

PACE Audit Guide External Version Version 1

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Section 2 A – Administrative PACE Elements

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Section 2B – Administrative Part D Elements

The following elements apply as written to PACE organizations and are taken from the “Medicare Advantage Prescription Drug Plan (MA-PD) Sponsor Part D Audit Guide”. References to MA-PD plans were changed to PACE organizations. Refer to the “Part D Auditing Standard Operating Procedures” for methods of evaluation and worksheets for these elements.

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Section 1 – Clinical PACE Elements

Element	Requirement	Met/Not
<p>PRS 02 §460.66</p> <p>Training</p>	<p>(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.</p> <p>(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.</p> <p>(c) Personal Care attendants must exhibit competency before performing personal care services independently.</p>	
<p>PRS 04 §460.71</p> <p>Oversight of direct participant care</p>	<p>(a) The PACE organization must ensure that all employees and contracted staff furnishing care directly to participants demonstrate the skills necessary for performance of their position.</p> <p>(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.</p> <p>(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).</p> <p>(3) The competency program must be evidenced as completed before performing participant care and on an ongoing basis by qualified professionals.</p> <p>(4) The PACE organization must designate a staff member to oversee these activities for employees and work with the PACE contractor liaison to ensure compliance by contracted staff.</p> <p>(b) The PACE organization must develop a program to ensure that all staff furnishing direct participant care services meet the following requirements:</p> <p>(1) Comply with any State or Federal requirements for direct patient care staff in their respective settings.</p> <p>(2) Comply with the requirements of Sec. 460.68(a) regarding persons with criminal convictions.</p> <p>(3) Have verified current certifications or licenses for their respective positions.</p> <p>(4) Are free of communicable diseases and are up to date with immunizations before performing direct patient care.</p> <p>(5) Have been oriented to the PACE program.</p> <p>(6) Agree to abide by the philosophy, practices, and protocols of the PACE organization.</p>	

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Element	Requirement	Met/Not
<p>ENV 01 §460.72 Physical Environment.</p>	<p>(a) <i>Space and equipment</i>—</p> <p>(1) Safe design. A PACE center must meet the following requirements:</p> <p>(i) Be designed, constructed, equipped, and maintained to provide for the physical safety of participants, personnel, and visitors.</p> <p>(ii) Ensure a safe, sanitary, functional, accessible, and comfortable environment for the delivery of services that protects the dignity and privacy of the participant.</p> <p>(2) <i>Primary care clinic</i>. 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.</p> <p>(3) <i>Equipment maintenance</i>.</p> <p>(i) A PACE organization must establish, implement and maintain a written plan to ensure that all equipment is maintained in accordance with the manufacturer's recommendations.</p> <p>(ii) A PACE organization must perform the manufacturer's recommended maintenance on all equipment as indicated in the organization's written plan.</p> <p>(b) <i>Fire safety</i>—</p> <p>(1) <i>General rule</i>. Except as otherwise provided in this section--</p> <p>(i) A PACE center must meet the applicable provisions of the 2000 edition of the Life Safety Code (LSC) of the National Fire Protection Association that apply to the type of setting in which the center is located. The Director of the Office of the Federal Register has approved the NFPA 101^[reg] 2000 edition of the Life Safety Code, issued January 14, 2000, for incorporation by reference in accordance with 5 U.S.C. 552(a) and 1 CFR part 51. A copy of the Code is available for inspection at the CMS Information Resource Center, 7500 Security Boulevard, Baltimore, MD or at the National Archives and Records Administration (NARA). For information on the availability of this material at NARA, call 202-741-6030, or go to: http://www.archives.gov/federal-register/code-of-federal--regulations/ibr--locations.html. Copies may be obtained from the National Fire Protection Association, 1 Batterymarch Park, Quincy, MA 02269. If any changes in this edition of the Code are incorporated by reference, CMS will publish notice in the Federal Register to announce the changes.</p> <p>(ii) Chapter 19.3.6.3.2, exception number 2 of the adopted edition of the LSC does not apply to PACE centers.</p> <p>(2) <i>Exceptions</i>.</p> <p>(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.</p> <p>(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.</p> <p>(3) Beginning March 13, 2006, a PACE center must be in compliance with Chapter 9.2.9, Emergency</p>	

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	<p>Lighting.</p> <p>(4) Beginning March 13, 2006, Chapter 19.3.6.3.2, exception number 2 does not apply to PACE centers.</p> <p>(5) Notwithstanding any provisions of the 2000 edition of the Life Safety Code to the contrary, a PACE center may install alcohol-based hand rub dispensers in its facility if--</p> <p>(i) Use of alcohol-based hand rub dispensers does not conflict with any State or local codes that prohibit or otherwise restrict the placement of alcohol-based hand rub dispensers in health care facilities;</p> <p>(ii) The dispensers are installed in a manner that minimizes leaks and spills that could lead to falls;</p> <p>(iii) The dispensers are installed in a manner that adequately protects against inappropriate access; and</p> <p>(iv) The dispensers are installed in accordance with chapter 18.3.2.7 or chapter 19.3.2.7 of the 2000 edition of the Life Safety Code, as amended by NFPA Temporary Interim Amendment 00-1(101), issued by the Standards Council of the National Fire Protection Association on April 15, 2004. The Director of the Office of the Federal Register has approved NFPA Temporary Interim Amendment 00-1(101) for incorporation by reference in accordance with 5 U.S.C. 552(a) and 1 CFR part 51. A copy of the amendment is available for inspection at the CMS Information Resource Center, 7500 Security Boulevard, Baltimore, MD and at the Office of the Federal Register, 800 North Capitol Street NW, Suite 700, Washington, DC. Copies may be obtained from the National Fire Protection Association, 1 Batterymarch Park, Quincy, MA 02269. If any additional changes are made to this amendment, CMS will publish notice in the Federal Register to announce the changes.</p> <p>(c) <i>Emergency and disaster preparedness</i>—</p> <p>(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.</p> <p>(2) Emergencies defined. Emergencies include, but are not limited, to the following:</p> <p>(i) Fire.</p> <p>(ii) Equipment, water, or power failure.</p> <p>(iii) Care-related emergencies.</p> <p>(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.)</p> <p>(3) <i>Emergency training</i>. 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.</p>	

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	<p>(4) <i>Availability of emergency equipment.</i> Emergency equipment, including easily portable oxygen, airways, suction, and emergency drugs, along with staff who know how to use the equipment, must be on the premises of every center at all times and be immediately available. The organization must have a documented plan to obtain emergency medical assistance from sources outside the center when needed.</p> <p>(5) <i>Annual test of emergency and disaster plan.</i> At least annually, a PACE organization must actually test, evaluate and document the effectiveness of its emergency and disaster plans.</p>	
<p>ENV02 §460.74 Infection control.</p>	<p>(a) <i>Standard procedures.</i> The PACE organization must follow accepted policies and standard procedures with respect to infection control, including at least the standard precautions developed by the Centers for Disease Control and Prevention.</p> <p>(b) <i>Infection control plan.</i> The PACE organization must establish, implement, and maintain a documented infection control plan that meets the following requirements:</p> <p>(1) Ensures a safe and sanitary environment.</p> <p>(2) Prevents and controls the transmission of disease and infection.</p> <p>(c) <i>Contents of infection control plan.</i> The infection control plan must include, but is not limited to, the following:</p> <p>(1) Procedures to identify, investigate, control, and prevent infections in every center and in each participant's place of residence.</p> <p>(2) Procedures to record any incidents of infection.</p> <p>(3) Procedures to analyze the incidents of infection to identify trends and develop corrective actions related to the reduction of future incidents.</p>	
<p>TRS 01 §460.76 Transportation services.</p>	<p>(a) <i>Safety, accessibility, and equipment.</i> A PACE organization's transportation services must be safe, accessible, and equipped to meet the needs of the participant population.</p> <p>(b) <i>Maintenance of vehicles</i></p> <p>(1) If the PACE organization owns, rents, or leases transportation vehicles, it must maintain these vehicles in accordance with the manufacturer's recommendations.</p> <p>(2) If a contractor provides transportation services, the PACE organization must ensure that the vehicles are maintained in accordance with the manufacturer's recommendations.</p> <p>(c) <i>Communication with PACE center.</i> The PACE organization must ensure that transportation vehicles are equipped to communicate with the PACE center.</p> <p>(d) <i>Training.</i> The PACE organization must train all transportation personnel (employees and contractors) in the following:</p> <p>(1) Managing the special needs of participants.</p>	

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	<p>(2) Handling emergency situations.</p> <p>(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.</p>	
<p>DTY 01 460.78 Dietary Services</p>	<p>(a) <i>Meal requirements.</i></p> <p>(1) Except as specified in paragraphs (a)(2) or (a)(3) of this section, the PACE organization must ensure, through the assessment and care planning process, that each participant receives nourishing, palatable, well-balanced meals that meet the participant's daily nutritional and special dietary needs. Each meal must meet the following requirements:</p> <p>(i) Be prepared by methods that conserve nutritive value, flavor, and appearance.</p> <p>(ii) Be prepared in a form designed to meet individual needs.</p> <p>(iii) Be prepared and served at the proper temperature.</p> <p>(2) The PACE organization must provide substitute foods or nutritional supplements that meet the daily nutritional and special dietary needs of any participant who has any of the following problems:</p> <p>(i) Refuses the food served.</p> <p>(ii) Cannot tolerate the food served.</p> <p>(iii) Does not eat adequately.</p> <p>(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.</p> <p>(b) <i>Sanitary conditions.</i> The PACE organization must do the following:</p> <p>(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.</p> <p>(2) Store, prepare, distribute, and serve foods (including nutritional supplements and nutrition support items) under sanitary conditions.(3) Dispose of garbage and refuse properly.</p>	
<p>SDY 01 §460.98 Service delivery</p>	<p>(a) <i>Plan.</i> 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.</p> <p>(b) <i>Provision of services.</i></p> <p>(1) The PACE organization must furnish comprehensive medical, health, and social services that integrate acute and long-term care.</p> <p>(2) These services must be furnished in at least the PACE center, the home, and inpatient facilities.</p> <p>(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, sexual orientation, mental or physical disability, or source of payment.</p>	

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Element	Requirement	Met/Not
	<p>(c) <i>Minimum services furnished at each PACE center.</i> At a minimum, the following services must be furnished at each PACE center:</p> <ol style="list-style-type: none"> (1) Primary care, including physician and nursing services. (2) Social services. (3) Restorative therapies, including physical therapy and occupational therapy. (4) Personal care and supportive services. (5) Nutritional counseling. (6) Recreational therapy. (7) Meals. <p>(d) <i>Center operation.</i> (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.</p> <p>(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.</p> <p>(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.</p> <p>(e) <i>Center attendance.</i> 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.</p>	
<p>SDY 02 §460. 100 Emergency Care</p>	<p>a) <i>Written plan.</i> 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.</p> <p>(b) <i>Emergency care.</i> Emergency care is appropriate when services are needed immediately because of an injury or sudden illness and the time required to reach the PACE organization or 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:</p> <ol style="list-style-type: none"> (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. (2) Are needed to evaluate or stabilize an emergency medical condition. <p>(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:</p> <ol style="list-style-type: none"> (1) Serious jeopardy to the health of the participant. (2) Serious impairment to bodily functions. 	

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	<p>(3) Serious dysfunction of any bodily organ or part.</p> <p>(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 and that no prior authorization is needed.</p> <p>(d) <i>On-call providers.</i> The plan must provide for the following:</p> <p>(1) An on-call provider, available 24-hours per 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.</p> <p>(2) Coverage of urgently needed out-of-network and post-stabilization care services when either of the following conditions are met:</p> <p>(i) The services are preapproved by the PACE organization.</p> <p>(ii) The services are not preapproved 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.</p> <p>(3) <i>Definitions.</i> As used in this section, the following definitions apply:</p> <p>(i) Post stabilization care means services provided subsequent to an emergency that a treating physician views as medically necessary after an emergency medical condition has been stabilized. They are not emergency services, which PACE Organizations are obligated to cover. Rather they are non-emergency services that the PO should approve before they are provided outside the service area.</p> <p>(ii) Urgent care means the care provided to a PACE participant who is out of the PACE service area and who believes their illness or injury is too severe to postpone treatment until they return to the service area, but their life or function is not in severe jeopardy.</p>	
<p>SDY 03 §460.102 Interdisciplinary team</p>	<p>(a) <i>Basic requirement.</i> A PACE organization must meet the following requirements:</p> <p>(1) Establish an interdisciplinary team at each center to comprehensively assess and meet the individual needs of each participant.</p> <p>(2) Assign each participant to an interdisciplinary team functioning at the PACE center that the participant attends.</p> <p>(b) <i>Composition of interdisciplinary team.</i> The interdisciplinary team must be composed of at least the following members:</p> <p>(1) Primary care physician.</p> <p>(2) Registered nurse.</p> <p>(3) Master's-level social worker.</p> <p>(4) Physical therapist.</p> <p>(5) Occupational therapist.</p> <p>(6) Recreational therapist or activity coordinator.</p>	

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	<p>(7) Dietitian. (8) PACE center manager. (9) Home care coordinator. (10) Personal care attendant or his or her representative. (11) Driver or his or her representative. (c) <i>Primary care physician.</i> (1) Primary medical care must be furnished to a participant by a PACE primary care physician. (2) Each primary care physician is responsible for the following: (i) Managing a participant's medical situations. (ii) Overseeing a participant's use of medical specialists and inpatient care. (d) <i>Responsibilities of interdisciplinary team.</i> (1) The interdisciplinary team is responsible for the initial assessment, periodic reassessments, plan of care, and coordination of 24 hour care delivery. (2) Each team member is responsible for the following: (i) Regularly informing the interdisciplinary team of the medical, functional, and psychosocial condition of each participant. (ii) Remaining alert to pertinent input from other team members, participants, and caregivers. (iii) Documenting changes of a participant's condition in the participant's medical record consistent with documentation policies established by the medical director. (3) The members of the interdisciplinary team must serve primarily PACE participants. (e) <i>Exchange of information between team members.</i> 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 Sec.460.200(e).</p>	
<p>SDY 04 §460.104 Participant assessment</p>	<p>(a) <i>Initial comprehensive assessment—</i> (1) <i>Basic requirement.</i> The interdisciplinary team must conduct an initial comprehensive assessment on each participant. The assessment must be completed promptly following enrollment. (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: (i) Primary care physician. (ii) Registered nurse. (iii) Master's-level social worker. (iv) Physical therapist. (v) Occupational therapist.</p>	

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	<p>(vi) Recreational therapist or activity coordinator.</p> <p>(vii) Dietitian.</p> <p>(viii) Home care coordinator.</p> <p>(3) At the recommendation of individual team members, other professional disciplines (for example, speech-language pathology, dentistry, or audiology) may be included in the comprehensive assessment process.</p> <p>(4) <i>Comprehensive assessment criteria.</i> The comprehensive assessment must include, but is not limited to, the following:</p> <p>(i) Physical and cognitive function and ability.</p> <p>(ii) Medication use.</p> <p>(iii) Participant and caregiver preferences for care.</p> <p>(iv) Socialization and availability of family support.</p> <p>(v) Current health status and treatment needs.</p> <p>(vi) Nutritional status.</p> <p>(vii) Home environment, including home access and egress.</p> <p>(viii) Participant behavior.</p> <p>(ix) Psychosocial status.</p> <p>(x) Medical and dental status.</p> <p>(xi) Participant language.</p> <p>(b) <i>Development of plan of care.</i> 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 team. 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.</p> <p>(c) <i>Periodic reassessment—</i></p> <p>(1) <i>Semiannual reassessment.</i> 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:</p> <p>(i) Primary care physician.</p> <p>(ii) Registered nurse.</p> <p>(iii) Master's-level social worker.</p> <p>(iv) Recreational therapist or activity coordinator.</p> <p>(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.</p> <p>(2) <i>Annual reassessment.</i> On at least an annual basis, the following members of the interdisciplinary team must conduct an in-person reassessment:</p>	

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Element	Requirement	Met/Not
	<p>(i) Physical therapist. (ii) Occupational therapist. (iii) Dietitian. (iv) Home care coordinator. (d) Unscheduled reassessments. In addition to annual and semiannual reassessments, unscheduled reassessments may be required based on the following: (1) A change in participant status. If the health or psychosocial status of a participant changes, the members of the interdisciplinary team, listed in paragraph (a)(2) of this section, must conduct an in-person reassessment. (2) At the request of the participant or designated representative. If a participant (or his or her designated representative) believes that the participant needs to initiate, eliminate, or continue a particular service, the appropriate members of the interdisciplinary team, as identified by the interdisciplinary team, 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. (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 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. (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: (A) The participant or designated representative requests the extension. (B) The team documents its need for additional information and how the delay is in the interest of the participant. (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. The PACE organization is responsible for the following: (A) Informing the participant or designated representative of his or her right to appeal the decision as specified in Sec.460.122. (B) Describing both the standard and expedited appeals processes, including the right to, and conditions for, obtaining expedited consideration of an appeal of a denial of services as specified in Sec.460.122. (C) Describing the right to, and conditions for, continuation of appealed services through the period of an appeal as specified in Sec.</p>	

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Element	Requirement	Met/Not
	<p>460.122(e).</p> <p>(v) If the interdisciplinary team fails to provide the participant with timely notice of the resolution of the request or does not furnish the services required 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 Sec.460.122.</p> <p>(d) <i>Changes to plan of care.</i> Team members who conduct a reassessment must meet the following requirements:</p> <ol style="list-style-type: none"> (1) Reevaluate the participant's plan of care. (2) Discuss any changes in the plan with the interdisciplinary team. (3) Obtain approval of the revised plan from the interdisciplinary team and the participant (or designated representative). (4) Furnish any services included in the revised plan of care as a result of a reassessment to the participant as expeditiously as the participant's health condition requires. <p>(e) <i>Documentation.</i> Interdisciplinary team members must document all assessment and reassessment information in the participant's medical record.</p>	
<p>SDY 05 §460.106 Plan of Care</p>	<p>(a) <i>Basic requirement.</i> The interdisciplinary team must promptly develop a comprehensive plan of care for each participant.</p> <p>(b) <i>Content of plan of care.</i> The plan of care must meet the following requirements:</p> <ol style="list-style-type: none"> (1) Specify the care needed to meet the participant's medical, physical, emotional, and social needs, as identified in the initial comprehensive assessment. (2) Identify measurable outcomes to be achieved. <p>(c) <i>Implementation of the plan of care.</i></p> <ol style="list-style-type: none"> (1) The team must implement, coordinate, and monitor the plan of care whether the services are furnished by PACE employees or contractors. (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 team and other providers. <p>(d) <i>Evaluation of plan of care.</i> On at least a semi-annual basis, the inter-disciplinary team must reevaluate the plan of care, including defined out-comes, and make changes as necessary.(e) <i>Participant and caregiver involvement in plan of care.</i> 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 pan of care and that the participant's concerns are addressed.(f) <i>Documentation.</i> The team must document the plan of care, and any changes made to it, in the participant's medical record.</p>	
<p>QAP 04</p>	<p>a) <i>Quality assessment and performance improvement requirements.</i> A PACE organization must do the</p>	

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Element	Requirement	Met/Not
<p>§460.136 Internal quality assessment and performance improvement activities.</p>	<p>following:</p> <p>(1) Use a set of outcome measures to identify areas of good or problematic performance.</p> <p>(2) Take actions targeted at maintaining or improving care based on outcome measures.</p> <p>(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.</p> <p>(4) Set priorities for performance improvement, considering prevalence and severity of identified problems, and give priority to improvement activities that affect clinical outcomes.</p> <p>(5) Immediately correct any identified problem that directly or potentially threatens the health and safety of a PACE participant.</p> <p>(b) <i>Quality assessment and performance improvement coordinator.</i> A PACE organization must designate an individual to coordinate and oversee implementation of quality assessment and performance improvement activities.</p> <p>(c) <i>Involvement in quality assessment and performance improvement activities.</i></p> <p>(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.</p> <p>(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 information about their satisfaction with services.</p>	

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Section 2A-Administrative: PACE Elements

Element	Requirement	Met/not met
CTS 01 §460.70 Contracted services.	<p>(a) <i>General rule.</i> 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 describe in §460.100.</p> <p>(b) <i>Contract requirements.</i> A contract between a PACE organization and a contractor must meet the following requirements</p> <p>(1) Contract only with an entity that meets all applicable Federal and State requirements... including Medicare and Medicaid requirements...</p> <p>(2) A contractor must be accessible to participants, located either within or near the PACE organization's service area.</p> <p>(3) A PACE organization must designate an official liaison to coordinate activities between contractors and the organization</p> <p>(d) <i>Content of contract.</i> Each contract must be in writing and include the following information:</p> <p>(1) Name of contractor</p> <p>(2) Services furnished (including work schedule if appropriate).</p> <p>(3) Payment rate and method.</p> <p>(4) Terms of the contract, including beginning and ending dates, methods of extension, renegotiation, and termination.</p> <p>(5) Contractor agreement to do the following:</p> <p>(i) Furnish only those services authorized by the PACE interdisciplinary team</p> <p>(ii) Accept payment from the PACE organization as payment in full, and not bill participants, CMS the State administering agency, or private insurers.</p> <p>(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.</p> <p>(iv) Not assign the contract or delegate duties under the contract unless it obtains prior written approval from the PACE organization.</p> <p>(v) Submit reports required by the PACE organization.</p> <p>(vi) Agree to perform all the duties related to its position as specified in this part.</p> <p>(vii) Participate in interdisciplinary team meeting as required.</p> <p>(viii) Agree to be accountable to the PACE organization.</p>	

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	<p>(ix) Cooperate with the competency evaluation program and direct participant care requirements specified in §460.71.</p> <p>(e) <i>Contracting with another entity to furnish PACE Center services.</i></p> <p>(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.</p> <p>(2) The PACE organization retains responsibility for all participants and may only contract for the PACE Center services identified in §460.98(d).</p>	
<p>FIN 01 §460.80 Fiscal Soundness</p>	<p>(a) <i>Fiscally Sound operation.</i> A PACE organization must have a fiscally sound operation, as demonstrated by the following:</p> <p>(1) Total assets greater than total liabilities</p> <p>(2) Sufficient cash flow and adequate liquidity to meet obligations as they become due.</p> <p>(3) A net operating surplus or a financial plan for maintaining solvency that is satisfactory to CMS and the State administering agency.</p> <p>(b) <i>Insolvency plan.</i> The organization must have a documented plan in the event of insolvency, approved by CMS and the State administering agency, which provides for the following:</p> <p>(1) Continuation of benefits for the duration of the period for which capitation payment has been made.</p> <p>(2) Continuation of benefits to participants who are confined in a hospital on the date of insolvency until their discharge.</p> <p>(3) Protection of participants from liability for payment of fees that are the legal obligation of the PACE organization.</p> <p>(c) <i>Arrangements to cover expenses.</i> (1) A PACE organization must demonstrate that it has arrangements to cover expenses in the amount of at least the sum of the following in the event it becomes insolvent:</p> <p>(i) One month's total capitation revenue to cover expenses the month before insolvency.</p> <p>(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 operations.</p> <p>(2) Arrangements to cover expenses may include, but are not limited to, the following:</p> <p>(i) Insolvency insurance or reinsurance.</p> <p>(ii) Hold harmless arrangement.</p> <p>(iii) Letters of credit, guarantees, net worth, restricted State reserves, or State law provisions.</p>	
<p>PRT 04 § 460.116 Explanation of Rights.</p>	<p>(a) <i>Written policies.</i> 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.</p> <p>(b) <i>Explanation of rights.</i> The PACE organization 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.</p>	

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	<p>(c) The PACE organization must meet the following requirements:</p> <p>(1) Write the participant rights in English and in any other principal languages of the community.</p> <p>(2) Display the participant rights in a prominent place in the PACE center.</p>	
<p>PRT 06 § 460.120 Grievance Process.</p>	<p>For purposes of this part, a grievance is a complaint, either written or oral, expressing dissatisfaction with services delivery or the quality of care furnished.</p> <p>(a) <i>Process to resolve grievances.</i> A PACE organization must have formal written process to evaluate and resolve medical and non-medical grievances by participants, their family members, or representatives.</p> <p>(b) <i>Notification to participants.</i> Upon enrollment, and at least annually thereafter, the PACE organization must give a participant written information on the grievance process.</p> <p>(c) <i>Minimum requirements.</i> At a minimum, the PACE organization's grievance process must include written procedures for the following:</p> <p>(1) How a participant files a grievance.</p> <p>(2) Documentation of a participant's grievance.</p> <p>(3) Response to, and resolution of, grievances in a timely manner.</p> <p>(4) Maintenance of confidentiality of a participant's grievance.</p> <p>(d) <i>Continuing care during grievance process.</i> The PACE organization must continue to furnish all required services to the participant during the grievance process.</p> <p>(e) <i>Explaining the grievance process.</i> 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.</p> <p>(f) <i>Analyzing grievance information.</i> 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.</p>	
<p>PRT 07 § 460.122 PACE Organization's Appeals Process.</p>	<p>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 including denials, reductions, or termination of services.</p> <p>(a) <i>PACE organization's written appeals process.</i> The PACE organization must have a formal written appeals process, with specified timeframes for response, to address noncoverage or nonpayment of a service.</p> <p>(b) <i>Notification of participants.</i> 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.</p> <p>(c) <i>Minimum requirements.</i> At a minimum, the PACE organization's appeals process must include written procedures for the following:</p>	

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<p>(1) Timely preparation and processing of a written denial of coverage or payment as provided in §460.104(c)(3).</p> <p>(2) How a participant files an appeal.</p> <p>(3) Documentation of a participant's appeal.</p> <p>(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.</p> <p>(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 received an appeal.</p> <p>(6) Maintenance of confidentiality of appeals.</p> <p>(d) <i>Notification.</i> A PACE organization must give all parties involved in the appeal the following:</p> <p>(1) Appropriate written notification.</p> <p>(2) A reasonable opportunity to present evidence related to the dispute, in person, as well as in writing.</p> <p>(e) <i>Services furnished during appeals process.</i> During the appeals process, the PACE organization must meet the following requirements:</p> <p>(f) <i>Expedited appeals process</i></p> <p>(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 or maintain maximum function could be seriously jeopardized, absent provision of the service in dispute.</p> <p>(2) Except as provided 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.</p> <p>(3) The PACE organization may extend the 72-hour timeframe by up to 14 calendar days for either of the following reasons:</p> <p>(i) The participant requests the extension.</p> <p>(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.</p> <p>(g) <i>Determination in favor of participant.</i> 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.</p> <p>(h) <i>Determination adverse to participant.</i> For a determination that is wholly or partially adverse to a participant, at the same time the decision is made, the PACE organization must notify the following:</p> <p>(1) CMS.</p> <p>(2) The State administering agency.</p> <p>(3) The participant.</p> <p>(i) <i>Analyzing appeals information.</i> A PACE organization must maintain, aggregate, and analyze information on appeal proceedings and use this information in the organization's internal quality</p>	
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	assessment and performance improvement program.	
PRT 08 § 460.124 Additional Appeal Rights Under Medicare or Medicaid.	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.	
MKT 03 §460.152 Enrollment Process	<p>(a) <i>Intake process.</i> Intake is an intensive process during which PACE staff members make one or 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:</p> <p>(1) The PACE staff must explain to the potential participant and his or her representative or caregiver the following information:</p> <p>(i) The PACE program, using a copy of the enrollment agreement described in Sec.460.154, specifically references the elements of the agreement including but not limited to Sec.460.154(e), (i) through (m), and (r).</p> <p>(ii) The requirement that the PACE organization would be the participant's sole service provider and clarification that the PACE organization guarantees access to services, but not to a specific provider.</p> <p>(iii) A list of the employees of the PACE organization who furnish care and the most current list of contracted health care providers under Sec. 460.70(c).</p> <p>(iv) Monthly premiums, if any.</p> <p>(v) Any Medicaid spenddown obligations.</p> <p>(vi) Post-eligibility treatment of income.</p> <p>(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.</p> <p>(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 have participated in the PACE demonstration waiver programs.</p> <p>(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.</p> <p>(b) <i>Denial of Enrollment.</i> 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</p>	

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	<p>following requirements:</p> <ol style="list-style-type: none"> (1) Notify the individual in writing of the reason for the denial. (2) Refer the individual to alternative services, as appropriate. (3) Maintain supporting documentation of the reason for the denial. (4) Notify CMS and the State administering agency and make the documentation available for review. 	
MKT 08 460.162 Voluntary Disenrollment	A PACE participant may voluntarily disenroll from the program without cause at any time.	
MKT 09 460.164 Involuntary disenrollment	<p>(a) <i>Reasons for involuntary disenrollment.</i> A participant may be involuntarily disenrolled for any of the following reasons:</p> <ol style="list-style-type: none"> (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. (2) The participant engages in disruptive or threatening behavior, as described in paragraph (b) of this section. (3) The participant moves out of the PACE program services 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. (4) The participant is determined to no longer meet the State Medicaid nursing facility level of care requirements and is not deemed eligible. (5) The PACE program agreement with CMS and the State administering agency is not renewed or is terminated. (6) The PACE organization is unable to offer health care services due to the loss of State licenses or contracts with outside providers. <p>(b) <i>Disruptive or threatening behavior.</i> For purposes of this section, a participant who engages in disruptive or threatening behavior refers to a participant who exhibits either of the following:</p> <ol style="list-style-type: none"> (1) A participant whose behavior jeopardizes his or her health or safety, or the safety of others; or (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. <p>(c) <i>Documentation of disruptive or threatening behavior.</i> 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:</p> <ol style="list-style-type: none"> (1) The reasons for proposing to disenroll the participant. (2) All efforts to remedy the situation. <p>(d) <i>Noncompliant behavior.</i></p> <ol style="list-style-type: none"> (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 condition of the 	

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	<p>participant, unless the participant's behavior jeopardizes his or her health or safety, or the safety of others.</p> <p>(2) For purposes of this section, noncompliant behavior includes repeated noncompliance with medical advice and repeated failure to keep appointments.</p> <p>(e) <i>State administering agency review and final determination.</i> 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.</p>	
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Section 2B – Administrative Part D Requirements

The following elements are taken verbatim from the Part D Audit guide.

Element	Requirement
<p>ER13</p>	<p><u>Confirmation of Enrollment for Members of Employer Group/Union Receiving Employer Subsidy</u></p> <p>The Part D sponsor must meet CMS requirements for obtaining a confirmation of the intent to enroll from any individual who attempts to enroll in the Part D plan, but whose enrollment is conditionally rejected by CMS due to a detected match indicating that the beneficiary may have existing Employer or Union drug coverage.</p> <p><i>PDP Guidance Eligibility, Enrollment and Disenrollment Medicare Managed Care Manual Ch. 2</i></p>
<p>PR02</p>	<p>Use of SSN/HICN</p> <p>The Part D sponsor must use a number other than an enrollee’s Social Security Number (SSN) or Healthcare Insurance Claim Number (HICN) on enrollee identification cards.</p> <p><i>PACE Part D Solicitation MA-PD Solicitation</i></p>
<p>EP01</p>	<p>Electronic Prescribing</p> <p>The Part D sponsor must establish and maintain an electronic prescription drug program that complies with the adopted standards.</p> <p>42 CFR § 423.159; § 423.160 <i>PACE Part D Solicitation MA-PD Solicitation</i></p>

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Element	Requirement
CB01	<p>Collecting and Updating Enrollees' Other Health Insurance Information</p> <p>The Part D sponsor must have a system for collecting and updating information from enrollees about their other health insurance, including whether such insurance covers outpatient prescription drugs, and must report that information to the Coordination of Benefits (COB) Contractor.</p> <p><i>PACE Part D Solicitation</i> <i>MA-PD Solicitation</i> <i>Medicare Prescription Drug Benefit Manual, Chapter 14-Coordination of Benefits</i></p>
CB03	<p>TrOOP Status at Disenrollment</p> <p>The Part D sponsor must provide the beneficiary's gross covered drug spend and true out-of-pocket (TrOOP) balance to the beneficiary as of the effective date of disenrollment, and if the disenrollment is due to a mid-year plan change, provides a report of these beneficiary data to the new plan of record.</p> <p><i>PACE Part D Solicitation</i> <i>MA-PD Solicitation</i></p>
CP06	<p>Internal Monitoring and Auditing Procedures</p> <p>The Part D sponsor must have and implement a compliance plan that includes procedures for effective internal monitoring and auditing.</p> <p>42 CFR § 423.504(b)(4)(vi)(F) <i>PACE Part D Solicitation</i> <i>MA-PD Solicitation</i></p>
CP07	<p>Response to Detected Offenses and Corrective Action Plan</p> <p>The Part D sponsor must have and implement a compliance plan that includes procedures to ensure a</p>

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Element	Requirement
	<p>prompt response to detected offenses relating to the organization’s contract as a Part D sponsor, and must conduct a timely, reasonable inquiry upon discovery of evidence of misconduct related to payment or delivery of prescription drug items or services under the contract. The Part D sponsor must also develop and conduct appropriate corrective actions in response to identified violations.</p> <p>42 CFR § 423.504(b)(4)(vi)(G) <i>PACE Part D Solicitation</i> <i>MA-PD Solicitation</i></p>
CP08	<p>Comprehensive Fraud and Abuse Plan</p> <p>The Part D sponsor must have and implement a compliance plan that includes a comprehensive plan to detect, correct, and prevent fraud, waste, and abuse.</p> <p>42 CFR § 423.504(b)(4)(vi)(H) <i>PACE Part D Solicitation</i> <i>MA-PD Solicitation</i> <i>Prescription Drug Benefit Manual: Chapter 9 – Part D Program to Control Fraud, Waste and Abuse</i></p>
CL01	<p>Online Claims Processing System</p> <p>The Part D sponsor must develop and operate a real-time online claims processing system that operates according to CMS standards.</p> <p><i>PACE Part D Solicitation</i> <i>MA-PD Solicitation</i></p>
CL02	<p>Data Elements Needed to Link Medicare Parts A, B and D Data</p> <p>The Part D sponsor must submit claims data that can be linked at the individual level to Medicare Parts A and B data.</p>

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Element	Requirement
	42 CFR § 423.329(b)(3)(i); § 422.310 <i>Instructions: Requirements for Submitting Prescription Drug Event Data</i>
CL03	Processing Systems The Part D sponsor has a detailed claims adjudication process including flow charts, claims management, data capture and claims data retrieval processes. <i>PACE Part D Solicitation</i> <i>MA-PD Solicitation</i>
CL04	Disputed Claims The Part D sponsor must have and implement policies and procedures surrounding disputed claims. <i>PACE Part D Solicitation</i> <i>MA-PD Solicitation</i>
CL06	Online Claims Processing System The Part D sponsor must develop and operate a real-time online claims processing system that operates according to CMS standards. <i>PACE Part D Solicitation</i> <i>MA-PD Solicitation</i>
PA01	Certification of Monthly Enrollment and Payment Data Relating to CMS Payment Payments to a Part D sponsor are conditioned upon its submittal and certification of enrollment, disenrollment, and change transactions to CMS each month. The Part D sponsor must submit reconciled enrollment/payment reports and signed attestation forms to CMS within 45 days of data availability.

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Element	Requirement
	<p>42 CFR § 423.505(k)(2) <i>PACE Part D Solicitation</i> <i>MA-PD Solicitation</i></p>
<p>PA02</p>	<p>Submission of Prescription Drug Event (PDE) Data By May 31 following the end of a coverage year, the Part D sponsor must provide to CMS PDE data that will be used to reconcile the reinsurance subsidy, low income cost-sharing subsidies, and risk corridors.</p> <p>42 CFR § 423.336(c)(1); § 423.343(c)(1); § 423.343(d)(1)</p>
<p>PA03</p>	<p>Overpayment and Underpayment Requirements The Part D sponsor must develop and have available to CMS upon request, policies and procedures that include a description of how overpayments and underpayments are handled, as well as recovery procedures. The Part D sponsor must also report to CMS data related to overpayments associated with Part D benefits.</p> <p><i>PACE Part D Solicitation</i> <i>MA-PD Solicitation</i> <i>Medicare Part D Reporting Requirements</i></p>

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