Topic Area	PACE Regulations	PACE Protocol
Program Purpose - ' 460.2	The regulations= s scope and purpose include the core values specified in the protocol, to: (1) Enhance the quality of life and autonomy for frail older adults. (2) Maximize the dignity of, and respect for, older adults, (3) Enable frail, older adults to live in the community as long as medically and socially feasible. (4) Preserve and support the older adult= s family unit.	Core values of a PACE provider= s philosophy: (1) Enhance the quality of life and autonomy for frail older adults. (2) Maximize the dignity of, and respect for, older adults, (3) Enable frail, older adults to live in the community as long as medically and socially feasible. (4) Preserve and support the older adult= s family unit.
PACE Definitions - ' 460.6	The regulations uses the term ***PACE organization*** to refer to the PACE entity that has in effect the program agreement to operate a PACE program. *The regulations define **trial period** as the first three years in which a PACE organization operates under a PACE program agreement, including any contract year the entity operated under a waiver demonstration. *The regulations include additional definitions and definitions unique to permanent PACE organizations. The additional include defining a PACE Center, a Medicare beneficiary, a Medicare participant, a Medicaid participant, contract year, a PACE program agreement, services, and state administering agency.	The protocol uses the term ***PACE provider*** to refer to the PACE entity under the demonstration. The PACE protocol defines the term **trial period** as one up to three years in length during which the PACE provider meets all the requirements in operating a PACE program except that financial risk is shared between the provider and the federal and state governments based on the arrangement developed by HCFA. .
Application	The regulations include detailed	In general, these requirements are not

Topic Area	PACE Regulations	PACE Protocol
Requirements - '' 460.10 - 460.24	requirements for receiving PACE applications and evaluating those applications. *An interested PACE organization must submit a complete application to HCFA. *Applications must include the service area designation. * Applications must include State assurances. *Time frames are set forth for receipt and evaluation of permanent provider applications. *Limits are set forth for the number of PACE program agreements. *Priority consideration is given to existing PACE demonstrations, and special consideration is given to certain entities expressing interest before a given date.	applicable to demonstrations operating under the PACE protocol. *Interested PACE organizations apply for demonstration waivers under ' 1115 and ' 222 of the Social Security Act. *Demonstration applications and contracts must designate a service area. *PACE providers enter into contracts with the federal and state administering agencies to operate a PACE program. Not applicable. Not applicable Not applicable
Program Agreements - ''460.30 - 460.54	Similar to the Protocol, PACE organizations must enter into an agreement with HCFA and State administering agencies. *Unlike the protocol, a three-way agreement, called the *program agreement*, is specified in the regulations. *The regulations mirror the elements which must be included in the program agreements, and provide additional specificity *(for example, a description*	The protocol requires formal contracts with federal and state administering agencies. *The protocol sets forth critical elements to be addressed in the formal contracts. *Critical elements include: Provider organization, participant rights, eligibility, enrollment disenrollment policies, service definitions, coverage and arrangement, quality assurance, reimbursement,

Topic Area	PACE Regulations	PACE Protocol
	of grievance and appeals process, levels of performance on required standard quality measures, and additional optional elements). *The regulations include detailed requirements in the areas of program agreement time frames, sanctions, other enforcement actions, and terminations. *The regulations provide further detail with respect to reasons for termination, transition care plans, and specific termination procedures.	administration, and Provider termination. * The protocol does not address contract time frames, sanctions, and other enforcement actions. * The protocol specifies reasons for provider termination.
Administrative Requirements - '' 460.60 -460.62	The regulations require the PACE organization: *To be a public or private not-for-profit entity. *To employ a director responsible for oversight and administration of the entity. The regulations use the term ***Program Director***. *To employ a medical director. *To have a current organizational chart including the names of the organizationFs officials and illustrating the relationship of the entity to the parent, affiliate, or subsidiary. *To have a ***governing body*** or designated person functioning as the governing body Awith full legal authority and responsibility.@ The function of the governing body are further detailed. *To establish a multidisciplinary team. *To have a PACE center. *To ensure community representation on issues related to participant care.	The Protocol requires a PACE provider to: *To be a public or private not-for-profit entity. *To employ a ***Project Director*** responsible for oversight and administration of the entity. *To employ a medical director *To make available a current organizational chart including the names of the organizationFs officials and illustrating the relationship of the entity to the parent, affiliate, or subsidiary. *To have a ***policy making body*** to oversee operations and administer resources. *To establish a multidisplinary team. *To have a PACE center. *To ensure community representation is provided on issues of program management and participant care.

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Topic Area	PACE Regulations	PACE Protocol
	* To establish a consumer advisory committee to provide advice to the governing body on matters of concern to participant.	
Personnel Qualifications - ' 460.64	The regulations set forth detailed qualification requirements for physicians, and absent State requirements, qualifications for: *registered nurses *social worker *physical therapist *occupational therapist *recreational therapist or activities coordinator *dietician *drivers	The PACE protocol refers to state licensing and certification requirements , but does not specify any further personnel requirements.
Training - ' 460.66	The regulations require the PACE organization to: *provide training to maintain and improve the skills of each staff member. *develop a training program for each personal care attendant.	The PACE protocol does not specify requirements for training of PACE personnel.
Program Integrity - ' 460.68	The regulations specify that a PACE organization must not employ or contract with individuals: *with criminal convictions *with direct or indirect interest in contracts (Under the regulations, waiver are permitted in limited circumstances).	The PACE protocol specifies that the PACE provider must not have any agents or management staff: *convicted of criminal convictions *have any direct or indirect interest in any contract.
Contracted Services - ' 460.70	The regulations refer to ***contracts***, as opposed to ***subcontracts***. Similar to the protocol, the regulations require the	The PACE protocol requires the PACE provider to establish sub-contracts for services not delivered directly by the

Topic Area	PACE Regulations	PACE Protocol
	PACE organization to have written contracts with outside organizations that furnish administrative or care-related services not provided by the PACE organization. Specifically, the regulations: *Specify overall contract requirements. *Require that a list of contractors be available at the PACE center. *Require the PACE organization to furnish a copy of each signed contract for inpatient care to HCFA and the State administering agency. *Specify content requirements of contracts	PACE provider. Specifically, the protocol: *Specifies overall subcontract requirements. *Requires that a list of subcontractors be available at the PACE center. *Requires the PACE provider to furnish a copy of each signed contract for inpatient care to HCFA and the State administering agency. *Specifies content requirements for subcontracts
Physical Environment - ' 460.72	The regulations specify detailed requirements for the following areas. *SPACE and equipment, including requirements for safe design, primary clinic, and equipment maintenance. *Fire Safety, including exceptions. *Emergency and Disaster Preparedness, including requirements for emergency training, availability of emergency equipment, and annual test of emergency and disaster plan.	The protocol requires a PACE provider to have facilities and equipment that meet applicable State requirements. Not addressed in the protocol. Not addressed in the protocol. Not addressed in the protocol.
Infection Control - ' 460.74	The regulations require the PACE organization to follow accepted policies and standard procedures with respect to infection control, including at least the standard precautions developed by the	The PACE protocol does not address infection control procedures.

Topic Area	PACE Regulations	PACE Protocol
	CDC. The regulations also establish requirements for an infection control plan.	
Transportation services - ' 460.76	The regulations specify transportation requirements in the following areas: *Safety, accessibility, and equipment. *Maintenance of vehicles. *Communication with the PACE center *Training * Changes in the care plan	The PACE protocol does not address transportation requirements.
Dietary Services - ' 460.78	The regulations establish meal requirements such that the PACE organization: *Provides each participant with a nourishing, palatable, well-balanced meal that meets the nutritional and special dietary needs of the participant. *Provides substitute foods or nutritional supplements to participants that have specified problems. *Provides nutrition support, if required by the participant=s medical condition or diagnosis. *Must abide by requirements to ensure sanitary conditions.	The PACE protocol does not address meal requirements.
Fiscal Soundness - ' 460.80	The regulations require a PACE organization to have a fiscally sound operation, with regard total assets, cash flow, and net operating surplus. *PACE organizations must also have an insolvency plan and arrangements to cover expenses.	The PACE protocol contains similar requirements that the PACE provider have a fiscally sound operation. *Under the protocol, PACE providers also must have an insolvency plan and arrangements to cover expenses.
Marketing - ' 460.82	The regulations specify the information that must be contained in a PACE	The protocol specifies the information that must be contained in a PACE

Topic Area	PACE Regulations	PACE Protocol
	organization=s marketing materials. These requirements are consistent with the protocol. The regulation also: *Establishes procedures which require all marketing materials be reviewed and approved by HCFA before distribution, including any revised or updated material. HCFA is permitted **45 days** from receipt of the information to review and approve marketing materials * Specifies language requirements. *Details prohibited marketing practices. *Requires PACE organizations to have a marketing plan.	provider=s marketing materials. The protocol also: *Requires all written marketing information be approved by HCFA **30 days** after receipt. The protocol does not address language requirements. *Details prohibited marketing practices. *Requires PACE providers to have a marketing plan.
PACE benefits - ' 460.90	The regulations specify that if a Medicare beneficiary or Medicaid recipient chooses to enroll in a PACE program, they: *are not subject to Medicare or Medicaid benefit limitations (i.e., amount, duration, and scope of services, deductibles, copayments, coinsurance, or other cost-sharing). *must receive Medicare and Medicaid benefits solely through the PACE organization.	The PACE protocol: *states that all usual limitations and conditions for covered services are waived. *states that participants enrolled in PACE must accept PACE as his/her sole service provider and its multidisciplinary team as his/her sole case manager.
PACE services - '	The regulations require that the PACE	The protocol specifies that, a minimum,

Topic Area	PACE Regulations	PACE Protocol
460.92	benefit package to include the following services: *all Medicaid State plan services *nursing facility care *multidisciplinary assessment and treatment planning. *primary care *social work services *restorative therapies *personal care and supportive services *nutritional counseling *recreational therapy *transportation *meals *medical specialty services *laboratory tests, x-rays, and other diagnostic procedures *drugs and biologicals *prosthetics, orthotics, durable medical equipment, corrective vision devices, hearing aids, dentures, and repair and maintenance of these items. *acute inpatient care *other services determined necessary by the multidisciplinary team.	the PACE service package shall provide the following services: *all current Medicaid and Medicare services *nursing facility care *multidisciplinary assessment and treatment planning. *primary care *social work services *restorative therapies *personal care and supportive services *nutritional counseling *recreational therapy *transportation *meals *medical specialty services *laboratory tests, x-rays, and other diagnostic procedures *drugs and biologicals *prosthetics, orthotics, durable medical equipment, corrective vision devices, hearing aids, dentures, and repair and maintenance of these items *acute inpatient care *additional services determined necessary by the multidisciplinary team.
Required Services for Medicare participants - ' 460.94	The regulations specify that, except for Medicare requirements that are waived for the PACE program, the PACE organization=s benefit package must include the hospital insurance and supplemental medical insurance described in the regulations.	The protocol specifies that the PACE service package includes, but is not limited to all covered Medicare and Medicaid services.

Topic Area	PACE Regulations	PACE Protocol
	The regulations specify the specific regulatory provisions that are waived. They include: *regulatory provisions which discuss limitation on coverage of institutional services, *regulatory provisions which relate to payment for benefits, *regulatory provisions that limit coverage of extended care services, *regulatory provisions which impose a three day prior hospitalization requirement for extended care services, and *regulatory provisions that may prevent payment for PACE program services to PACE participants.	The protocol states that all usual limitations and conditions for covered services are waived.
Excluded services - ' 460.96	The regulations specify services that are excluded from coverage under PACE, including: *any service not authorized by the multidisciplinary team, except for an emergency, *private room, private duty nursing, and non-medical items in an inpatient facility, unless authorized, *cosmetic surgery, except in certain circumstances *experimental medical, surgical, or other health procedures, and *services furnished outside the United States, with certain exceptions. Not specifically mentioned in the	The protocol specifies that the following services are excluded: *any service not authorized by the multidisciplinary team, except for an emergency, *private room, private duty nursing, and non-medical items in an inpatient facility, unless authorized, *cosmetic surgery, except in certain circumstances, experimental medical, surgical, or other health procedures, and *services furnished outside the United States, with certain exceptions, *services rendered in a non-emergency

Topic Area	PACE Regulations	PACE Protocol
	regulations. Not specifically stated in the regulations. Not specifically stated in the regulations. Not specifically stated in the regulations.	setting or for a non-emergency reason without authorization, *prescription and over-the counter drugs not prescribed by the PACE provider physician, *care in a government hospital (VA, federal/State hospital) unless authorized, and *service in any county hospital for the treatment of tuberculosis or chronic, medically uncomplicated drug dependency or alcoholism.
Service delivery - ' 460.98	The regulations require PACE organizations to establish a written plan to furnish care that meets the needs of its participants in all care settings 24 hours a day, every day throughout the year. The regulations also set forth detailed information on provision of services, such that: *The PACE organization must furnish comprehensive medical, health, and social services that integrate acute and long term care *The PACE organization must furnish services in the PACE center, the home, or inpatient facility, *The PACE organization provide minimum services to be furnish in each PACE center (primary care, social services, restorative therapies, personal care and supportive services, nutritional counseling, recreational therapy, and meals). *The PACE organization is required to operate at least one PACE Center in its	The protocol requires PACE providers must provide its participants with access to medical care and other services, as applicable, 24 hours per day, 7 days a week, 365 days per year. The protocol also states the following: *PACE is a comprehensive health and social services delivery system which integrates acute and long term care services. The PACE staff provides services in all settings which may include, but are not limited to the PACE Center, the home, and inpatient facilities. *The PACE Center must provides the following minimum services (primary care, social services, restorative therapies, personal care and supportive services, nutritional counseling, recreational therapy, and meals). * The PACE provider must operate at least one PACE Center in its defined

Topic Area	PACE Regulations	PACE Protocol
	defined service area with sufficient capacity to allow routine attendance by participants. *The PACE organization must ensure adequate and accessible services to meet the needs of its participants, including increasing the number of Centers, staff, or other services. *Center attendance is determined by the multidisciplinary team, based on needs and preferences. *The PACE organization may not discriminate against any participant.	service area with sufficient capacity to allow routine attendance by participants. The PACE provider must ensure adequate and accessible services to meet the needs of its participants, including increasing the number of Centers, staff, or other services. Center attendance is determined by the multidisciplinary team, based on needs and preferences. Does not speak to this requirement. *Center attendance is determined by the multidisciplinary team, based on the needs and preferences of each participant Center attendance is determined by the multidisciplinary Center attendance is determined by the multidisciplinary
Emergency Care - ' 460.100	The regulations require the PACE organization to have a written plan to handle emergency care. The regulations also: *Further define emergency care according to a prudent layperson definition. *Require explanations on how to access emergency care be provided to participants. *Require on-call providers 24 hours a day and coverage of urgently needed out-of-network and post-stabilization care services.	The protocol defines an emergency, but does not require a written plan for how to handle emergency care. The protocol: *Does not reference a prudent layperson definition. *Does not speak to this requirement. *Does not speak to this requirement.
Composition of Multidisciplinary team - ' 460.102(a)	The regulations require the PACE organization to establish a multidisciplinary team composed of at least the following	The protocol establishes that the multidisciplinary team must be comprised of the following members:

Topic Area	PACE Regulations	PACE Protocol
and (b)	members: *primary care physician *registered nurse *social worker *physical therapist *occupational therapist *recreational therapist or activity coordinator *dietician *PACE Center manager *home care coordinator *personal care attendant of his or her representative *driver or his or her representative	 *primary care physician *nurse *social worker *physical therapist *occupational therapist *recreational therapist or activity coordinator *dietician *PACE Center supervisor *home care liaison *health workers/aides or their representatives *driver or their representatives
Roles and Responsibilities of the Multidisciplinary team - '460.102(c), (d), and (e)	With respect to multidisciplinary teams, the regulations include the following: *Primary medical care must be furnished by the primary care physician and further defines the role of primary care physicians. *Sets forth the responsibilities of the multidisciplinary team, including requiring that team members serve primarily PACE participants. *Requires a PACE organization to have documented internal procedures governing the exchange of information among team members.	The protocol states that the multidisciplinary team authorizes PACE covered services which meet the specific needs of the participant. In addition: *Primary medical care is furnished by the primary care physician(s) to all participants. *The multidisciplinary team, must serve primarily PACE participants. *Does not speak to this requirement.
Organization of the Multi-disciplinary team - ' 460.102(f)	The regulations require that the following members of the multidisciplinary team be employees of the organization: *primary care physician	The protocol states that the following members of the multidisciplinary team be employees of the PACE provider or Center: *primary care physician

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Topic Area	PACE Regulations	PACE Protocol
	*registered nurse *social worker *recreational therapist or activity coordinator *PACE Center manager *home Care Coordinator *PACE Center personal care attendant	*nurse *social worker *recreational therapist or activity coordinator *PACE Center supervisor *home Care liaison *PACE Center health workers/aides
Waivers of requirements for the Multidisciplinary team - ' 460.102(g)	The regulations grant specific authority to HCFA and the State administering agency to: *waive the requirement that multidisciplinary team members be an employee of the PACE organization *waive the requirement that the primary care physician be an employee of the PACE organization The regulations also set forth procedures governing submission of waiver requests.	The protocol generally states that, at the request of the provider, HCFA and the State Medicaid agency shall have the authority to waive specific requirements.
Participant Assessment - ' 460.104	The regulations require PACE organization to do the following: *Conduct an initial comprehensive assessment of each participant, *Ensure that, as part of the initial comprehensive assessment, each member of the multidisciplinary team evaluates the participant in person and develops a discipline-specific assessment, *Permit other professional disciplines to be included in the comprehensive assessment process. *Require the comprehensive assessment criteria to include a number of minimum factors. *Require the multidisciplinary team to consolidate discipline specific assessments	The protocol requires the PACE provider to do the following: *Conduct an initial assessment of each participant, *Ensure that, as part of the initial comprehensive assessment, each member of the multidisciplinary team evaluates the participant in person and develops a discipline-specific treatment plan, *Permit other professional disciplines to be included in the comprehensive assessment process. *Does not speak to this requirement. *Require the discipline specific treatment

Topic Area	PACE Regulations	PACE Protocol
	into a single plan of care, which must be updated with any reassessments and documented in the participant=s medical record. *Require periodic reassessments on a semiannual basis by the primary care physician, registered nurse, social worker, recreational therapist or service coordinator, and other team members actively involved in the participants plan of care. *Requires annual reassessments by the physical therapist, dietician, and home care coordinator. *Requires reassessments based on a change in the participant=s status or at the request of the participant, *Requires procedures for resolutions of requests to initiate, eliminate, or continue a particular service.	plans be documented in the participant=s medical record, and at least on a semi-annual basis, consolidated into a single plan of care. *Require periodic reassessments on a semiannual basis by the primary care physician, nurse, social worker, recreational therapist or activity coordinator, and other team members actively involved in the participants plan of care. *Requires annual reassessments by the physical therapist, dietician, and home care liaison. *Requires reassessments based on a change in the participant=s status or at the request of the participant. *States that the treatment plan is discussed and finalized with the participant and/or his/her significant others.
Plan of Care - ' 460.106	The regulations contain detailed requirements governing the content, implementation, evaluation, and documentation of the plan of care: *The plan of care must specify the care needed to meet the participant=s medical, physical, emotional, and social needs, as well as measurable outcomes to be achieved. *The team must continuously monitor the participant=s health and psychosocial status, as well as the effectiveness of the plan of care.	The protocol is not as detailed as the regulations. It specifies the following with respect to the treatment plan/ plan of care: *Services are authorized to meet the specific needs of the participant. The team implements the treatment plan by providing services directly and supervising delivery of services provided by contract providers. *The team must continuously monitor the participant=s health and psychosocial status, as well as the effectiveness of the treatment plan

Topic Area	PACE Regulations	PACE Protocol
	*On at least a semi-annual basis, the team must reevaluate the plan of care, including the defined outcomes, and make changes as necessary. *The team must collaborate with participants or caregivers in the development, review, and reevaluation of the plan of care. *The team must document the plan of care in the participant=s medical record.	*On at least a semi-annual basis, the team must consolidate discipline-specific plans into a single plan of care. *The team must collaborate with participants or caregivers in the development, review, and reevaluation of the plan of care. *The team must document the treatment plan in the participant=s medical record.
Bill of Rights - ' 460.110	The regulations require: *A PACE organization have a written bill of rights, *Provide an explanation of those rights to participants, and *Protect and provide for the exercise of those rights.	The protocol specifies a formal Participant Bill of Rights, posted in a prominent place in the PACE center (in English and any other predominant language), and which is orally reviewed with the participant and family at enrollment. A copy is included in the member handbook given at enrollment.
Specific Rights to which a participant is entitled - ' 460.112	The regulations specify that a participant is afforded the right to: *Respect and nondisrimination *Information disclosure *Choice of providers *Access to emergency services *Participation in treatment decisions *Confidentiality of health information *Complaints and appeals	The protocol specifies participant rights in the following areas: *Respect and nondisrimination *Information disclosure *Choice of providers *Access to emergency services *Participation in treatment decisions *Confidentiality of health information *Complaints and appeals
Restraints- ' 460.114	The regulations specify that PACE organization must limit the use of physical or chemical participant restraints to the least restrictive and most effective method available. *The regulations also define physical and chemical restraints, and require that the use of a restraint meet certain conditions	The protocol does not address the use of restraints.

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Topic Area	PACE Regulations	PACE Protocol
	on time of use and safety, as well as restrained participant monitoring.	
Explanation of Rights- ' 460.116	The regulations specify that a PACE organization must: * have written policies and procedures in place to ensure that participants as well as staff understand the rights above. * explain the rights to the participant at the time of enrollment. * set conditions on the display of participant rights (language, prominence)	The protocol specifies a formal Participant Bill of Rights, posted in a prominent place in the PACE center (in English and any other predominant language), and which is orally reviewed with the participant and family at enrollment. A copy is included in the member handbook given at enrollment.
Violation of Rights- ' 460.118	The regulations require that procedures exist to respond to and rectify violations of rights.	The protocol does not address procedures for responding to and rectifying participant rights violations.
Grievance Process ' 460.120	The regulations detail requirements on a PACE organization to deal with complaints: * formal written grievance process * notification to participants * minimum requirements on the grievance process. * continuance of care * explanation of the process * analysis of grievance information	The protocol requires the following: * formal written grievance process * notification to participants * timeliness of grievance processing **The protocol does not address any minimum requirements, continuance of care, process explanation, or analysis of grievance information.
PACE Organizations Appeals Process ' 460.122	The regulations set requirements on the PACE organization for appeals, including: * that a formal, written process exist * that participants be provided information on the appeals process after a denial * certain minimum requirements that must be met * notification of interested parties * services provided during the appeal	For the appeals process, the protocol requires that: *the participant be informed of his/her right to appeal. *reconsideration of grievances be made by persons not involved in the initial determination *does not address minimum appeal requirements. * all determinations adverse (in part or in

Topic Area	PACE Regulations	PACE Protocol
	* existence of an expedited appeals process * analysis of appeals information	whole) to the participant are forwarded to HCFA and the State Medicaid agency, and if the determination is reversed the PACE provider must take appropriate action in a timely manner. The protocol does not prescribe requirements for analysis of appeals information
Quality Assessment and Performance Improvement Plan ' 460.130-132	The regulations require a written Quality Assessment and Improvement Plan, with an annual review, that meets certain basic requirements.	The protocol specifies a written Quality Assurance and Improvement plan, with annual review by the program board.
Minimum Requirements for quality assessment and performance improvement program ' 460.134	The regulations specify a wide range of specific objective measures to demonstrate improved performance The regulations also define the basis for outcome measures, set minimum levels on performance, and require accuracy.	The protocol does not include specific objective measures. It focuses on setting standards to meet applicable licensing and certification criteria, among others, and goals and objectives to guide activities, evaluation, and correction. It mentions that the QA plan will include measurable variables.
Internal Quality Assessment and Performance Improvement Activities ' 460.136-140	The regulations specify: * requirements on the implementation of the QA/PI plan * the designation of a QA/PI coordinator * that all team members, staff, etc., are fully informed and involved in the process. * that participants be encouraged to be involved in QA/PI activities. * that the PACE organization establish committees, with community input, to aid the QA/PI process. * that the PACE organization meet certain external quality assessment requirements.	The protocol states that the QA plan shall include, at a minimum: * the designation of a QA coordinator * process to review effectiveness of PACE multidisciplinary teams * participant involvement * policies and procedures related to establishing committees, with community input, to aid the process. * Board level accountability for overall oversight of program activities and review of the QA plan.

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Topic Area	PACE Regulations	PACE Protocol
Eligibility to enroll in a PACE program ' 460.150	The regulations define eligibility requirements for PACE, including: * age 55 or older * reside in the service area of the PACE organization * be determined to need the level of care required * meet additional conditions under the PACE program agreement. * be able to live in the community without jeopardizing his/her health. The regulations note that PACE is not restricted to Medicare/Medicaid beneficiaries.	The protocol sets eligibility requirements for PACE, including: * age 55 or older * reside in the service area of the PACE organization * assessed by the PACE provider=s multidiciplinary team, * certified by the State Medicaid Agency as eligible for nursing home level of care. The protocol provides the option for the PACE provider not to enroll those participants whose health and safety would be jeopardized by remaining in their home and community.
Enrollment Process ' 460.152	The regulations set required activities to occur during the intake process, including the description of the program, disclosure of monthly premiums, and patient assessment. The regulations also detail procedures for individual and HCFA notification in the event that enrollment is denied.	The protocol requires a screening visit to explain PACE, the lock-in provision, monthly fees, if any, and patient assessment. Written notification is to be provided to the individual in the event that enrollment is denied, with referral to alternative agencies.
Enrollment Agreement ' 460.154	The regulations detail the minimum contents of the enrollment agreement between the prospective participant and the PACE Organization.	The protocol defined Enrollment Agreement closely follows the regulations, with the following notes: * Distribution of the Bill of Rights is not covered, though mentioned in other areas of the protocol. * Any discussion of spenddown liability is presumably included in the conditions for enrollment/disenrollment in Medicare/Medicaid (e), as are the consequences of subsequent enrollment

Topic Area	PACE Regulations	PACE Protocol
		in Medicare/Medicaid programs.
Other Enrollment Procedures ' 460.156-158	The regulations specify: * which items the PACE organization must give the participant following enrollment, including a copy of the agreement, a membership card, emergency information, and stickers for Medicare and Medicaid cards. * that the PACE organization submit participant information to HCFA. * that the PACE organization communicate any plan changes to the participant. * that the effective date of enrollment is the first day of the calendar month following the date the PACE organization receives the agreement.	The protocol requires: * after signing the Enrollment Agreement, the distribution of a copy of the agreement, a membership card, emergency sticker, and stickers for Medicare and Medicaid cards * Enrollment documents to be submitted to HCFA and the State Medicaid Agency. * not covered in the enrollment procedures * the effective date of enrollment to be the first day of the calendar month following the signing date of the Enrollment Agreement.
Continuation of Enrollment ' 460.160	The regulations define: * enrollment duration * the annual recertification requirement, including its waiver and Adeemed continued@ eligibility option. * who makes the determination of continued eligibility (the State administering agency in consult with the PACE organization.)	The protocol covers enrollment duration. *Annual recertification and continued eligibility determination are not discussed.
Voluntary Disenrollment ' 460.162	The regulations provide that a participant may voluntarily disenroll at any time.	The protocol states that a participant may voluntarily disenroll at any time.
Involuntary Disenrollment ' 460.164	The regulations provide reasons that allow for the involuntary disenrollment of a participant, including: * non-payment of premiums * disruptive behavior	The protocol lists reasons for involuntary disenrollment of a participant as follows: * non-payment of amounts due * there exists a breakdown in the physician-team/participant relationship such that the ability to furnish services is

Topic Area	PACE Regulations	PACE Protocol
	* moving out of the service area * participant no longer meets level of care requirements * termination of the PACE program * inability of PACE organization to offer services due to loss of licensure or contracts. *The regulation also further defines disruptive and threatening behavior, and allows for disenrollment based on non-compliant behavior. It also provides that the State administering agency must review all involuntary disenrollments prior to their taking effect.	seriously impaired * non-compliant behavior * participant moves out of service area * not discussed * not discussed * inability of the PACE program to offer services due to loss of licensure or contracts. * refuses to provide accurate financial information, provides false information, or illegally transfers assets. * remains out of the service area for more than 30 days (absent other arrangements).
Effective date of disenrollment ' 460.166-168,172	The regulations require the following actions when disenrolling a participant. The PACE organization must: * use the most expedient process allowed * coordinate with Medicare and Medicaid * provide reasonable advance notice * properly document reasons for disenrollment and make such documentation available to HCFA for review.	The protocol requires the PACE provider to: * use the most expedient process allowed * include disenrollment procedures in contracts with HCFA and the State Medicaid Agency. * not discussed * document and make available to HCFA and the State Medicaid Agency all voluntary and involuntary disenrollments.
Reinstatement in PACE ' 460.170	The regulations state that previously disenrolled participants may be reenrolled, and that a participant disenrolled for non-payment of premiums may be reinstated if the premiums are paid before the effective date of the disenrollment.	A one-time only reinstatement for voluntary disenrollees is allowed, if the participant meets the eligibility requirements. A participant will be reenrolled if payment of the monthly fee before the end of the month of disenrollment is made.

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Topic Area	PACE Regulations	PACE Protocol
Medicare payment to PACE organizations ' 460.180	The regulations describe the principle of payment, in that HCFA makes a prospective monthly payment (capitated for each Medicare participant in a given service area) to the PACE organization. * The monthly capitation rates are to be adjusted by frailty factors necessary to ensure comparability between PACE and reference populations. *The regulations specify how the capitation rate is determined, and that adjustments for actual participants will be made. *The regulations also specify that HCFA will not pay for services for which Medicare is not the primary payer. The PACE organization has the responsibility for identifying which payers are primary to Medicare, determining amounts to be paid, and charging those payers	The protocol describes the monthly capitation rate as equal to the Adjusted Average Per Capita Cost calculated by HCFA adjusted by necessary frailty factors. * The capitation payment is fixed, regardless of changes in the participant=s health status. * HCFA procedures for accretions and deletions, payment mechanism, cost finding, and risk sharing are included in the PACE contract * The PACE provider shall accept the capitation payments as payment in full and not charge HCFA or the participant, except for the private pay premium.
Medicaid Payment ' 460.182-184	The regulations state that the State administering agency shall make a prospective monthly payment to the PACE organization capitated on the number of Medicaid participants in the service area. *The amount of this fixed payment is negotiated between the PACE organization and the State agency, may be renegotiated annually. *The PACE organization must accept this payment as payment in full for any Medicaid participant.	The protocol states that the monthly capitation payment is negotiated between the PACE provider and the State Medicaid Agency. * The capitation payment is fixed and adjusted annually. *The PACE organization must accept this payment as payment in full for any Medicaid participant.
PACE Premiums ' 460.186	The regulations limit the monthly premium a PACE organization can charge a participant: * Medicare Parts A and B: premium	The protocol lists private pay premiums as follows: * Medicare only: premium equal to

Topic Area	PACE Regulations	PACE Protocol
	equals Medicaid capitation amount * Medicare Part A only: premium equals sum of Medicaid and Medicare Part B capitation rate * Medicare Part B only: premium equals sum of Medicaid and Medicare Part A capitation rates * Medicaid only: no premium	Medicaid capitation. * Medicare and Medicaid with share of cost: premium equal to share of cost reimbursement. * Medicare and Medicaid: no premium * Medicaid only: no premium
Monitoring during trial period ' 460.190	The regulations state that HCFA will conduct comprehensive annual reviews of the PACE organization=s operations during the trial period, with a defined scope: * onsite visit * review of participants= charts * interviews with staff, participants, contractors, etc. * observation of operations * assessment of fiscal soundness * assessment of service capacity	The protocol lists certain data collection and reporting requirements during the trial period, but with no reference to an annual review with an onsite visit.
Ongoing monitoring after trial period ' 460.192	The regulations require that an appropriate review by HCFA of the PACE organization take place at least every 2 years.	The protocol recognizes external oversight activities to include: * a periodic review of the financial status of the PACE provider, * a periodic on-site survey conducted at least once every two years.
Corrective Action ' 460.194-196	The regulations require the PACE organization to take action to correct identified deficiencies, with monitoring by HCFA and possible sanction or termination for non-compliance. The regulations also require HCFA to timely transmit the results of the review to the PACE organization, where it must be available for review by staff and participants.	The protocol states that procedures will be established to determine whether corrective action has been taken by the PACE provider to resolve deficiencies identified during the on-site survey.

Note: This document is intended for illustrative purposes only and should not be relied on for purposes of meeting regulatory requirements.

Topic Area	PACE Regulations	PACE Protocol
Maintenance of records and reporting of data ' 460.200	The regulations require the PACE organization to collect and maintain data and submit reports as required by HCFA or the State administering agency. The regulations include that the PACE organization shall: * provide access to data and records to HCFA and the State agency, * submit reports as requested * safeguard all data * protect the confidentiality of health information. * retain records according to State law or 6 years after last entry	The protocol requires a standard set of participant-specific intake, assessment, and utilization data, subject to change to meet new HCFA or State Medicaid Agency reporting requirements. * The right for HCFA or its agent to review the data is preserved. * Confidentiality, safeguarding of data, and data retention are not discussed.
Participant health outcomes data ' 460.202	The regulations require the PACE organization establish and maintain a health information system to produce reports required by HCFA.	At a minimum, the protocol requires participant-specific utilization data updated to one month prior to the present. This data is transmitted to HCFA or its agent. The protocol allows HCFA or its agent to provide training to the provider in the use of data collection tools.
Financial recordkeeping and reporting requirements ' 460.204	The regulations state that the PACE organization must provide financial reports: * using the accrual basis of accounting * with CPA certification * containing certain specified information * on a quarterly basis during the trial period	The protocol requires a YTD Budgeted vs. Actual Financial Report to be submitted to HCFA on a monthly basis during the first year, quarterly thereafter.
Medical records ' 460.210	The regulations require that the PACE organization keep a single, comprehensive medical record for each participant. The regulations set forth basic readability and content requirements, demand the prompt	The protocol refers to participant specific intake, assessment, and service utilization data, coded according to the guidelines in the PACE Data Collection Manual.

Topic Area	PACE Regulations	PACE Protocol
	transfer of records when needed, and that the records be authenticated.	