br>(iii) For medical records of disenrolled participants, 6 years after the date of disenrollment.<br>(2) If litigation, a claim, a financial management review, or an audit arising from the operation of the PACE program started before the expiration of the retention period, specified in paragraph (f)(1) of this section, the PACE Organization must retain the records until the completion of the litigation, or solution of the claims or audit findings. | • The PACE Organization must assess data for accuracy, completeness, logic and consistency on an ongoing basis and take steps to improve their performance.<br>• Is there a system for comparing reported data to a sample of medical records, to verify the accuracy of reporting or transmission?<br>• What procedure is followed when a participant or caregiver requests to review and copy his or her own medical record or to amend those records?<br>• The PO must take into consideration any Federal or State laws regarding confidentiality and disclosure for mental health records and medical records.<br>• The retention policy must include either the State law, six years from last entry, or 6 years after the date of disenrollment for disenrolled records whichever is longest period.<br><br>HIPAA Privacy Compliance:<br>**Minimum necessary standard:**<br>• The organization has policies and procedures to demonstrate that they have instituted a minimum necessary disclosure of PHI.<br>The minimum necessary standard is the organizations' efforts to limit the requests for, or uses and disclosure of, PHI to the minimum necessary to accomplish the intended purpose of the use, disclosure or request.<br>The organization needs to evaluate all practices and enhance the protection of PHI to limit unnecessary or | |

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| | inappropriate access to, and disclosure of, the PHI both internally and externally. The organization needs to apply the minimum necessary standard to the current data elements they permit access to for the job being accomplished. The same principle applies for the PHI that they disclose.<br>Exceptions<br>The organization does not have to administer the minimum necessary standard for the following circumstances:<br>• Uses by and disclosures to a health care provider for treatment<br>• Permissible uses or disclosures to the individual<br>• Uses and disclosures made pursuant to an individual's authorization<br><br>**De-identified Health Information and Limited Data Set:**<br><br>If it I necessary to disclose PHI, there are two methods to accomplish the release of information. The organization may de-identify the information or may use a limited data set. The de-identified information then is not PHI and is outside the HIPAA privacy standards. Information contained in a limited data set is PHI.<br>Under the HIPAA privacy requirements there are two ways to de-identify PHI:<br>• The organization may do de-identification in accordance with "generally accepted statistical and scientific principles and methods"<br>• The organization may remove all identifiers listed in the safe harbor method in the regulation [[§164.514(b)] | |

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| | ○ Names,<br>○ All geographic subdivisions smaller than a State (see reg. for further explanation)<br>○ All elements of dates for dates directly related to an individual, including birth date, admission date, discharge date, date of death: and all age over 89 and all elements of dates (including year) indicative of such age, except that such ages and elements may be aggregated into a single category of age 90 or older;<br>○ Telephone numbers;<br>○ Fax numbers;<br>○ Electronic mail addresses;<br>○ Social security numbers;<br>○ Medical record numbers;<br>○ Health plan beneficiary numbers;<br>○ Account numbers;<br>○ Certificate/license numbers;<br>○ Vehicle identifiers and serial numbers, including license plate numbers;<br>○ Device identifiers and serial numbers;<br>○ Web URLs<br>○ IP address numbers;<br>○ Biometric identifiers, including finger and voice prints;<br>○ Full face photographic images and any comparable images; and Any other unique identifying number, characteristic, or code<br><br>The organization may assign a code or other means | |

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| | of record identification to allow information de-identified to be re-identified.<br><br>☐ Verify the process that the organization is using to de-identify data<br><br>**HIPAA Compliance for Safeguarding PHI:**<br>• The organization has a contingency plan and disaster recovery plan for all PHI;<br>• The organization has security policy and procedures for **data (already addressed in this element)** | |
| **§ 460.202 Participant health outcomes**<br><br>(a) A PACE Organization must establish and maintain a health information system that collects, analyzes, integrates and reports data necessary to measure the organization's performance, including outcomes of care furnished to participants<br>(b) A PACE Organization must furnish data and information pertaining to its provision of participant care in the manner, and at the time intervals specified by CMS and the State | **Cross-reference: §**460.132; Quality assessment and performance improvement plan; §460.134, Minimum requirements for quality assessment and performance improvement program.<br>**Desk Review:**<br>• **Review the organization's description** of the health information system that is designed to collect their outcome data. This system should include:<br>  • Collecting, integrating, analyzing and reporting data to measure the organization's performance<br>  • Reference to the organization's QAPI plan that details who will be responsible for this system and how it will be maintained. Cross-reference QAPI section, Chapter 7.<br>  • **Review the organization's description** of the system in place to ensure the data | |

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| Administering Agency.<br>The items collected are specified in the PACE program agreement. | of the system in place to ensure the data that is to be furnished to CMS and the SAA in the manner and time intervals required will be provided. | |
| **§ 460.210 Medical Records**<br><br>(a) *Maintenance of medical records.* (1) A PACE organization must maintain a single, comprehensive medical record for each participant, in accordance with accepted professional standards.<br>(2) The medical record for each participant must meet the following requirements:<br>(i) Be complete.<br>(ii) Accurately documented.<br>(iii) Readily accessible. | **Cross-reference:** §460.52 Transitional care during termination; §460.104 Participant Assessment; §460.106 Plan of care; §460.154 Enrollment Agreement; §460.162 Voluntary Disenrollment; §460.164 Involuntary Disenrollment.<br>**Desk Review:**<br>• Review the description for use of the participant medical record:<br>  • Does the process include incorporating all of the data in a single medical record?<br>  • Are there practice guidelines for the acceptable forms of documentation to include: how corrections to the record are made, what abbreviations are acceptable, what the expectations are for completion of the required documentation?<br>  • How are electronic data held confidential?<br>  • Is there a procedure for thinning the medical record as necessary (when it becomes too | |

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| (iv) Systematically organized.<br>(v) Available to all staff.<br>(vi) Maintained and housed at the PACE center where the participant receives services.<br>(b) *Content of medical records.* At a minimum, the medical record must contain the following:<br>(1) Appropriate identifying information.<br>(2) Documentation of all services furnished, including the following:<br>(i) A summary of emergency care and other inpatient or long-term care services.<br>(ii) Services furnished by employees of the PACE center.<br>(iii) Services furnished by contractors and their reports.<br>(3) Interdisciplinary assessments, reassessments, plans of care treatment, and progress notes that include the participant's response to treatment.<br>(4) Laboratory, radiological and other test reports.<br>(5) Medication records.<br>(6) Hospital discharge summaries, if applicable.<br>(7)Reports of contact with informal support (for example, caregiver, legal guardian, or next of kin). | thick for the medical record jacket/binder, etc.)? What is taken out of the record? There should always be certain documents remaining in the present active record, such as any consents, the initial assessment, the latest reassessment, labs and other tests and participant demographic information<br>• How does medical staff receive results of tests in a timely manner?<br>• Review the organization's procedure for computer authentication of the primary author. Does the organization have identification unique to each discipline that is responsible for documentation? How and what frequency is the author reviewing and approving the entry? Does State laws allow electronic signatures? If so, what is the procedure? Written law must be reviewed. | |

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| (8) Enrollment Agreement.<br>(9) Physician orders<br>(10) Discharge summary and disenrollment justification, if applicable.<br>(11) Advance directives, if applicable.<br>(12) A signed release permitting disclosure of personal information.<br>(13) Accident and incident reports.<br>(c) *Transfer of medical records.* The organization must promptly transfer copies of medical record information between treatment facilities.<br>(d) *Authentication of medical records.*<br>(1) All entries must be legible, clear, complete, and appropriately authenticated and dated.<br>(2) Authentication must include signatures or a secured computer entry by a unique identifier of the primary author who has reviewed and approved the entry. | | |