



DEPARTMENT OF HEALTH & HUMAN SERVICES
Health Care Financing Administration

7500 Security Boulevard
Baltimore, MD 21244-1850

November 2, 2000

Christine Grant, Commissioner
New Jersey Department of Health and Senior Services
PACE State Administering Agency
P.O. Box 360
John Fitch Plaza
Trenton, New Jersey 08625-0360

Dear Ms. Grant:

The purpose of this letter is to provide additional information on Section 1894 and 1934 of the Social Security Act (enacted in Sections 4801 and 4802 of the BBA), which establishes the Program of All-Inclusive Care for the Elderly (PACE) as a Medicare benefit and Medicaid State plan option.

We have included the following two documents to be utilized by State Administering Agencies (SAA) and PACE organizations to comply with PACE regulatory requirements:

- The *Readiness Review* will be conducted of potential non-operational PACE organizations by the SAA before a program agreement is approved between HCFA, the SAA, and the PACE organization. Enclosure 1A provides a narrative description of the Readiness Review process.

Enclosure 1B provides a suggested tool to be used by States during the readiness review. States may incorporate additional review criteria, but must provide the minimum information requested by HCFA.

- The *Program Agreement* is the contract executed between HCFA, SAA and the PACE organization. Statutory requirements mandated that the agreement contain substantial detailed information. Enclosure 2A contains the template of the Program Agreement.

Data required to be furnished on a quarterly basis are also contained in the Program Agreement. Enclosure 2B provides a more detailed description of these data elements. Enclosure 2C is a list of the required data elements.

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If you have any questions about these documents, please contact either Sandra Bastinelli at (410) 786-3630 or Melissa Harris at (410) 786-3397.

Sincerely,

Sincerely,

Susan N. Hill
Director
Division of Program Support & Field Liason
Center for Health Plans and Providers

Theresa A. Pratt
Director
Division of Integrated Health Systems
Center for Medicaid and State Operations

Enclosures

cc:
All State Medicaid Agencies
All HCFA Regional Offices

Enclosure 1A

State Readiness Review

During the PACE demonstration project, applicants were fully operational when they applied for demonstration funding. Once On Lok had determined that a potential site had successfully replicated the PACE model of service delivery, application for HCFA funding was requested. Once approved by HCFA, demonstration sites were permitted to assume full financial risk over an initial period.

In developing the application process for potential PACE providers, States expressed concern over 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 HCFA as a PACE provider before the site is able to market its program and begin to enroll participants. Absent HCFA approval of a site as a PACE provider, the entity has no authority to enroll participants, provide PACE services, or receive payment. In addition, the State representatives believed that providing PACE-like services using Medicaid waiver authority, supplemented with Medicare fee-for-service payments for dual eligible participants is no longer supported by the statute and is not an indicator that an entity would be able to assume full financial risk as a PACE provider.

As an alternative for sites that are not operational at the time of application, the States recommended that HCFA 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 HCFA Central Office in conjunction with the Regional Offices and the States. The States will add any additional criteria to the readiness review they deem necessary to help them determine if the applicant has met the requirements necessary under the State license.

The SRR will focus on 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 the appropriate 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. States play a significant role in selecting appropriate organizations, developing the PACE programs in the SRR process, and monitoring PACE organizations.

Upon completion of the SRR, the State is responsible for preparing and submitting a report of their findings to HCFA. 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 HCFA 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 HCFA. The report will include an explanation of the State's review process, any additional review criteria that were utilized, the initial compliance plan (if necessary), 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, HCFA 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.

Enclosure 1B

**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:

PROPOSED FORMAT FOR THE READINESS REVIEW

PACE REGULATION REQUIREMENT	READINESS CRITERIA	CRITERIA MET	NOTES
PHYSICAL ENVIRONMENT (Section 460.72)			
<p>1. The PACE center must be designed, constructed, equipped, and maintained to provide for the physical safety of participants, personnel, and visitors.</p>	<p>A. EVIDENCE OF COMPLIANCE WITH ALL STATE AND LOCAL BUILDING, FIRE SAFETY AND HEALTH CODES. IF THIS APPLIES, SKIP TO ITEM #2.</p> <p>B. Evidence of the following:</p> <ol style="list-style-type: none"> 1. Fire exit system 2. Doorways that provide adequate width to allow easy access and movement of participants by wheelchair or stretcher; 3. Doorways and stairways that provide access free from obstructions at all times; 4. Lights and handrails in stairways, corridors, bathrooms, and at exits used by participants; 5. Toilets and stalls in the public bathrooms that are accessible to allow 	<p><input type="checkbox"/> MET <input type="checkbox"/> NOT MET <input type="checkbox"/> N.A.</p> <p><input type="checkbox"/> MET <input type="checkbox"/> NOT MET</p> <p><input type="checkbox"/> MET <input type="checkbox"/> NOT MET</p> <p><input type="checkbox"/> MET <input type="checkbox"/> NOT MET</p> <p><input type="checkbox"/> MET <input type="checkbox"/> NOT MET</p>	

	<p>use by nonambulatory and handicapped participants, staff and visitors;</p> <p>6. Evidence of compliance with the ADA (28 CFR Part 36 Title III).</p> <p>7. Facility equipped with call lights for a communication system that alerts staff of participant problems in bathrooms, therapy areas, etc.</p> <p>8. Design features to safeguard cognitively impaired clients who may wander (e.g. fences, door alarms, detector bracelets, etc.)</p> <p>C. Written plan that outlines scheduled maintenance for the PACE center to include building maintenance.</p> <p>D. OTHER (SPECIFY)</p>	<p><input type="checkbox"/> MET</p> <p><input type="checkbox"/> NOT MET</p> <p><input type="checkbox"/> MET</p> <p><input type="checkbox"/> NOT MET</p> <p><input type="checkbox"/> MET</p> <p><input type="checkbox"/> NOT MET</p> <p><input type="checkbox"/> MET</p> <p><input type="checkbox"/> NOT MET</p> <p><input type="checkbox"/> Other (Specify and Attach)</p>	
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<p>2. The PACE center must ensure a safe, functional, accessible and comfortable environment for the delivery of services to the participant.</p>	<p>A. EVIDENCE OF CERTIFICATION OR LICENSURE BY THE STATE OR A RECOGNIZED ENTITY FOR ADULT DAY CENTERS THAT ENCOMPASSES APPROPRIATE CRITERIA. IF THIS APPLIES, SKIP TO ITEM #3.</p> <p>B. Evidence of the following:</p> <ol style="list-style-type: none"> 1. 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.; 2. The center must have lighting and sound levels in care areas, activity and dining rooms appropriate for individuals with vision, hearing, and cognitive impairments; 3. Written policies and procedures for an effective pest control program to control household pests and rodents not limited to roaches, ants, flies, and mice; 4. Proper ventilation; 5. Designated areas for smoking that are clearly marked and limited to participants and staff. 6. Posted signs that prohibit smoking while oxygen therapy is being administered and clearly designated universal oxygen signs. 7. Written policies and procedures to determine if or when participants may smoke without supervision. 	<p><input type="checkbox"/> MET <input type="checkbox"/> NOT MET <input type="checkbox"/> N.A.</p> <p><input type="checkbox"/> MET <input type="checkbox"/> NOT MET</p> <p><input type="checkbox"/> MET <input type="checkbox"/> NOT MET</p> <p><input type="checkbox"/> MET <input type="checkbox"/> NOT MET</p> <p><input type="checkbox"/> MET <input type="checkbox"/> NOT MET</p>	
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	<p>8. 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;</p> <p>9. Equipment stored in a manner to ensure participant's safety at all times.</p> <p>C. OTHER (SPECIFY)</p>	<p><input type="checkbox"/> MET <input type="checkbox"/> NOT MET</p> <p><input type="checkbox"/> MET <input type="checkbox"/> NOT MET</p> <p><input type="checkbox"/> MET <input type="checkbox"/> NOT MET</p> <p><input type="checkbox"/> MET <input type="checkbox"/> NOT MET</p> <p><input type="checkbox"/> C Other (Specify and Attach)</p>	
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3. 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.

A. 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)

1. team meetings

- MET
- NOT MET

2. medical treatment and other care

- MET
- NOT MET

3. therapeutic recreation

- MET
- NOT MET

4. restorative therapies

- MET
- NOT MET

5. socialization

- MET
- NOT MET

6. personal care

- MET
- NOT MET

7. dining

- MET
- NOT MET

MET

	<p>B. 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.</p> <p>C. OTHER (SPECIFY)</p>	<p><input type="checkbox"/> NOT MET</p> <p><input type="checkbox"/> MET</p> <p><input type="checkbox"/> NOT MET</p> <p><input type="checkbox"/> C Other (Specify and /or attach)</p>	
<p>4. 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</p>	<p>A. 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.</p> <p>B. A written plan and monitoring programs to check all contracts related to maintenance agreements.</p> <p>C. 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</p>	<p><input type="checkbox"/> MET</p> <p><input type="checkbox"/> NOT MET</p> <p><input type="checkbox"/> MET</p> <p><input type="checkbox"/> NOT MET</p> <p><input type="checkbox"/> NA</p>	

<p>equipment (mechanical, electrical, and patient care) free of defect. This includes any equipment in the patient's home.</p>	<p>Act of 1990.</p> <p>D. Evidence of manufacturer's manuals for all equipment (mechanical, electrical, and patient care).</p> <p>E. OTHER (SPECIFY)</p>	<p><input type="checkbox"/> MET</p> <p><input type="checkbox"/> NOT MET</p> <p><input type="checkbox"/> MET</p> <p><input type="checkbox"/> NOT MET</p> <p><input type="checkbox"/> E Other (Specify and attach)</p>	
<p>5. The PACE center must meet the occupancy provisions of the 1997 edition of the LSC for the type of setting in which it is located (ie. Hospital, office building, etc.)</p> <p>a. Fire Alarm System</p> <ol style="list-style-type: none"> 1. Initiation 2. Notification 3. Control <p>a. Air Condition Shutdown</p> <p>b. Automatic release of fire doors held open by magnetic devices</p>	<p>A. EVIDENCE OF COMPLIANCE WITH THE CURRENT EDITION OF THE NFPA 101 (1997) LIFE SAFETY CODES.</p> <p>B. OTHER (SPECIFY)</p>	<p><input type="checkbox"/> MET</p> <p><input type="checkbox"/> NOT MET</p> <p><input type="checkbox"/> B Other (Specify and /or attach)</p>	

<p>c. Staff training and Drills d. Fire evacuation Plans e. Fire Procedures</p>			
<p>6. Requirements for the PACE center to prepare for emergency situations. a. 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. b. PACE organization must train all staff (employees and contractors) on the actions necessary to address different</p>	<p>A. IF APPLICABLE, EVIDENCE OF CERTIFICATION OR LICENSURE BY THE STATE OR RECOGNIZED ENTITY THAT REQUIRES PLANNING AND PREPARATION FOR MEDICAL AND NONMEDICAL EMERGENCIES. B. Evidence of: 1. 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. 2. Written plan and procedures(s) for the periodic examination of all emergency drugs to confirm expiration date(s) and inventory control. 3. 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; 4. Evidence that all staff on site (during hours the center(s) have participant’s present) are trained and certified in at least Basic Life Support. 5. Verify that emergency drugs and emergency equipment</p>	<p><input type="checkbox"/> MET <input type="checkbox"/> NOT MET <input type="checkbox"/> N.A. <input type="checkbox"/> MET <input type="checkbox"/> NOT MET <input type="checkbox"/> MET <input type="checkbox"/> NOT MET <input type="checkbox"/> MET <input type="checkbox"/> NOT MET</p>	

<p>medical and nonmedical emergencies.)</p> <p>c) 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.</p>	<p>are readily available, operating, and clean including:</p> <ul style="list-style-type: none"> a. PORTABLE OXYGEN b. AIRWAYS c. SUCTION EQUIPMENT d. PHARMACEUTICALS APPROPRIATE TO STABILIZE PARTICIPANTS. <p>6. Written plan and procedures to manage nonmedical emergencies and any natural disasters affecting the center's geographic location, including:</p> <ul style="list-style-type: none"> a. method of containment of fire; b. evacuation plans and routes; c. adequate emergency lighting at exits and corridors; d. plans for power outages, problems with water supply, and transfer of participants to other sites that meet their special needs; e. periodic drills; 	<ul style="list-style-type: none"> <input type="checkbox"/> MET <input type="checkbox"/> NOT MET <ul style="list-style-type: none"> <input type="checkbox"/> MET <input type="checkbox"/> NOT MET <ul style="list-style-type: none"> <input type="checkbox"/> MET <input type="checkbox"/> NOT MET <ul style="list-style-type: none"> <input type="checkbox"/> MET <input type="checkbox"/> NOT MET <ul style="list-style-type: none"> <input type="checkbox"/> MET <input type="checkbox"/> NOT MET 	
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	<p>f. documentation of drills and training; and</p> <p>g. plan for assuring the health and safety of participants at home to ensure their continuing care needs will be met.</p> <p>7. Facility structure and characteristics that will accommodate an expedient and safe evacuation of staff, participants, and visitors;</p> <p>C. OTHER (SPECIFY)</p>	<p><input type="checkbox"/> MET</p> <p><input type="checkbox"/> NOT MET</p> <p><input type="checkbox"/> MET</p> <p><input type="checkbox"/> NOT MET</p> <p><input type="checkbox"/> MET</p> <p><input type="checkbox"/> NOT MET</p> <p><input type="checkbox"/> MET</p> <p><input type="checkbox"/> NOT MET</p> <p><input type="checkbox"/> C Other (Specify and attach)</p>	
<p>INFECTION CONTROL (Section 460.74)</p>			
<p>7. At a minimum, the PACE center must have an infection control plan that includes: 7-1. Procedures to identify, investigate,</p>	<p>A. IF APPLICABLE, EVIDENCE OF CERTIFICATION OR LICENSURE BY THE STATE OR RECOGNIZED ENTITY THAT REVIEWS INFECTIOUS DISEASE POLICIES AND PROCEDURES. <i>Attach appropriate license</i></p>	<p><input type="checkbox"/> MET</p> <p><input type="checkbox"/> NOT MET</p> <p><input type="checkbox"/> N.A.</p>	

<p>control, and prevent infections in every center and in each participant's place of residence</p> <p>7-2. Procedures to record any incidents of infection</p> <p>7-3. Procedures to analyze the incidents of infection, to identify trends, and develop corrective actions related to the reduction of future incidents.</p>	<p>B. Written policies and procedures for the investigation, control, and prevention of infections including:</p> <ol style="list-style-type: none"> 1. A written OSHA Exposure Control Plan which includes the Universal Precautions and Bloodborne Pathogen exposure procedures for staff; 2. Vaccinating participants and staff against diseases of particular concern for the PACE participant and the center's geographic location, i.e. influenza and pneumonia; 3. 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. 4. Written plans and procedures for the investigation, evaluation, resolution, and reporting of all incidences of staff and participant infection. 5. 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. 	<p><input type="checkbox"/> MET <input type="checkbox"/> NOT MET</p> <p><input type="checkbox"/> MET <input type="checkbox"/> NOT MET</p> <p><input type="checkbox"/> MET <input type="checkbox"/> NOT MET</p> <p><input type="checkbox"/> MET <input type="checkbox"/> NOT MET</p> <p><input type="checkbox"/> MET <input type="checkbox"/> NOT MET</p>	
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	<p>6. Written plans and procedures for reporting required communicable diseases to the appropriate state and local officials.</p> <p>7. Plans and procedures for staff providing direct care to patients with infection(s);</p> <p>8. Provision of adequate facilities and supplies necessary for infection control to include:</p> <p style="padding-left: 20px;">a. Hand washing facilities and supplies;</p> <p style="padding-left: 20px;">b. Laundry facilities and supplies;</p> <p style="padding-left: 20px;">c. Isolation facilities and supplies</p> <p>9. Written plans and procedures for addressing how laundry will be handled. If the service is contracted out, written agreements to comply with the requirements.</p> <p>10. Written plans and procedures for the ongoing monitoring of the contractual agreement provisions for laundry and waste disposal.</p>	<p><input type="checkbox"/> MET <input type="checkbox"/> NOT MET</p> <p><input type="checkbox"/> MET <input type="checkbox"/> NOT MET</p> <p><input type="checkbox"/> MET <input type="checkbox"/> NOT MET</p> <p><input type="checkbox"/> MET <input type="checkbox"/> NOT MET</p> <p><input type="checkbox"/> MET <input type="checkbox"/> NOT MET</p> <p><input type="checkbox"/> MET <input type="checkbox"/> NOT MET</p>	
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	<p>11. 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.</p> <p>C. OTHER (SPECIFY)</p>	<p><input type="checkbox"/> MET <input type="checkbox"/> NOT MET</p> <p><input type="checkbox"/> C Other (Specify and Attach)</p>	
<p>Transportation Services (Section 460.76)</p>			
<p>The PACE organization should take appropriate steps to ensure that participants can be safely transported from their homes to the center and to appointments.</p> <p>8-1 Requirements for the organization's transportation program include: 1. Maintenance of</p>	<p>A. Evidence of appropriate state vehicle inspections.</p> <p>B. If the service is contracted out, written agreements to comply with the requirements.</p> <p>C. Written plans and procedures for the ongoing monitoring of the contractual agreement provisions for transportation services.</p> <p>D. Evidence of the ability to provide adequate and safe</p>	<p><input type="checkbox"/> MET <input type="checkbox"/> NOT MET</p> <p><input type="checkbox"/> MET <input type="checkbox"/> NOT MET</p> <p><input type="checkbox"/> MET <input type="checkbox"/> NOT MET</p>	

<p>transportation vehicles according to the manufacturer's recommendations.</p> <p>2. Transportation vehicles equipped to communicate with the PACE center.</p> <p>3. Training transportation personnel on the special needs of participants and appropriate emergency responses.</p> <p>4. As a part of the multi-disciplinary process, communicating relevant changes in the participant's care plans to transportation personnel.</p>	<p>transportation of center participants:</p> <ol style="list-style-type: none"> 1. Sufficient staff 2. Written policies and procedures for the training and monitoring of drivers including: <ol style="list-style-type: none"> a. proper transfer of nonambulatory and ambulatory participants. b. proper use of equipment needed to transfer and secure participants . c. Emergency procedures during transfer, transport, and arrival of participants. 3. Ability for communication between the driver and center during transportation activities. 4. Evidence of written policies and procedures on the maintenance of vehicles utilized in the transport of participants. 5. Written plans and procedures for communicating between the multidisciplinary team and the transport staff the needs of the participants being transported. 6. Written plans and procedures for monitoring the performance of all drivers. 	<p><input type="checkbox"/> MET <input type="checkbox"/> NOT MET</p> <p><input type="checkbox"/> MET <input type="checkbox"/> NOT MET</p> <p><input type="checkbox"/> MET <input type="checkbox"/> NOT MET</p> <p><input type="checkbox"/> MET <input type="checkbox"/> NOT MET</p> <p><input type="checkbox"/> MET <input type="checkbox"/> NOT MET</p> <p><input type="checkbox"/> MET <input type="checkbox"/> NOT MET</p> <p><input type="checkbox"/> MET <input type="checkbox"/> NOT MET</p>	
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	<p>7. Written procedures to check or audit for the following information on the drivers:</p> <p>a. Current driver's license – <u>Evidence of compliance of State required special class of license, if any, for transporting PACE participants</u></p> <p>b. Record of any traffic violations or accidents that may constitute a potential hazard for the transport of participants.</p> <p>E. OTHER (SPECIFY)</p>	<p><input type="checkbox"/> MET <input type="checkbox"/> NOT MET</p> <p><input type="checkbox"/> MET <input type="checkbox"/> NOT MET</p> <p><input type="checkbox"/> MET <input type="checkbox"/> NOT MET</p> <p><input type="checkbox"/> E Other (Specify and Attach)</p>	
Dietary Services (Section 460.78)			
9. PACE center is required to provide food that is nourishing, palatable, well-balanced, and meets acceptable safety standards:	<p>A. Evidence of certification or licensure from state or local health agencies for the preparation and serving of food.</p> <p>B. Written policies and procedures that ensure the safe Delivery of food and nutritional supplements including:</p> <p>1. Safe procurement of food and nutritional supplements;</p>	<p><input type="checkbox"/> MET <input type="checkbox"/> NOT MET <input type="checkbox"/> N.A.</p>	

<p>9-1 Procure food from sources approved or considered satisfactory by Federal, State, Tribal or local authorities that have jurisdiction over the service area.</p> <p>9-2 Store, prepare, distribute, and serve food under sanitary conditions</p> <p>9-3 Dispose of garbage and refuse properly</p>	<p>2. Safe storage of food and nutritional supplements both perishable and nonperishable to prevent contamination;</p> <p>3. Safe handling of food and nutritional supplements;</p> <p>4. Safe preparation of food and medication, including policies for admixtures;</p> <p>5. Safe and adequate water supply;</p> <p>6. Safe and proper disposal of sewage;</p> <p>7. Provisions for substitute foods or nutritional supplements;</p> <p>8. Safe garbage storage and disposal;</p> <p>9. Training of staff in safe food delivery; and</p> <p>10. Written policies and procedures for emergency food supplies and emergency nutritional supplements.</p> <p>C. Written policies and procedures for dietitian, physician, and pharmacist involvement to determine the nutritional adequacy of menus and the</p>	<p><input type="checkbox"/> MET <input type="checkbox"/> NOT MET</p> <p><input type="checkbox"/> MET <input type="checkbox"/> NOT MET</p> <p><input type="checkbox"/> MET <input type="checkbox"/> NOT MET</p> <p><input type="checkbox"/> MET <input type="checkbox"/> NOT MET</p> <p><input type="checkbox"/> MET <input type="checkbox"/> NOT MET</p> <p><input type="checkbox"/> MET <input type="checkbox"/> NOT MET</p> <p><input type="checkbox"/> MET <input type="checkbox"/> NOT MET</p>	
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	<p>caloric and nutritional needs for the participant population.</p> <p>D. OTHER (SPECIFY)</p>	<input type="checkbox"/> MET <input type="checkbox"/> NOT MET <input type="checkbox"/> MET <input type="checkbox"/> NOT MET <input type="checkbox"/> MET <input type="checkbox"/> NOT MET <input type="checkbox"/> D Other (Specify and Attach)	
<p>Bill of Rights (Section 460.110)</p>			
<p>10.The PACE organization must have written policies and implement procedures to ensure that the participant, his or her representative, and staff understand their rights.</p>	<p>A. Written policies and procedures governing the participant Bill of Rights including:</p> <p>1. The parameters on the use of physical or chemical restraints;</p>	<input type="checkbox"/> MET <input type="checkbox"/> NOT MET <input type="checkbox"/> MET <input type="checkbox"/> NOT MET	

	<p>2. The reporting of mental or physical abuse or neglect.</p> <p>B. Written policies and procedures for distributing the Bill of Rights to the participant and his or her representative upon enrollment.</p> <p>C. Written policies and procedures to ensure that the participant and his or her representative understand their rights.</p> <p>D. 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. <i><u>Evidence of compliance with State requirement, if any, for specific criteria of the principle language</u></i></p> <p>E. The participant Bill of Rights should be in a large print for the elderly to read.</p> <p>F. Written policies and procedures to respond to and rectify a violation of a participant's rights.</p> <p>G. Written policies and procedures regarding sanctions</p> <p>H. OTHER (SPECIFY)</p>	<p><input type="checkbox"/> MET <input type="checkbox"/> NOT MET</p> <p><input type="checkbox"/> MET <input type="checkbox"/> NOT MET</p> <p><input type="checkbox"/> MET <input type="checkbox"/> NOT MET</p> <p><input type="checkbox"/> MET <input type="checkbox"/> NOT MET</p> <p><input type="checkbox"/> MET <input type="checkbox"/> NOT MET</p> <p><input type="checkbox"/> MET <input type="checkbox"/> NOT MET</p> <p><input type="checkbox"/> MET <input type="checkbox"/> NOT MET</p>	
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		<input type="checkbox"/> H OTHER (Specify and attach)	
Personnel Qualifications (Section 460.64)			
11. The PACE center must have qualified staff to provide care to its frail elderly participants.	<p>A. Signed employment agreements for all employees of the PACE center (i.e. medical director, primary care physician, registered nurse, social worker, recreational therapist or activities coordinator, PACE center manager, home care coordinator, and PACE center personal care attendants.</p> <p>B. Signed contracts for all contractors and contracted personnel.</p> <p>C. Written position descriptions for all staff (employees and contractors).</p> <p>D. Evidence 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) are employees of the PACE center and not contractors.</p> <p>E. Evidence in personnel files that appropriate professional licenses and criminal background checks have been done on all staff – employees and contractors.</p> <p>F. Evidence of disclosure forms in personnel files to ensure that staff – employees and contractors – has no direct or indirect financial relationship with the organization.</p> <p>G. OTHER (SPECIFY)</p>	<input type="checkbox"/> MET <input type="checkbox"/> NOT MET <input type="checkbox"/> MET <input type="checkbox"/> NOT MET <input type="checkbox"/> MET <input type="checkbox"/> NOT MET <input type="checkbox"/> MET	

		<input type="checkbox"/> NOT MET <input type="checkbox"/> MET <input type="checkbox"/> NOT MET <input type="checkbox"/> G Other (Specify and attach)	
TRAINING (Section 460.66)			

<p>12-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>12-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>A. Written individual training programs for all types of staff, including van drivers, specific to each position that includes at least the following:</p> <ol style="list-style-type: none"> 1. training to ensure that each staff member continuously exhibits competency in the skills needed to provide appropriate, culturally competent care to participants; training should be specific and within the scope of practice. 2. training on the transport of nonambulatory participants; 3. training on all emergency equipment and all other equipment necessary for the performance of his or her specific position; 4. training on center emergency procedures; 5. training on restraint use; 6. training on participant rights, including dignity and privacy, to all participants; 7. training in response to participant complaints or center quality improvement activities; and 8. training in therapeutic communication specific to the PACE setting and population. <p>A. Written training manual for personal care attendants to ensure that they exhibit competency in basic skills for providing personal care, including:</p> <ol style="list-style-type: none"> 1. how to maintain a clean, safe and healthy environment; 2. appropriate and safe techniques in personal hygiene and grooming; 	<p><input type="checkbox"/> MET <input type="checkbox"/> NOT MET</p> <p><input type="checkbox"/> MET <input type="checkbox"/> NOT MET</p> <p><input type="checkbox"/> MET <input type="checkbox"/> NOT MET</p> <p><input type="checkbox"/> MET <input type="checkbox"/> NOT MET</p> <p><input type="checkbox"/> MET <input type="checkbox"/> NOT MET</p> <p><input type="checkbox"/> MET <input type="checkbox"/> NOT MET</p> <p><input type="checkbox"/> MET <input type="checkbox"/> NOT MET</p> <p><input type="checkbox"/> MET <input type="checkbox"/> NOT MET</p>	
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GENERAL PROVISIONS			
13. General provisions	<p>A. Written plans and procedures regarding the safeguarding of participant data and records.</p> <p>B. Written plans and procedures regarding the confidentiality and retention of participant health information.</p> <p>C. Written plan and procedures for all participant reassessments which include periodic reassessments and reassessments at the participant or caregiver's request.</p> <p>D. Verify the PACE organization's actual service area.</p> <p>E. Verify the process the PACE organization has in place to ensure participant access to care 24 hours a day, 7 days a week.</p> <p>F. Verify that all required services will be provided by the PACE organization.</p> <p>G. Evidence of a health information system to collect, analyze, and report participant data.</p> <p>H. Identify any additional sites.</p> <p>I. OTHER (SPECIFY)</p>	<p><input type="checkbox"/> MET <input type="checkbox"/> NOT MET</p> <p><input type="checkbox"/> MET <input type="checkbox"/> NOT MET</p> <p><input type="checkbox"/> MET <input type="checkbox"/> NOT MET</p> <p><input type="checkbox"/> MET <input type="checkbox"/> NOT MET</p> <p><input type="checkbox"/> MET <input type="checkbox"/> NOT MET</p> <p><input type="checkbox"/> MET <input type="checkbox"/> NOT MET</p> <p><input type="checkbox"/> MET <input type="checkbox"/> NOT MET</p>	

		<input type="checkbox"/> I Other (Specify and Attach)	
General Safety Requirements			
14. Overall PACE center safety requirements 14-a. Medication rooms 14-b. Oxygen Storage	A. If applicable, evidence of state pharmacy licensure. B. Written plans and procedures for narcotic inventory control and disposal. C. Locked medication rooms or rooms that have the capability to be locked when medications are on site. D. Written plans and procedures for refrigerator temperature logs used for medication and food storage. E. Written plans and procedures for oxygen storage that is in compliance with fire safety and FDA laws.	<input type="checkbox"/> MET <input type="checkbox"/> NOT MET <input type="checkbox"/> N.A. <input type="checkbox"/> MET <input type="checkbox"/> NOT MET <input type="checkbox"/> MET <input type="checkbox"/> NOT MET <input type="checkbox"/> MET <input type="checkbox"/> NOT MET <input type="checkbox"/> MET	

	<p>F. Evidence of CLIA certification if the PACE center is performing waived lab services on site, e.g. glucose meter testing, urine testing, fecal occult testing, blood testing, cholesterol screening, or hemoglobin or hematocrit testing.</p> <p>G. OTHER (SPECIFY)</p>	<p><input type="checkbox"/> NOT MET</p> <p><input type="checkbox"/> MET</p> <p><input type="checkbox"/> NOT MET</p> <p><input type="checkbox"/> G Other (Specify and Attach)</p>	
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This version completed August 4, 2000

Enclosure 2A

PACE Program Agreement

AGREEMENT No.

An Agreement Between

The Secretary of the Department of Health and Human Services, who has delegated authority to the Administrator of the Health Care Financing Administration, hereinafter referred to as HCFA, and _____ the State Administering Agency, hereinafter referred to as SAA,

and
_____, hereinafter referred to as the PACE Organization

The Secretary, in finding the PACE Organization to be an eligible organization by the Administrator of HCFA and the **Title** _____ of the SAA, agrees to the following with the PACE Organization for the purposes of enacting sections 1894 and 1934 of the Social Security Act:

ARTICLE I

TERM OF AGREEMENT

[?460.32(a)(3)] ; [?460.34]

This Agreement is effective for the contract year beginning _____ through _____ and may be extended for subsequent contract years in the absence of a notice by a party (HCFA, SAA, or the PACE Organization) to terminate the agreement. This agreement supersedes any previous understanding, agreement, arrangement or contract with respect to the provision of and/or the payment for PACE services. This Agreement is subject to termination as contained in Article IV.

The PACE Organization agrees to comply with all regulations or general instructions or other terms and conditions as HCFA or the SAA may find necessary and appropriate from time to time for the administration of the PACE program.

ARTICLE II

GENERAL CONDITIONS

A. Governing Body [?460.32(a)(4)] ; [?460.62] ; [?460.60]

(1). The name and telephone number of the PACE Organization's program director and the names of all members of the governing body, and the name and phone number of a governing body member who will serve as a liaison between the governing body and HCFA and the SAA is contained in **Appendix A**.

(2). Any changes in names or telephone numbers shall be reported to HCFA and to the SAA prior to the effective date of the change(s).

B. PACE Structure [?460.32(a)(4)] ; [?460.60]

(1). A description of the organizational structure of the PACE Organization, including the relationship to, at a minimum, the governing body, program director, medical director, and to any parent, affiliate or subsidiary entity is shown in **Appendix B**.

(2). A PACE Organization planning a change in organizational structure shall notify HCFA and the SAA, in writing, at least 60 days before the change takes effect.

C. Service Area [460.32(a)(1)]

(1). The PACE Organization shall restrict the furnishing of PACE services to participants who live within the designated service area, approved by the SAA and HCFA, which is identified by zip code, county, perimeter street boundaries, census tract, block, or tribal jurisdictional area (as applicable).

(2). HCFA and the SAA shall approve any change in the designated service area. The designated service area is included in **Appendix C**.

D. Participant Bill of Rights [?460.32(a)(5)]; [?460.110 and ?460.112]

The PACE Organization shall make available to all enrollees a list and explanation of the rights to which they are entitled. The PACE Organization shall assure that those rights and protections are provided. The participant Bill of Rights that will be used to satisfy this requirement is included in **Appendix D**.

E. Services [?460.32(a)(8)] ; [?460.92 and ?460.94]

The PACE Organization agrees to make available comprehensive health care services that include, at a minimum, all services required by 42 CFR ? 460.92 and 42 CFR ? 460.94.

F. Eligibility, Enrollment and Disenrollment [?460.32(a)(7) & ?460.32(b)(1)]; [?460.150]; [?460.160(b)(3)(ii)]; [?460.162]; [?460.164]

(1). The PACE Organization shall consider for enrollment and enroll only those persons who:

- are 55 years or older,
- are determined by the SAA to need the level of care required under the State Medicaid plan for coverage of nursing facility services,
- are able to live in a community setting without jeopardizing their health or safety, and
- reside in the organization's approved designated service area.

(2). The PACE Organization's eligibility and enrollment policies, including the criteria used to determine if persons are able to live in a community setting without jeopardizing their health or safety, is contained in **Appendix E**.

(3). The SAA, in consultation with the PACE Organization, makes a determination of continued eligibility based on a review of the participant's medical record and plan of care. The criteria used to make the determination of continued eligibility are contained in **Appendix E**.

(4). The PACE Organization may establish other enrollment criteria in addition to that found in Article II F(1) of this Agreement that support decisions to not enroll persons because of certain circumstances. This criteria, however, shall not modify the criteria in Article II F(1) above. All additional enrollment criteria, if any, are specified in **Appendix F**.

(5). The PACE Organization agrees that any participant, for any reason, may voluntarily disenroll and, upon doing so, is not liable for any additional or penalty payments. The voluntary disenrollment policy is contained in **Appendix G**.

(6). The PACE Organization may not involuntarily disenroll a participant except for specific causes. The PACE Organization's involuntary disenrollment policy is located in **Appendix H**.

G. Grievance and Appeals [?460.32(a)(6)]; [?460.122]; [?460.124]

(1). All participants are afforded the right to grieve a PACE Organization's medical and non-medical decisions. They also have the right to appeal the PACE Organization's refusal to provide a particular care-related service or its decision not to pay for a service received by a PACE participant. Internal grievance and appeal procedures for participants are contained in **Appendix I**.

(2). PACE participants will be informed, in writing, of his or her appeal rights under Medicare or Medicaid managed care, or both. PACE participants will be assisted in choosing which to pursue if both are applicable. The additional appeal rights procedures under Medicare or Medicaid are contained in **Appendix J**.

H. Quality Assessment and Performance Improvement [?460.32(a)(9), (a)(10), (a)(11)]; [?460.130, ?460.134(c), ?460.136, ?460. 140]; [?460.202(b)]

(1). The PACE Organization's quality assessment and performance improvement program is contained in **Appendix K**.

(2). The PACE Organization shall meet or exceed minimum levels of performance on standardized quality measures as established by HCFA and the SAA. The minimum level of performance is: The organization will achieve an immunization rate for both influenza and pneumococcal vaccinations of 80 % for the participant population that is appropriate. (Rate will exclude those participants who refused or the vaccines are medically contraindicated).

(3). The PACE Organization shall furnish data and information on participant care activities, as established by HCFA and the SAA. These data are contained in **Appendix L**.

I. Data Collection and Reporting Requirements [?460.200(a)(b)(c) and ?460.204]; [?460.70]

(1). The PACE Organization shall collect data, maintain records and submit reports as required by HCFA and the SAA. The PACE Organization shall allow HCFA and the SAA access to data and records including, but not limited to, participant health outcomes data, financial books and records, medical records, personnel records, any aspect of services furnished, reconciliation of participants' benefit liabilities and determination of Medicare and Medicaid amounts payable.

(2). The PACE Organization agrees to require that all related entities, contractors or subcontractors agree that the U.S. Department of Health and Human Services, HCFA, or their designee(s) have the right to inspect, evaluate and audit any pertinent contracts, books, documents, papers, and records of any related entity contractor(s) or subcontractor(s) involving transactions related to this Agreement.

ARTICLE III
PAYMENT
[?460.32(a)(12)]

For each enrolled participant who is Medicare and/or Medicaid eligible, the PACE Organization will be paid a prospective, monthly capitation amount. The PACE Organization will be paid in the following manner:

A. For Participants Eligible for Medicare [?460.180]

(1). Separate rates are established for Part A and Part B. For a participant entitled to Part A benefits and enrolled under Part B, both the Part A and Part B rates are paid. For a participant who is entitled to Part A benefits but not enrolled under Part B, only the Part A rate is paid. For a participant enrolled under Part B but not entitled to Part A benefits, only the Part B rate is paid.

(2). Except as specified in (3) below, the payment rate for each participant is based on the Medicare Part A and Part B aged rate (i.e., the Medicare+Choice rates) published by HCFA, adjusted by a frailty factor of 2.39%.

(3). The payment rates for end stage renal disease (ESRD) entitled beneficiaries are based on the Medicare+Choice ESRD rates published by HCFA, adjusted by applying a frailty factor. The ESRD Part A rate is adjusted by a frailty factor of 1.46% and the ESRD Part B rate is adjusted by a frailty factor of 1.36%.

(4). The payment amount is specified in **Appendix M**.

B. For Participants Eligible for Medicaid [?460.182]

(1). The monthly capitated Medicaid payment amount is negotiated between the PACE Organization and the SAA. This payment amount is specified in **Appendix M**.

(2). The SAA shall describe the enrollment/disenrollment reconciliation procedures, to adjust for the difference between the estimated number of participants on which the prospective monthly payment was based and the actual number of participants claimed in that month. The reconciliation method is contained in **Appendix N**.

ARTICLE IV

TERMINATION OF THE AGREEMENT

[?460.32(a)(13)] [?460.50, ?460.52 ?460.54]

- A.** HCFA or the SAA may terminate this Agreement at any time for cause, including, but not limited to: uncorrected deficiencies in the quality of care furnished to participants, the PACE Organization? s failure to comply substantially with the conditions for a PACE program, or non-compliance with the terms of this Agreement.
- B.** The PACE organization may terminate this agreement after timely notice to HCFA, the SAA and the participants. Notifications shall be made as follows: To HCFA and the SAA, 90 days before termination. To the participants, 60 days before termination.
- C.** The PACE Organization? s detailed written plan for phase-down, in the event of termination, is included in **Appendix O**.

ARTICLE V

REQUIREMENTS OF LAWS AND REGULATIONS

[460.32(a)(2)]

- A.** The PACE Organization agrees to comply with all applicable Federal, State, and local laws and regulations, including, but not limited to:
- (1). Sections 1894 and 1934 of the Social Security Act as implemented by regulations at 42 CFR Part 460;
 - (2). Title VI of the Civil Rights Act of 1964 as implemented by regulations at 45 CFR Part 84;
 - (3). The Age Discrimination Act of 1975 as implemented by regulations at 45 CFR Part 91;
 - (4). The Americans with Disabilities Act; and
 - (5). Other laws applicable to the receipt of Federal funds.

AGREEMENT No. _____

In witness whereof, the parties hereby execute this agreement.

For the PACE Organization

Printed Name Title

Signature Date

Address

For (name of the SAA)

Printed Name Title

Signature Date

Address

For the Health Care Financing Administration

Gary A. Bailey - Director, Health Plan Administration Group, Center for Health Plans and Providers

Signature Date

Address

APPENDIX: B. ORGANIZATIONAL STRUCTURE

APPENDIX: C. SERVICE AREA

1. Identify the entire catchment area the PACE program will be covering.
2. Identify the catchment area by zip codes (if the entire county is not included in the service area), and counties or tribal jurisdictional areas (if applicable).

APPENDIX: D. PARTICIPANT BILL OF RIGHTS

APPENDIX: E. ELIGIBILITY AND ENROLLMENT POLICIES; AND CONTINUED
ELIGIBILITY CRITERIA

APPENDIX: F. ADDITIONAL ENROLLMENT CRITERIA

APPENDIX: G. VOLUNTARY DISENROLLMENT POLICY

APPENDIX: H. INVOLUNTARY DISENROLLMENT POLICY

APPENDIX: I. INTERNAL GRIEVANCE AND APPEAL PROCEDURES

APPENDIX: J. ADDITIONAL APPEAL RIGHTS UNDER MEDICARE OR MEDICAID

APPENDIX: K. QUALITY ASSESSMENT AND PERFORMANCE IMPROVEMENT PROGRAM

APPENDIX: L. PARTICIPANT DATA

APPENDIX: M. MEDICARE AND MEDICAID PAYMENT AMOUNTS

Medicare:

_____ County

_____ State

Part A \$

Part B \$

Frailty factor

x 2.39

x 2.39

Monthly Rate =

M+C End Stage Renal Disease Rate(s):

Part A \$

Part B \$

Frailty Factor

x 1.46

x 1.36

Monthly Rate =

Medicaid:

Monthly Capitation rate: \$ _____

APPENDIX: N. STATE ENROLLMENT/DISENROLLMENT RECONCILIATION
METHODOLOGY

APPENDIX: O. TERMINATION PHASE - DOWN PLAN

Enclosure 2B

DATA ELEMENTS FOR MONITORING

HCFA is currently developing two different data sets for the PACE program: data collection for OBCQI and data collection for monitoring. Data collection for OBCQI is useful in identifying opportunities to improve participant care and in evaluating the results of internal performance improvement activities. This type of data collection is also useful in comparing performance across PACE sites. Data collection for monitoring is a way to signal HCFA and the State of any potential problems, aberrant outcomes or unusual events that may be the first indication of trouble in patient care, site operations, or financial solvency.

These data elements would be used to determine if additional onsite monitoring activities by HCFA or the State should occur. This information gives HCFA and the States an opportunity to gauge the organization's status and quickly intervene when necessary. For example, if an organization's financial data showed it was struggling and the monitoring data indicated it had a noteworthy number of grievances or emergency room visits, HCFA or the State might contact or visit the PACE organization to ensure that adequate and appropriate care was being provided.

Since we have limited resources to implement the data elements for monitoring, we purposely limited the data elements to a small list that will present the most accurate picture of the PACE site's activities and overall operation. We decided to have PACE organizations report the information quarterly because that reporting timeframe is most useful in determining and monitoring trends and patterns of care and to coincide with the reporting of financial data.

We anticipate that the data collection for OBCQI will be complete and ready for operation by the fall of 2002. Because we expect to start receiving applications for permanent PACE organizations by the fall of 2000 (prior to the completion and implementation of the PACE OBCQI project), we thought it was critical that we develop data elements to monitor the PACE organizations in the interim. Thus, we developed the PACE data elements for monitoring. If it becomes evident that HCFA and the States are not able to conduct appropriate monitoring activities with the information provided from the OBCQI project, we will continue collecting the elements, or a modified version, from the monitoring data elements.

Though we are solely collecting elements for monitoring purposes in the interim, we do not plan to disregard quality assessment and performance improvement activities. In the interim, pending completion of the PACE OBCQI project, we would expect the PACE organization to collect the participant care data that are indicated in the regulation and use this information for its internal quality improvement activities. These data would not be submitted to HCFA. When HCFA conducts its onsite review, we would expect the PACE site to have records of the information collected. We would then evaluate the extent of the sites quality improvement projects to ensure compliance with regulatory requirements. However, it is our intention that the PACE OBCQI project would serve as the mechanism for monitoring all quality activities by PACE organizations when it is implemented.

Enclosure 2C

1) Routine Immunizations:

Definition:

PACE participants who received routine immunizations during the reporting year.

What data will be reported:

- 1) Number of participants who received a flu immunization this year;
- 2) Number of participants who have received the pneumococcal immunization in the last ten years;
- 3) Total number of participants at the PACE organization.
- 4a) Number of participants not immunized for flu
- 4b) Number of participants not immunized for pneumococcal
- 5) Reason for not immunizing

Frequency:

During the inoculation time period (e.g. Sept. to Jan.)

How to use the measure:

Compare the number of PACE participants who were enrolled during the reporting year to the number of participants who received routine immunizations (flu and pneumococcal) during the reporting year.

Minimum levels of Performance: The organization will achieve an immunization rate for both influenza and pneumococcal vaccinations of 80 % for the participant population that is appropriate. (Rate will exclude those participants who refused or the vaccines are medically contraindicated).

2) Grievances and Appeals

Definition:

Grievances are defined as either a written or oral complaints that expresses dissatisfaction with service delivery or the quality of care provided. Appeals are defined as a written complaint for the noncoverage or nonpayment of a service or item.

What data will be reported:

The PACE organization will be asked to submit a copy of its grievance and appeal log each quarter. The information in the log should, at a minimum, include the following:

- 1) Total number of participants during the quarter;
- 2) Total number of grievances filed during the quarter;
- 3) Total number of appeals filed during the quarter;
- 4) Source of each grievance or appeal (participant, family, caregiver, etc.);
- 5) Date of initiation of each grievance or appeal; and
- 6) Date of resolution of each grievance or appeal.

Frequency: Quarterly

How to use the measure: Monitor trends and patterns. The actual number of grievances and appeals alone should not be viewed as an indicator of a problem. The high number of grievances could mean that participants are encouraged to speak up for themselves and voice their concerns.

3) Enrollments

Definition: Individuals who had an encounter with the PACE organization and subsequently enrolled in the PACE program.

What data will be reported: Number of individuals who enrolled in the program, identified by payer.

Frequency: Quarterly

How to use the measure: Monitor trends and patterns to determine if there are any accessibility issues and to determine if the PACE organization has sufficient financial resources to conduct appropriate marketing activities. This information can also be used to evaluate the PACE organization's ability to maintain an appropriate census.

4) Disenrollments

Definition: Participants who disenrolled from the program for reasons other than death.

What data will be reported:

- 1) Total number of participants;
- 2) Number of participants who disenrolled from the program for reasons other than death;
- 3) Number of voluntary disenrollments;
- 4) Number of involuntary disenrollments; and
- 5) Reason for each disenrollment: leaving the service area, experience with the physician, accessing out of network or other.

Frequency: Quarterly

How to use the measure: Utilize this information to determine if there are any problems with site operations, such as accessibility, provision of services, etc. that are causing voluntary disenrollments. In addition, this information can be used to review the organization's policies on involuntary disenrollments.

5) Prospective Enrollees

Definition: Potential participants who were interviewed but did not enroll in the PACE program.

What data will be reported:

- 1) Number of potential participants who were interviewed but did not enroll in the PACE program; and
- 2) Indicate the category that explains the reason each potential participant did not enroll, e.g. too sick, not safe to remain in the community, mental health concerns, lack of support network, requiring 24-hour care, preference for own physician, preference for other health care provider or institution, financial reason to avoid share of cost, unwilling to comply with treatment plan, or other with explanation.

Frequency: Quarterly

How to use the measure: This information can be utilized to determine if the PACE organization is following the appropriate eligibility criteria and to determine if the organization is conducting appropriate marketing activities.

6) Unscheduled Hospitalizations

Definition: PACE participants admitted to an acute care hospital (excluding hospitalizations for diagnostic tests).

What data will be reported:

- 1) Total number of participants;
- 2) Total number of participants admitted to the hospital;
- 3) Specific reason, including diagnosis, for participant's admission;
- 4) Number of participant hospital readmissions for the same reason in a 31-day period.

Frequency: Quarterly

How to use the measure: Review those with high usage to determine if intervention by the PACE organization could have prevented some of the hospitalizations. Readmission for the same reason in a 31-day period could indicate that the length of stay is too short or there is inadequate follow-up care by the PACE organization. Conduct quarterly comparisons to get a total picture of the care provided by the organization.

7) Emergent (unscheduled) Care

Definition: PACE participants seen in the hospital emergency room (including care from a PACE physician in a hospital emergency department) or an outpatient department/clinic emergency, urgicenter.

What data will be reported:

- 1) Number of participants seen in the emergency room;
- 2) Total number of participants; and
- 3) Specific reason including diagnosis.

Frequency:

Quarterly

How to use the measure:

Review those with high usage to determine if intervention by the PACE organization could have prevented some of the visits to the ER.

8) Unusual Incidents for Participants and the PACE site (to include staff)

Definition:

Unanticipated circumstances, occurrences or situations which have the potential for serious consequences for the participants. **Examples include, but are not limited to:** falls at home or the adult day health center; falls while getting into the van; van accidents other than falls; participant suicide or attempted suicide; staff criminal records; infectious or communicable disease outbreaks; food poisoning; fire or other disasters; participant injury that required follow-up medical treatment; participant injury on equipment; lawsuits; medication errors and any type of restraint use. This is not an inclusive list, so we would expect PACE sites to submit quarterly information on any unanticipated situations that occur.

What data will be reported: Number of unusual incidents

Frequency:

Quarterly

How to use the measure:

Analyze categories focusing on whether these incidents were preventable, what steps were taken to resolve the problem, and what changes are being made to improve prevention. Is there a pattern that indicates a need for follow-up to investigate health and safety issues and procedures? Is this a program problem (e.g. negligence by staff) or a participant problem (e.g. verbal outbursts by participant with mental illness or severe dementia)?

9) Deaths

Definition:

Death of participants during the given reporting period.

What data will be reported:

- 1) Number of deaths;
- 2) Number of participants;
- 3) Cause of the participant's death; and
- 4) Setting of the participant's death.

Frequency:

Quarterly

How to use the measure: Analysis to determine if there is a pattern indicating inappropriate setting for the participant or problems with accessibility to 24 hour care. Because of the link between the number of deaths and enrollment, this information may also indicate if the PACE organization is maintaining an appropriate census to remain fiscally viable.

The data submitted must come exclusively from the PACE organization, not the parent organization.

If the PACE organization has more than one site of care/treatment, each site must be identified separately.