PROVIDER REQUIREMENTS

Provider Certifications/Recertification Requirements

The State Readiness Review, developed by Centers for Medicare and Medicaid Services (CMS), is used by the State Administering Agency (SAA) to perform the readiness review of non-operational Program of All-Inclusive Care for the Elderly (PACE) organization applicants prior to enrolling recipients. The SAA must conduct an assessment of provider readiness prior to operation. The SAA reviews the PACE organizations policies and procedures, the design and construction of the building, emergency preparedness, compliance with Occupational Safety and Health Administration (OSHA), Food and Drug Administration (FDA), state and local laws and life safety codes. For the non-operational PACE programs CMS and the SAA shall conduct a site review within six months of the provider enrolling its first recipient.

As required by 42 Code of Federal Regulations (CFR) 460.190, CMS and SAA must conduct comprehensive annual reviews of PACE organizations during the trial period of review, the first three years of operation, to ensure compliance with the PACE regulation. After the initial three year period, reviews shall be conducted by CMS and State, including an on-site visit at least every two years, in accordance with 42 CFR 460.192.

CMS and the SAA report the results of the reviews to the PACE organization, along with any recommendations for changes to the organization's program. The PACE organization must write a corrective action plan (CAP), a description of the action plan that will be taken to correct the identified deficiency. Disclosure of the review results must be available as demonstrated in 42 CFR 460.196.

Accreditation, Licensure, Other Applicable Standards for Participation

The PACE organization must be enrolled in the Medicaid program and hold a Medicaid provider agreement/provider number as a PACE provider. PACE is a Medicaid State plan service; not a waiver service. PACE will not be enrolled in the Medicaid program as an Adult Day Health Care (ADHC).

In an exception, the PACE organization shall be licensed by the Health Standards Section (HSS) as an ADHC facility. HSS shall grant appropriate waivers of ADHC licensing requirements in instances where ADHC licensing regulations conflict with PACE requirements when such waivers are determined to have no adverse effect on recipient health and safety and quality of life.

In an exception to the State of Louisiana licensing requirement for ADHC, a center shall not admit more clients into care than the number specified on their license. PACE may enroll more

people in PACE than the license for ADHC will allow, but shall not exceed the licensed capacity on any day.

In an exception to the licensing requirement for ADHC an individual who has not attended a center at least 36 days each quarter (every 3 months) shall not be eligible for ADHC services. A PACE recipient may have supports at their home during the day and may not need the daily support provided by the ADHC component of PACE. The frequency of a recipient's attendance at the center is determined by the PACE interdisciplinary team (IDT) based on the needs and preferences of the recipient in accordance with 42 CFR 460.98(e). The recipient may not attend the center within 36 days per quarter period. The recipient must not be disenrolled from PACE.

Provider Responsibilities

The following characteristics must apply:

- Must be operating under the control of an identifiable governing body that includes at least one recipient representative, as specified in 42 CFR 460.62(a) with full legal authority and responsibility for:
    - Governance and operation of the organization;
    - Development of policies consistent with mission;
    - Management and provision of all services, including the management of contractors;
    - Establishment of personnel policies that address adequate notice of termination by employees or contractors with direct patient care responsibilities;
    - Fiscal operation;
    - Development of policies on recipient health and safety, including a comprehensive systemic operational plan to ensure the health and safety of recipients; and
    - Quality Assessment and Performance Improvement (QAPI) program (with the purpose of linking the development, implementation, and coordination of the ongoing QAPI program with all aspects of the PACE program).

- Be able to provide the complete service package regardless of frequency or duration of services;
- Have a physical site and staff to provide primary care, social services, restorative therapies, personal care and supportive services, nutritional counseling, recreational therapy, and meals as specified in 42 CFR 460.98(c);
- Have a defined service area;
- Have safeguards against conflict of interest, as defined in 42 CFR 460.68;
- Have demonstrated fiscal soundness, as defined in 42 CFR 460.80 and 42 CFR 460.208;
- Have a formal Recipient Bill of Rights, as defined in 42 CFR 460.110 and 42 CFR 460.112; and
- Have a process to address grievances and appeals.

The following advisory committees must also be established to advise the governing body:

- Recipient Advisory Committee must provide advice to the governing body on matters of concern to recipients. Recipients and representatives of recipients (his/her care giver) shall constitute a majority of the membership. The committee must provide the liaison to the governing body to present issues from the recipient advisory committee in accordance with 42 CFR 460.62(b);
- Ethics Committee; and
- Other committees as required by CMS and/or SAA.

The PACE organization must not discriminate against any recipient in the delivery of required PACE services based on race, ethnicity, national origin, religion, sex, age, mental, or physical disability or source of payment.

The PACE organization must establish, implement, and maintain a documented infection control plan that meets the requirements as specified in 42 CFR 460.74. The PACE organization must follow accepted policies and standard procedures with respect to infection control, including at least the standard precautions developed by the Centers for Disease Control and Prevention.

The PACE organization must have a current organizational chart in accordance with 42 CFR 460.60. The PACE organization planning a change in organizational structure must notify CMS and the SAA, in writing, at least 14 days before the change takes effect.

The PACE organization is required to establish, implement, and maintain a documented marketing plan with measurable enrollment objectives and a system to track effectiveness as described in 42 CFR 460.82. All marketing material, including any initial, revised or updated marketing material, must be reviewed and approved by CMS and SAA.

As required by 42 CFR 460.116 the PACE organization must have written polices and implements procedures to ensure that the explanation of rights to the recipient, his or her representative, and staff are fully explained and understood. The PACE organization must have established documented procedures to respond to and rectify a violation of a recipient's rights in accordance with 42 CFR 460.118. The PACE organization must limit the use of chemical or physical restraints to the least restrictive method as described in 42 CFR 460.114.

In accordance with 42 CFR 460.72 the PACE organization must have a written plan and procedure for handling emergency situations. At least annually the PACE organization must test, evaluate, and document the effectiveness of its emergency and disaster plans to ensure and maintain appropriate responses to situations and needs from both medical and non-medical emergencies. The PACE organization must have a documented plan to obtain emergency medical assistance from sources outside the center when needed.

The minimum emergency equipment that must be available for use at each PACE center includes easily portable oxygen, airways, suction, and emergency drugs, along with staff on the premises at all times who know how to use the equipment. The PACE organization must establish, implement and maintain a written plan to ensure that all equipment is maintained in accordance with manufacturer's recommendations.

The PACE organization must maintain owned, rented, or leased transportation vehicles in accordance with manufacturer's recommendations. If a contractor provides transportation services the PACE organization must ensure that the vehicles are maintained in accordance with manufacturer's recommendations.

If there are changes in the PACE Enrollment Agreement information at any time during the recipient's enrollment, the PACE organization must:

- Give an updated copy of the information to the recipient; and
- Explain the changes to the recipient and his or her representative or caregiver in a manner they understand.

A PACE organization must only involuntarily disenroll a PACE recipient from the PACE program, in accordance with 42 CFR 460.164, for the following reasons:

- If a recipient fails to pay, or make satisfactory arrangements to pay, any premium due the PACE organization after a 30 day grace period;
- The recipient engages in disruptive or threatening behavior;
- The recipient moves out of the PACE service area or is out of the service area for more than 30 days, unless the PACE organization agrees to a longer absence due to extenuating circumstances;
- The PACE program agreement with CMS and Office of Aging and Adult Services (OAAS) is not renewed or is terminated;
- The PACE organization is unable to offer health care services due to the loss of state licenses or contracts with outside providers; and
- The recipient is determined no longer to meet Medicaid state nursing facility level of care requirements and is not deemed eligible. The PACE organization must make the determination that the recipient no longer meets level of care and would not reasonably be expected to become eligible for PACE services within 6 months in the absence of continued coverage under the PACE program.

The following behaviors are behaviors considered disruptive or threatening behaviors for purposes of involuntary disenrollment as specified by 42 CFR 460.164(b) (1&2):

- The behavior that jeopardizes his/her health or safety, or the safety of others; and
- Consistent refusal to comply with his/her individual plan of care or the terms of the PACE enrollment agreement by a recipient with decision making capacity, but not if the behavior is related to a mental or physical condition of the recipient. Noncompliant behavior includes repeated noncompliance with medical advice and repeated failure to keep appointments.

Under the authority of Section 903 of the Benefits Improvement and Protection Act (BIPA), as noted in 42 CFR 460.26, a PACE organization must have a CMS approved wavier to expand the request to involuntarily disenroll a recipient. This is a request typically made at the time of program development.

- The ability to disenroll a recipient for behaviors or actions taken by the recipient's family or care giver that renders the recipient noncompliant, as specified in 42 CFR 460.164(d); and

- The recipient who is permanently placed in a nursing facility fails to pay or to make satisfactory arrangements to pay, the amount of patient liability that would be required to be paid by a Medicaid eligible resident of a nursing facility if he/she was not a recipient in a PACE organization.

The PACE organization must document reasons for the involuntary disenrollment and all efforts to resolve the problem. Involuntary disenrollment shall occur only after all attempts at resolving the issues have been exhausted. The PACE organization must submit all documentation used to support the involuntary disenrollment to the Office of Aging and Adult Services Regional Office (OAAS RO) in accordance with 42 CFR 460.164(e).

The OAAS RO shall submit their preliminary determination to approve/deny the involuntary disenrollment to the OAAS State Office (SO) PACE program designated contact person within 3 business days of receipt of all supportive documentation from the PACE organization. The final justification to proceed with disenrollment will be determined by the OAAS SO within two business days of receipt of the OAAS RO preliminary determination and supporting documentation. OAAS SO shall notify OAAS RO of the final determination if involuntary disenrollment is approved by OAAS SO. The PACE organization shall be notified by the OAAS RO within one business day of receipt of the final determination from OAAS SO.

As specified in 42 CFR 460.160(b), an annual MDS-HC recertification assessment must be completed to reevaluate whether the recipient continues to meet level of care required under the state Medicaid plan for coverage of nursing facility services. The PACE applicant must receive a face-to-face Minimum Data Set-Home Care (MDS-HC) assessment by OAAS trained and certified PACE staff to verify that the applicant continues to meet the required nursing facility level of care criteria for enrollment in PACE.

In accordance with 42 CFR 460.160(b) (2), OAAS may determine that a PACE recipient, who no longer meets the State Medicaid nursing facility level of care requirements, may be deemed to continue to be eligible for the PACE program until the next annual reevaluation. The PACE organization may request "deemed continued eligibility" based on the following criteria:

- The recipient no longer meets the nursing facility level of care criteria but would reasonably be expected to become eligible within six months in the absence of continued coverage under the program; and

- The recipient's medical record and plan of care support deemed continued eligibility.

The PACE organization must submit the request for Deemed Continued Eligibility Form (OAAS-PF-10-002) to the OAAS RO within five business days of notification of a PACE recipient not having met nursing facility level of care.

The PACE IDT must submit a brief justification summary and supporting documentation from the recipient's medical record/Plan of Care that supports the request for Deemed Continued Eligibility Form (OAAS-PF-10-002). Supporting documentation includes any information that, in the absence of PACE services, the recipient would reasonably be expected to experience a decline in functional abilities or health to a degree that he/she would meet nursing facility level of care criteria within six months.

Examples of supporting documentation include, but are not limited to:

- Diagnosis of a chronic, and/or disabling condition;

- Physician and/or nursing progress notes documenting the treatment and impact of same on chronic, and/or disabling condition(s);

- Physician's Orders and a list of services currently provided to the recipient (e.g. physical therapy, occupational therapy, dietary management, blood pressure checks, etc.); and

- Frequency of medical appointments and/or frequency of medical treatments/interventions that point to unstable medical condition that must be treated, and or monitored to avoid complications.

OAAS RO shall review all documentation and respond within 10 business days upon the receipt of the request and all supporting documentation. OAAS RO may request an onsite visit to meet with the recipient, conduct its own level of care assessment and/or request additional information. The PACE organization must submit the requested information no later than 5 business days from the date of receipt of OAAS' request for the additional information. If OAAS does not receive the requested information within the five business days, OAAS shall proceed with the denial process.

The PACE organization will be notified in writing via the Deemed Continued Eligibility Form (OAAS-PF-10-002) if the OAAS RO deems continued eligibility and enrollment will continue until the next annual reassessment.

OAAS RO shall make a notation in the MDS-HC Notebook that deemed continued eligibility criteria met on -------- (date goes in the blank space) for continuation of PACE program until next annual MDS-HC reassessment.

The PACE organization shall continue to conduct annual MDS-HC reassessments for level of care and may request Deemed Continued Eligibility each year as appropriate.

Staffing Requirements

A PACE organization must have the ability to manage the comprehensive care (including acute and long term) of a complex nursing facility eligible population 365 days a year, 24 hours per day, seven days per week regardless of the setting. A PACE organization must develop a provider network in order to provide/contract for all required covered services and other services necessary to meet recipient needs.

As specified in 42 CFR 460.68, the PACE organization must not employ individuals, contract with organizations or individuals who have been:

- Excluded from participation in the Medicare and Medicaid programs;
- Convicted of Medicare, Medicaid, or other health insurance or health care programs, or any social service program related crimes; and
- Convicted of physical, sexual, drug or alcohol abuse in a capacity where an individual's contact with recipients would pose a potential risk.

As required by 42 CFR 460.71, the PACE organization must develop a program to ensure that staff and contractors furnishing direct recipient care services:

- Comply with any state or federal requirements for direct patient care staff in their respective settings;
- Be currently certified, licensed or registered to practice in the state in which they provide services;

- Demonstrated competency prior to performing direct recipient care;
- Have one year of experience with a frail or elderly population; and
- Be medically cleared for communicable diseases and have all immunizations up-to-date before engaging in direct recipient contact.