

**READINESS REVIEW
FINDINGS AND COMPLIANCE
REPORT**

PACE ORGANIZATION:

DATE (S) OF REVIEW:

REVIEWER (S) – NAME, TITLE AND DEPARTMENT:

SUMMARY OF FINDINGS (SITE ONLY THOSE AREAS NOT MET):

ORGANIZATION'S COMPLIANCE PLAN:

CHANGES MADE THAT BROUGHT ORGANIZATION INTO COMPLIANCE:

PACE ORGANIZATION'S READINESS REVIEW COMPLETE
ORGANIZATION HAS MET ALL ON-SITE REVIEW CRITERIA

DATE OF COMPLETION:

STATE ADMINISTERING AGENCY:

SAA REPRESENTATIVE SIGNATURE:

STATE READINESS REVIEW

In developing the application process for potential PACE providers, States expressed concern on the feasibility of requiring an entity to be operational at the time of application. The State representatives maintained that potential PACE sites need approval by CMS as a PACE provider before the site is able to market its program and begin to enroll participants. Absent CMS approval of a site as a PACE provider, the entity has no authority to enroll participants, provide PACE services or receive payment.

As an alternative for sites that are not operational at the time of application, the States recommended that CMS only approve applications from potential PACE organizations that satisfy Federal requirements and have met the requirements of a State Readiness Review (SRR). The SRR is performed by the State at the applicant's site. At the time of the SRR, the entity will not be operational and thus will have no enrolled participants. The purpose of this review is to determine the organization's readiness to administer the PACE program and enroll participants. The SRR will include a minimum set of criteria established by CMS in conjunction with the States. The States are free to add any additional criteria to the readiness review they deem necessary to help them determine if the applicant: 1) meets the requirements stipulated in the PACE regulation; 2) has developed policies and procedures consistent with the PACE regulation; and 3) has established the contracts necessary to provide all-inclusive, quality care to its participants.

The SRR will focus on a wide variety of areas, including evidence of the site's policies and procedures, the design and construction of the building, emergency preparedness, the site's compliance with OSHA, FDA, State and local laws, and adherence life safety codes. There are several areas of the SRR that defer to state and local laws and regulations for compliance. If the applicant's state has more stringent laws and regulations, those laws will apply in place of the federal requirement. However, it is incumbent upon the SRR team to ensure that their state laws or regulations encompass each of the items identified in the federal requirement.

This program recognizes the unique partnership with the States for implementation of the PACE program and the substantial financial commitment States have with PACE organizations. Experience has shown that States are extremely active in the PACE program. States will play a significant role in selecting appropriate organizations, developing the PACE programs in the SRR process, and monitoring PACE organizations. Even though CMS will not conduct the SRR, we may accompany the States on the readiness review to provide technical assistance in order to assure compliance with federal standards.

Upon completion of the SRR, the State will be responsible for preparing and submitting a report of their findings to CMS. Each time a readiness review is conducted, the State will submit a copy of the completed readiness review, a report that explains the State's review process, and any additional review criteria that were utilized. If the applicant meets all of the criteria in the readiness review, the State will submit a brief report to CMS on its findings.

If the applicant does not meet all of the established criteria, the State, in conjunction with the applicant, will develop an initial compliance plan to bring the applicant into compliance. This plan will outline both the unmet criteria and the plan of correction. We have chosen to not specify a timeframe for completion of the initial compliance plan to provide both the State and the applicant with flexibility in meeting the requirements in the SRR. However, we do not anticipate that completion of the initial compliance plan will take an extended period of time since the applicants should be ready to enroll participants at the time of the SRR. Once the initial compliance plan has been completed to the satisfaction of the State, the review team will submit a complete report to CMS. The report will include an explanation of the State's review process, any additional review criteria that were utilized, the list of unmet criteria, the reason the applicant failed to meet the criteria, the initial compliance plan, and an explanation of the changes that were made to bring the applicant into compliance with the requirements.

Once the organization's census reaches a specified level, CMS will conduct an operational review to ensure that the organization's policies have been implemented and that all services are being provided consistent with the PACE regulation.

PROPOSED FORMAT FOR THE READINESS REVIEW

PACE REGULATION REQUIREMENT	READINESS CRITERIA	CRITERIA MET	NOTES
PHYSICAL ENVIRONMENT (\$460.72)			
I.A. The PACE center must be designed, constructed, equipped, and maintained to provide for the physical safety of participants, personnel, and visitors.	EVIDENCE OF COMPLIANCE WITH ALL STATE AND LOCAL BUILDING, FIRE SAFETY AND HEALTH CODES. Evidence of the following: • Fire exit system • Doorways that provide adequate width to allow easy access and movement of participants by wheelchair or stretcher; • Doorways and stairways that provide access free from obstructions at all times; • Lights and handrails in stairways, corridors, bathrooms, and at exits used by participants; • Toilets and stalls in the public bathrooms that are accessible to allow use by nonambulatory and handicapped participants, staff and visitors;	☐ MET ☐ NOT MET ☐ MET ☐ NOT MET ☐ MET ☐ NOT MET ☐ MET ☐ NOT MET ☐ MET ☐ NOT MET	

PACE REGULATION REQUIREMENT	READINESS CRITERIA	CRITERIA MET	NOTES
	- Evidence of compliance with the ADA (28 CFR Part 36 Title III). - Facility equipped with call lights for a communication system that alerts staff of participant problems in bathrooms, therapy areas, etc. - Design features to safeguard cognitively impaired clients who may wander (e.g. fences, door alarms, detector bracelets, etc.) Written plan that outlines scheduled maintenance for the PACE center to include building maintenance. OTHER (SPECIFY)	☐ MET ☐ NOT MET ☐ MET ☐ NOT MET ☐ MET ☐ NOT MET ☐ Other (Specify and Attach)	

PACE REGULATION REQUIREMENT	READINESS CRITERIA	CRITERIA MET	NOTES
I. B. The PACE center must ensure a safe, functional, accessible and comfortable environment for the delivery of services to the participant.	EVIDENCE OF CERTIFICATION OR LICENSURE BY THE STATE OR A RECOGNIZED ENTITY FOR ADULT DAY CENTERS THAT ENCOMPASSES APPROPRIATE CRITERIA. Evidence of the following: • Written policies and procedures for ensuring an environment that provides privacy and dignity for participants, i.e. doors for exam rooms, privacy curtains, appropriate clothing and linen to cover participants during treatment, etc.; • The center must have lighting and sound levels in care areas, activity and dining rooms appropriate for individuals with vision, hearing, and cognitive impairments; • Proper ventilation; • Written policies and procedures for an effective pest control program to control household pests and rodents not limited to roaches, ants, flies, and mice; • Designated areas for smoking that are clearly marked and limited to participants and staff.	☐ MET ☐ NOT MET ☐ N.A. ☐ MET ☐ NOT MET ☐ MET ☐ NOT MET ☐ MET ☐ NOT MET ☐ MET ☐ NOT MET	

PACE REGULATION REQUIREMENT	READINESS CRITERIA	CRITERIA MET	NOTES
	• Posted signs that prohibit smoking while oxygen therapy is being administered and clearly designated universal oxygen signs. • Written policies and procedures to determine if or when participants may smoke without supervision. • Written policies and procedures on the proper storage, handling, and disposal of all chemicals, compounds and biohazardous waste, including Material Safety Data Sheets for any chemical, cleaning and medical supplies; • Equipment stored in a manner to ensure participant's safety at all times. OTHER (SPECIFY)	☐ MET ☐ NOT MET ☐ MET ☐ NOT MET ☐ MET ☐ NOT MET ☐ Other (Specify and Attach)	

PACE REGULATION REQUIREMENT	READINESS CRITERIA	CRITERIA MET	NOTES
I. C. 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.	Evidence of Adequate Space For: (Adequate space would be determined by the provisions, if any, that are included in the PACE center Life Safety Code building occupancy license) • Team meetings • Medical treatment and other care • Therapeutic recreation • Restorative therapies • Socialization • Personal care • Dining	☐ MET ☐ NOT MET ☐ MET ☐ NOT MET ☐ MET ☐ NOT MET ☐ MET ☐ NOT MET ☐ MET ☐ NOT MET ☐ MET ☐ NOT MET	

PACE REGULATION REQUIREMENT	READINESS CRITERIA	CRITERIA MET	NOTES
	Evidence of sufficient and maintained equipment for safely transferring disabled participants on to exam tables and restorative therapy treatment equipment, such as tubs, beds, etc. OTHER (SPECIFY)	☐ MET ☐ NOT MET ☐ Other (Specify and Attach)	
I. D. The PACE organization must establish, implement and maintain a written plan to ensure that all equipment is maintained in accordance with the manufacturer's recommendations and keep all	A written maintenance plan that identifies the individual responsible for the implementation and monitoring of the plan, what logs or records will be required, what equipment is included, and the maintenance schedules according to manufacturer's recommendations. A written plan and monitoring program to check all contracts related to maintenance agreements. Written plans and procedures to report device related death and serious injuries to the FDA and/or the manufacturer of the equipment in accordance with the Safe Medical Devices Act of 1990.	☐ MET ☐ NOT MET ☐ MET ☐ NOT MET ☐ MET ☐ NOT MET	

PACE REGULATION REQUIREMENT	READINESS CRITERIA	CRITERIA MET	NOTES
equipment (mechanical, electrical, and patient care) free of defect. This includes any equipment in the patient's home.	Evidence of manufacturer's manuals for all equipment (mechanical, electrical, and patient care). OTHER (SPECIFY)	☐ MET ☐ NOT MET ☐ Other (Specify and Attach)	
I.E. The PACE center must meet the occupancy provisions of the 2000 edition of the LSC for the type of setting in which it is located	EVIDENCE OF COMPLIANCE WITH THE CURRENT EDITION OF THE NFPA 101 (2000) LIFE SAFETY CODES. In addition have evidence of a: Fire Alarm System: • Initiation • Notification • Control • Air Condition Shutdown • Automatic release of fire doors held open by magnetic devices Staff training and Drills Fire evacuation Plans Fire Procedures OTHER (SPECIFY)	☐ MET ☐ NOT MET ☐ MET ☐ NOT MET ☐ Other (Specify and Attach)	

PACE REGULATION REQUIREMENT	READINESS CRITERIA	CRITERIA MET	NOTES
I.F. Establish, implement, and maintain documented procedures to manage medical and nonmedical emergencies and disasters that threaten the health and safety of participants, staff, or visitors. I.G. PACE organization must train all staff (employees and contractors) on the actions necessary to address different medical and nonmedical emergencies.	Evidence of: • Written plan and procedures to manage medical emergencies, including responding to DNRs, or any other Advance directives; choking; chest pain; seizures; stopped breathing or cessation of heart; • Written plan and procedures(s) for the periodic examination of all emergency drugs to confirm expiration date(s) and inventory control; • Written plans and procedures for staff training on and drills for the center's emergency procedures, including the use of emergency drugs and emergency equipment; • At least one staff member during hours the center(s) have participant's present will be trained and certified in Basic Life Support (CPR). • Verify that emergency drugs and emergency equipment is readily available, operating, and clean including: - o PORTABLE OXYGEN - o AIRWAYS - o SUCTION EQUIPMENT - o PHARMACEUTICALS APPROPRIATE TO STABILIZE PARTICIPANTS.	☐ MET ☐ NOT MET ☐ MET ☐ NOT MET ☐ MET ☐ NOT MET ☐ MET ☐ NOT MET ☐ MET ☐ NOT MET	

PACE REGULATION REQUIREMENT	READINESS CRITERIA	CRITERIA MET	NOTES
I.H. The PACE center must have emergency equipment, along with staff who know how to use the equipment at the center at all times and immediately available to adequately support participants until Emergency Medical Assistance responds to the center.	• Written plan and procedures to manage nonmedical emergencies and any natural disasters affecting the center's geographic location, including: • Method of containment of fire; • Evacuation plans and routes; • Adequate emergency lighting at exits and corridors; • Plans for power outages, problems with water supply, and transfer of participants to other sites that meet their special needs; • Periodic drills; • Plan for assuring the health and safety of participants at home to ensure their continuing care needs will be met; • Facility structure and characteristics that will accommodate an expedient and safe evacuation of staff, participants, and visitors;	☐ MET ☐ NOT MET ☐ MET ☐ NOT MET ☐ MET ☐ NOT MET ☐ MET ☐ NOT MET ☐ MET ☐ NOT MET ☐ MET ☐ NOT MET ☐ MET ☐ NOT MET	

PACE REGULATION REQUIREMENT	READINESS CRITERIA	CRITERIA MET	NOTES
	OTHER (SPECIFY)	☐ Other (Specify and Attach)	
INFECTION CONTROL (\$460.74)			
II. At a minimum, the PACE center must have an infection control plan that includes: A. Procedures to identify, investigate,	Written policies and procedures for the investigation, control, and prevention of infections including: A written OSHA Exposure Control Plan which includes the Universal Precautions and Bloodborne Pathogen exposure procedures for staff;	☐ MET ☐ NOT MET ☐ MET ☐ NOT MET	

PACE REGULATION REQUIREMENT	READINESS CRITERIA	CRITERIA MET	NOTES
control, and prevent infections in every center and in each participant's place of residence; B. Procedures to record any incidents of infection; C. Procedures to analyze the incidents of infection, to identify trends, and develop corrective actions related to the reduction of future incidents.	• Vaccinating participants and staff against diseases of particular concern for the PACE participant and the center's geographic location, i.e. influenza and pneumonia (are required minimally); • Initial and ongoing health screening and vaccinations for staff and participants in accordance with OSHA regulations (staff) and CDC guidelines for tuberculosis, Hepatitis B and other communicable diseases. • Written plans and procedures for the investigation, evaluation, resolution, and reporting of all incidences of staff and participant infection. • Written plans and procedures for maintaining records of staff and participant infections to include post-exposure evaluation, training records, and participant and staff surveillance reports. • Written plans and procedures for reporting required communicable diseases to the appropriate state and local officials. • Plans and procedures for staff providing direct care to patients with infection(s);	☐ MET ☐ NOT MET ☐ MET ☐ NOT MET ☐ MET ☐ NOT MET ☐ MET ☐ NOT MET ☐ MET ☐ NOT MET	

PACE REGULATION REQUIREMENT	READINESS CRITERIA	CRITERIA MET	NOTES
	• Provision of adequate facilities and supplies necessary for infection control to include: • Hand washing facilities and supplies; • Laundry facilities and supplies; • Isolation facilities and supplies • Written plans and procedures for addressing how laundry will be handled. If the service is contracted out, written agreements to comply with the requirements. • Written plans and procedures for the ongoing monitoring of the contractual agreement provisions for laundry and waste disposal. • Written plans and procedures for the appropriate handling and disposal of all waste products including blood and urine specimens for outside lab tests and other biohazardous wastes.	☐ MET ☐ NOT MET ☐ MET ☐ NOT MET ☐ MET ☐ NOT MET ☐ MET ☐ NOT MET ☐ NA ☐ MET ☐ NOT MET	

PACE REGULATION REQUIREMENT	READINESS CRITERIA	CRITERIA MET	NOTES
	OTHER (SPECIFY)	☐ Other (Specify and Attach)	
Transportation Services (\$460.76)			
III. The PACE organization should take appropriate steps to ensure that participants can be safely transported from their homes to the center and to appointments. A. Requirements for the organization's transportation program include: 1. Maintenance of transportation vehicles according to the manu-	Evidence of appropriate state vehicle inspections. If commercial vehicles (greater than 12 seats, usually) are being used, a commercial license is required by all drivers. If the service is contracted out, written agreements to comply with the contract requirements under §460.70. Written plans and procedures for the ongoing monitoring of the contractual agreement provisions for transportation services. Evidence of the ability to provide adequate and safe transportation of center participants: • Sufficient staff	☐ MET ☐ NOT MET ☐ MET ☐ NOT MET ☐ MET ☐ NOT MET ☐ NA ☐ MET ☐ NOT MET ☐ NA ☐ MET ☐ NOT MET	

PACE REGULATION REQUIREMENT	READINESS CRITERIA	CRITERIA MET	NOTES
facturer's recommendations. 2. Transportation vehicles equipped to communicate with the PACE center. 3. Training transportation personnel on the special needs of participants and appropriate emergency responses. 4. As a part of the multi-disciplinary process, communicating relevant changes in the participant's care plans to transportation personnel.	- Written policies and procedures for the training and monitoring of drivers including: - Proper transfer of nonambulatory and ambulatory participants; - Proper use of equipment needed to transfer and secure participants; - Emergency procedures during transfer, transport, and arrival of participants. - Ability for communication between the driver and center during transportation activities. - Evidence of written policies and procedures on the maintenance of vehicles utilized in the transport of participants. - Written plans and procedures for communicating between the multidisciplinary team and the transport staff the needs of the participants being transported.	☐ MET ☐ NOT MET ☐ MET ☐ NOT MET ☐ MET ☐ NOT MET ☐ MET ☐ NOT MET ☐ MET ☐ NOT MET	

PACE REGULATION REQUIREMENT	READINESS CRITERIA	CRITERIA MET	NOTES
	- Written plans and procedures for monitoring the performance of all drivers. - Written procedures to check or audit for the following information on the drivers: - Current driver's license - Record of any traffic violations or accidents that may constitute a potential hazard for the transport of participants. - OTHER (SPECIFY)	☐ MET ☐ NOT MET ☐ MET ☐ NOT MET ☐ Other (Specify and Attach)	
Dietary Services (\$460.78)			
IV. PACE center is required to provide food that is nourishing, palatable, well-balanced, and meets acceptable safety standards:	Evidence of certification or licensure from state or local health agencies for the preparation and/or serving of food (including the last Department of Health Inspection). Written policies and procedures that ensure the safe Delivery of food and nutritional supplements including: Safe procurement of food and nutritional supplements;	☐ MET ☐ NOT MET ☐ N.A. ☐ MET ☐ NOT MET	

PACE REGULATION REQUIREMENT	READINESS CRITERIA	CRITERIA MET	NOTES
A. Procure food from sources approved or considered satisfactory by Federal, State, Tribal or local authorities that have jurisdiction over the service area; B. Store, prepare, distribute, and serve food under sanitary conditions; C. Dispose of garbage and refuse properly	• Safe storage of food and nutritional supplements both perishable and nonperishable to prevent contamination (at required temperatures – freezer below 0 degrees F or below and refrigerator 41 degrees or below); • Safe handling of food and nutritional supplements; • Safe preparation of food and medication, including policies for admixtures; • Safe and adequate water supply; • Safe and proper disposal of sewage; • Provisions for substitute foods or nutritional supplements; • Safe garbage storage and disposal;	☐ MET ☐ NOT MET ☐ MET ☐ NOT MET ☐ MET ☐ NOT MET ☐ MET ☐ NOT MET ☐ MET ☐ NOT MET ☐ MET ☐ NOT MET	

PACE REGULATION REQUIREMENT	READINESS CRITERIA	CRITERIA MET	NOTES
	• Training of staff in safe food delivery; and • Written policies and procedures for emergency food supplies and emergency nutritional supplements. Written policies and procedures for dietitian, physician, and pharmacist involvement to determine the nutritional adequacy of menus and the caloric and nutritional needs for the participant population. OTHER: List outside vendors/contracts:	☐ MET ☐ NOT MET ☐ MET ☐ NOT MET ☐ MET ☐ NOT MET ☐ Other (Specify and Attach)	
Bill of Rights (\$460.110)			
V. The PACE organization must have written policies and implement procedures to	Written policies and procedures governing the participant Bill of Rights including: • The parameters on the use of physical or chemical restraints;	☐ MET ☐ NOT MET ☐ MET ☐ NOT MET	

PACE REGULATION REQUIREMENT	READINESS CRITERIA	CRITERIA MET	NOTES
ensure that the participant, his or her representative, and staff understand their rights.	The reporting of mental or physical abuse or neglect. Written policies and procedures for distributing the Bill of Rights to the participant and his or her representative upon enrollment. Written policies and procedures to ensure that the participant and his or her representative understand their rights. The participant Bill of Rights should be in English and any other principal language of the community and be displayed in an area frequented by the public. <u>Evidence of compliance with State requirement, if any, for specific criteria of the principle language</u> The participant Bill of Rights should be in a large print for the elderly to read. Written policies and procedures to respond to and rectify a violation of a participant's rights. OTHER (SPECIFY)	☐ MET ☐ NOT MET ☐ MET ☐ NOT MET ☐ MET ☐ NOT MET ☐ MET ☐ NOT MET ☐ OTHER (Specify and Attach)	

PACE REGULATION REQUIREMENT	READINESS CRITERIA	CRITERIA MET	NOTES
Personnel Qualifications (\$460.64)			
VI. The PACE center must have qualified staff to provide care to its frail elderly participants.	Signed contracts for all contractors and contracted personnel by the time the PACE center becomes operational. Written position descriptions for all staff (employees and contractors). Evidence (by the State completion of the assurance page, in the application, for this element) that the required members of the multidisciplinary team (primary care physician, registered nurse, social worker, recreational therapist or activities coordinator, PACE center manager, home care coordinator, and PACE center personal care attendants, drivers) are/will be employees or contractors of the PACE center. Evidence that appropriate professional licenses/certifications have been verified by primary source (licensing/certification board) and background checks have been done on all staff – employees and contractors (per state law requirements). If no direct participant care employees are yet hired then this review would entail the evidence of the procedures that will be completed to comply with this area. OTHER (SPECIFY)	☐ MET ☐ NOT MET ☐ MET ☐ NOT MET ☐ MET ☐ NOT MET ☐ Other (Specify and Attach)	

PACE REGULATION REQUIREMENT	READINESS CRITERIA	CRITERIA MET	NOTES
TRAINING AND COMPETENCY (§460.66 AND §460. 71)			
VII. 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. B. The PACE organization must develop a training program for each personal care attendant to	Written individual competency and training programs for all team positions, specific to each position that includes at least the following: - Competency program to ensure that each staff member initially and ongoing demonstrates competency in the skills needed to provide appropriate, culturally competent care to participants. The competency program must include: - Initial hires and ongoing skills demonstration; - Skills demonstration method of evaluation based on standard protocols; - Competent evaluator (including peer evaluator); - Skills that reflect scope of practice and appropriate for the PACE center, home setting and level of care.	☐ MET ☐ NOT MET ☐ MET ☐ NOT MET ☐ MET ☐ NOT MET ☐ MET ☐ NOT MET ☐ MET ☐ NOT MET	

PACE REGULATION REQUIREMENT	READINESS CRITERIA	CRITERIA MET	NOTES
establish the individual's competency in furnishing personal care services and specialized skills associated with specific care needs of individual participants.	• Training should be specific and within the scope of practice. To include at least the following: • Training and demonstrated competency on the transport of nonambulatory participants for drivers and any other applicable staff; • Training and demonstrated competency on all emergency equipment and all other equipment necessary for the performance of his or her specific position; • Training and demonstrated competency on center emergency procedures; • Training and demonstrated competency on restraint use; • Training and demonstrated competency on participant rights, including dignity and privacy, to all participants; • Training and demonstrated competency in response to participant grievances or center quality improvement activities; and	☐ MET ☐ NOT MET ☐ MET ☐ NOT MET ☐ MET ☐ NOT MET ☐ MET ☐ NOT MET ☐ MET ☐ NOT MET ☐ MET ☐ NOT MET ☐ MET ☐ NOT MET	

PACE REGULATION REQUIREMENT	READINESS CRITERIA	CRITERIA MET	NOTES
	• Training and demonstrated competency in therapeutic communication specific to the PACE setting and population. Written training manual for personal care attendants to ensure that they exhibit competency in basic skills for providing personal care, including: • How to maintain a clean, safe and healthy environment; • Appropriate and safe techniques in personal hygiene and grooming; • Safe transfer techniques and ambulation; • Observation, reporting, and documentation of patient status and the care or service furnished. • Training in therapeutic communication specific to the PACE setting and population; and • Other elements consistent with their assigned duties.	☐ MET ☐ NOT MET ☐ MET ☐ NOT MET ☐ MET ☐ NOT MET ☐ MET ☐ NOT MET ☐ MET ☐ NOT MET ☐ MET ☐ NOT MET ☐ MET ☐ NOT MET	

PACE REGULATION REQUIREMENT	READINESS CRITERIA	CRITERIA MET	NOTES
	OTHER (SPECIFY)	☐ Other (Specify and Attach)	
GENERAL PROVISIONS			
VIII. General provisions	Evidence of all current licensure required in the State: ☐ ADHC ☐ HH ☐ Clinic ☐ HMO ☐ Ambulatory Care Center ☐ Other - specify Written plans and procedures regarding the safeguarding of participant data and records according to HIPAA compliance for security (electronic and paper). Written plans and procedures regarding the confidentiality and retention of participant health information. Written plan and procedures for all participant reassessments which include periodic reassessments and reassessments at the participant or caregiver's request.	☐ MET ☐ NOT MET ☐ MET ☐ NOT MET ☐ MET ☐ NOT MET	

PACE REGULATION REQUIREMENT	READINESS CRITERIA	CRITERIA MET	NOTES
	Verify the PACE organization's actual service area. Verify the process the PACE organization has in place to ensure participant access to care 24 hours a day, 7 days a week. Verify that all required services will be provided by the PACE organization. Evidence of a health information system to collect, analyze, and report participant data. Identify any additional sites: OTHER (SPECIFY)	☐ MET ☐ NOT MET ☐ MET ☐ NOT MET ☐ MET ☐ NOT MET ☐ NA ☐ Other (Specify and Attach)	
General Safety Requirements			
IX. Overall PACE center safety requirements	Evidence of state pharmacy licensure.	☐ MET ☐ NOT MET ☐ N.A.	

PACE REGULATION REQUIREMENT	READINESS CRITERIA	CRITERIA MET	NOTES
	Written plans and procedures for narcotic inventory control and disposal. All Medications are locked in a cabinet, room or cart. Written plans and procedures for refrigerator temperature logs used for medication and food storage. Written plans and procedures for oxygen storage that is in compliance with fire safety and FDA laws. Evidence of CLIA certification if the PACE center is performing waived lab services on site or in the home, e.g. glucose meter testing, urine testing, fecal occult testing, blood testing, cholesterol screening, or hemoglobin or hematocrit testing. OTHER (SPECIFY)	☐ MET ☐ NOT MET ☐ MET ☐ NOT MET ☐ MET ☐ NOT MET ☐ MET ☐ NOT MET ☐ Other (Specify and Attach)	

This version completed October 28, 2003