STATE WORK GROUP ON PACE

ISSUE BRIEF #4

Operationalizing PACE From the State Perspective

January 24, 2001
Objectives of State Work Group on PACE

Upon passage of The Balanced Budget Act of 1997 (P.L. 105-33), the Program of All-inclusive Care for the Elderly (PACE) became a permanent provider under Medicare and a State option under Medicaid. PACE is a managed care program designed for a subset of the older adult population who meet the following eligibility requirements: 1) are a minimum of 55 years of age; 2) live within a defined geographic catchment area; and 3) are certified eligible by the State for nursing home level of care. The program provides a comprehensive array of Medicare and Medicaid institutional and community-based benefits under capitation financing, assuming financial risk for the full range of primary, acute and long-term care services.

In January 1998, the State Work Group on PACE was convened by the National PACE Association with the objective of building upon States’ extensive experience in developing and implementing both PACE and pre-PACE, i.e., capitated Medicaid long-term care programs. The Group’s work is intended to ease the transition from demonstration to provider status for States already implementing PACE or pre-PACE programs and to be a resource to States considering whether or not to pursue PACE development under expanded provider authority.

With funding from The Retirement Research Foundation, the Work Group met over a period of 30 months. At the direction of Work Group members, staff developed a series of issue briefs on a variety of topics of interest to States including “Site Selection and Application Process for PACE”, “Where PACE Fits in States’ Managed Care and Long-Term Care Strategies”, and “PACE Capitation Rate-Setting”, to be made available to States, as well as other interested organizations and individuals. These issue briefs are intended to be a resource to State policy makers and others, reflecting the state-of-the-art in PACE development, identifying areas in which further work is required and raising key questions for States to consider in implementing PACE. The Work Group is made up of ten members including representatives of nine States and one staff person from the Health Care Financing Administration’s Center for Medicaid and State Operations. Staff support is provided by the National PACE Association and consultants.
Acknowledgements

This paper is the product of the State Work Group on PACE, convened by the National PACE Association (NPA) with funding from The Retirement Research Foundation. The NPA is extremely appreciative for the time, expertise and thoughtfulness provided by Work Group members and wishes to acknowledge the contribution of: Regina Anderson-Cloud and, upon Ms. Anderson-Cloud’s resignation, T.C. Jones, IV (Virginia Department of Medical Assistance); Lora Connolly (California Department of Health Services); Diane Flanders (Massachusetts Division of Medical Assistance); Linda Gowdy (New York State Department of Health); Nicki Harvey (South Carolina Department of Health and Human Services); Leslie Hendrickson (New Jersey Department of Health and Senior Services); Mary James (Michigan Department of Community Health); Dee O’Connor (Connecticut Department of Social Services); James Pezzuti (Pennsylvania Department of Public Welfare); and Terry Pratt (U.S. Health Care Financing Administration). Additional staff from the States represented on the Work Group also have contributed significantly, especially Cindy Proper (Pennsylvania Department of Public Welfare) and Cheryl MacDougall (New Jersey Department of Health and Senior Services) and the NPA thanks them as well. Lastly, NPA appreciates the contribution of Judy Baskins of Palmetto SeniorCare, the PACE program in Columbia, SC, for contributing her experience with PACE program operations to the Work Group’s deliberations.
Introduction

Upon passage of The Balanced Budget Act (BBA) of 1997 (P.L. 105-33), the Program of All-inclusive Care for the Elderly (PACE) became a permanent provider under Medicare and a State option under Medicaid. The total number of authorized programs was increased substantially from a maximum of 15 demonstration sites (authorized under §9412(b) of the Omnibus Budget Reconciliation Act) to up to 40 providers in the year following enactment of P.L. 105-33. An additional 20 sites are authorized each year thereafter. On November 24, 1999, the Health Care Financing Administration (HCFA) issued the interim final regulation implementing the statute (42 CFR Part 460).¹

With passage of the BBA, the process for PACE development and the specific role of States in this process changed significantly. This issue brief, the fourth in a series, is intended to provide guidance to States as to their role and required activities for PACE implementation under permanent provider status. Under the original PACE demonstration, providers typically initiated development of PACE programs, secured the cooperation and participation of their States; and together, providers and States applied to the HCFA for a limited number of Medicare 222 and Medicaid 1115 research and demonstration waivers. The BBA offers the promise of easing PACE development by eliminating the need for waivers and redefines the role of States in PACE development and oversight.

From the State’s perspective, the development and implementation of PACE occurs through a series of developmental and operational phases that are explained in the following sections and identified on the State workplan included as Attachment A. These phases include the following:

- Initial Policy Development
- Address Federal Requirements
- Establishment of State Legislative & Regulatory Requirements
- Identification and Selection of Providers
- Implementation Activities and Contract Development
- Federal Provider Approval Process
- Program Oversight and Monitoring

Specific activities in each of these phases are described in the following sections. For those phases that have been described in one of the State Work Group’s prior issue briefs, a summary of activities is included here along with a reference to the appropriate brief for more detail.

¹ The Federal regulation establishing requirements for PACE organizations are available on HCFA’s website at the following address: www.hcfa.gov/medicaid/pace/pacereg.pdf.
I. Initial Policy Development

In this phase of PACE development, States must make key policy decisions related to PACE, the most important of which is the choice to pursue PACE. Other policy determinations which should be addressed early-on include: 1) identification of the State agency which will have key responsibilities in implementing PACE, including those defined in Federal regulation; and 2) agreement on the preferred start-up strategy for its PACE program(s). Decisions made during this phase as to how PACE fits into the State’s overall system will impact how the State proceeds with various aspects of program implementation, including decisions regarding the number of PACE providers to be developed, their geographic location within the State, the State’s approach to rate setting, etc.

A. Relationship to Existing State Systems

The essential policy decision that must be made is whether to include PACE in the State’s long-term care system and, if so, to determine the relationship of PACE to the State’s other long-term care and, if applicable, managed care programs. In all States, PACE programs co-exist with other institutional, and home and community-based services. Because these programs may serve a comparable population in terms of clinical eligibility requirements, it is often crucial to be able to articulate the added value of PACE. Among existing States with PACE programs, PACE is viewed as enhancing choice for individuals desiring community-based care. Consolidation of services and PACE’s expanded benefit package may provide additional value for the consumer. Also, because of the specialized needs of the long term care population and the difficulty in addressing these needs through standard managed care plans, the PACE benefit package and service delivery model may be more appropriate than other Medicaid managed care programs for a frail elderly population.

The State’s development of a policy position related to PACE undoubtedly will require an analysis of the benefits and limitations of the model. The State Work Group considers the following to be potential limitations from States’ perspectives: 1) PACE does not serve the entire dual eligible population (due to the program’s eligibility requirement that all PACE enrollees be certified eligible for nursing home level of care); 2) PACE programs typically serve small numbers of enrollees; and 3) to date, PACE has been primarily an urban model. On the other hand, in addition to expanding consumer choice and providing a managed
care model specifically tailored to the needs of the frail elderly, PACE offers the following benefits to States:

- Demonstrated success in caring for a nursing home certified population on a pre-paid, capitated budget; studies have found substantially reduced use of inpatient services as well as improved outcomes relative to comparable individuals served in traditional settings.\(^2\)
- Opportunity to encourage providers to develop the capability to effectively manage comprehensive services for a frail, long-term care population in a community setting;
- Opportunity to fully integrate the delivery of Medicare and Medicaid acute and long term care services; and
- Opportunity to use a working model as a laboratory for learning in preparation for launching other managed care initiatives.

The State Work Group’s Issue Brief #2, “Where PACE Fits in States’ Managed Care and Long-Term Care Strategies,” discusses these issues and describes in more detail the role of PACE vis-à-vis States’ other long-term care and managed care programs.

Once a decision is made to proceed with PACE, the State must define its role vis-à-vis prospective providers in initiating PACE development. Under the PACE demonstration, States typically responded to provider-initiated interest. Under provider status, however, there is more opportunity for States to be proactive in determining the number of providers and their location within the State and in establishing targets for total enrollment as part of their long-term care planning processes. These decisions will determine how States proceed with site selection activities described further below.

**B. State Administering Agency**

Each State must identify the appropriate State agency to administer the PACE program.\(^3\) As is the case with Medicaid home and community-based waiver programs, the State administering agency for PACE may but is not required to be the State Medicaid agency. The experience to date under the demonstration has been that the State administering agency has been the State Medicaid agency. This differs from the administration of Medicaid home and community-based waiver programs which, in many States, are administered by State agencies on

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3 Section 4802 of P.L. 105-33 defines the State administering agency as follows: “For purposes of this section, the term ‘State administering agency’ means, with respect to the operation of a PACE program in a State, the agency of that State (which may be the single agency responsible for administration of the State plan under title XIX in the State) responsible for administering PACE program agreements under this section and section 1894 in the State.”
aging. This difference may reflect the fact that in addition to community-based long-term care, PACE includes medical, acute and nursing facility care --services that are under the oversight of the State’s Medicaid agency.

C. Start-up Strategy

To date, providers and States have utilized one of two strategies to implement PACE. The first is to immediately apply for PACE status, initiating the full PACE service program with the provider assuming full financial risk from the onset under capitated financing from both Medicare and Medicaid. The second involves a more gradual assumption of financial risk through initiation of operations as a Medicaid prepaid health plan (PHP) prior to securing full provider status. The latter start-up approach has been termed “Pre-PACE” and can be done under States’ existing authority to operate Medicaid prepaid health plans (42 CFR 434.21(c)).

Pre-PACE programs provide a comprehensive package of institutional and community-based long-term care services to their enrollees. In addition, they coordinate and, to the extent possible without Medicare waiver authority, integrate the delivery of Medicare covered services with the long-term care benefit. During the pre-PACE phase of development, Medicare services are reimbursed on a fee-for-service basis and no restrictions exist on beneficiaries’ use of Medicare providers. Under the PACE waiver demonstration, most providers initiated operations as PHPs, in part due to the limited availability of PACE waivers.

The following are advantages to pre-PACE start-up:

- Providers gain operational experience in managing long-term care services under capitation for frail elderly enrollees prior to assuming risk for acute care expenditures;
- States have some assurance regarding providers’ capabilities to manage service delivery and financial risk under capitation. (This assurance may be particularly important to States in working with small community-based providers that may have limited risk-based experience and may benefit from a transitional phase during which financial strength is gained to meet solvency requirements.)

Disadvantages associated with pre-PACE start-up are:

- Substantially higher start-up costs to the provider due to the inability to use Medicare revenue to offset the expense of expanding community-based long-term care benefits;
- Medicaid financial eligibility requirements for pre-PACE may be more restrictive than for PACE, thereby limiting the size of the program’s target population. (Specifically, States’ Medicaid financial eligibility
rules for PACE can be the same as for an institutionalized population, for example 300% of (Federal) SSI. This may not be the case for pre-PACE programs.)

- Providers’ ability to manage a capitated long-term care benefit does not necessarily prove their capability to effectively manage enrollees’ use of Medicare-covered services;
- States will need to repeat some implementation activities when providers move from pre-PACE to full PACE status, e.g. modifications to the MMIS system for lock-in of covered benefits, rate setting analyses, etc.

The decision to initiate operations under pre-PACE or PACE lies entirely with the State and providers. There is no Federal requirement that providers use a particular start-up approach. Therefore, each State should evaluate the pros and cons of pre-PACE vs. PACE start-up in the context of PACE development within the State. The State may wish to leave the choice of the particular start-up approach to the prospective providers which are the entities assuming risk under the respective approaches.

To summarize, the preceding section identifies three critical policy decisions that must be made early on in a State’s deliberations regarding PACE development. Assuming a State opts to develop PACE, other policy decisions lie ahead. These will be highlighted in bold throughout the remainder of this document.

II. Address Federal Requirements

The BBA dictates a cooperative relationship between HCFA and States in future development, implementation and administration of the PACE program. In multiple instances, the statute specifically instructs the Secretary of the U.S. Department of Health and Human Services to work “in close cooperation with” or “in consultation with” the State administering agency. With regard to their respective roles and responsibilities, States decide whether to pursue PACE development by voluntarily electing to amend their State Medicaid plans. Further, each State that elects PACE as a State plan option has the choice to pursue development of just one or multiple sites in one or more geographic areas within the State. Further, the State can limit the total number of PACE enrollees although this decision should be made in recognition of PACE programs’ need to achieve adequate census in order to manage financial risk effectively.

Both the State and HCFA must review and approve each PACE provider application that includes specifications of the provider’s catchment area, marketing materials, enrollment and disenrollment procedures, a quality assurance plan, and grievance and appeal processes. Following its review and attachment of an assurance certifying that the State is supportive of the provider’s application, the State formally submits the provider application to HCFA. Contingent on HCFA’s approval of the application, both HCFA and the
State must sign a PACE Program Agreement with the provider and be responsible for on-going administration and program monitoring. States responsibilities include establishing clinical eligibility requirements for PACE enrollees; recertifying enrollees’ program eligibility on at least an annual basis; and, pursuant to the regulation, reviewing all involuntary disenrollments; denials of enrollments; and grievances and appeals.  

Amending the State Medicaid Plan. The BBA establishes PACE as a voluntary state option under Medicaid. Therefore, to implement PACE, the State must elect to include PACE as an optional benefit and amend its State plan. Further, the State plan must be amended each time the State enters into a Program Agreement with an additional PACE organization. HCFA has developed suggested pre-print pages that can be utilized by State Medicaid agencies electing to cover PACE under their State plans.

Attachment B is a flow chart identifying the relevant timeframes and roles of States, HCFA Regional Offices (RO) and HCFA Central Office (CO) in the State plan amendment process. HCFA’s approval of the State’s request to amend its State plan is required before the three-way PACE Program Agreement between HCFA, the State and the PACE provider may be signed.

III. Establishment of State Legislative and Regulatory Requirements

The next step in PACE development is to establish appropriate statutory and regulatory requirements for PACE.

A. Determine the Need for and Obtain Legislation, if Required ** Policy Decision **

Under the demonstration many, though not all, States passed legislation explicitly authorizing their Medicaid agencies to participate in the PACE demonstration. Even if not required, legislation can be an effective means of establishing PACE as a priority within the State’s long-term care and/or managed care systems. State policymakers must assess the need for and/or benefit of State legislation as a prerequisite to pursuing PACE as a Medicaid State plan option. If legislation is required, timeframes for implementation must be adapted accordingly.

The question of whether legislation for PACE is required at the State level is discussed in detail in Issue Brief #1, “The Site Selection and Application Process for PACE.” Examples of legislative language also are included in that brief.

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4 The PACE provider application and program agreement are available on HCFA’s website at the following address: www.hcfa.gov/medicaid/pace/pacest.htm.
5 HCFA’s suggested pre-print pages are available to States on HCFA’s website at the following address: www.hcfa.gov/medicaid/pace/pacest.htm.
B. Determine Provider Licensure and/or Certification Requirements  

**Policy Decision**

Under the demonstration, PACE programs have operated under a variety of State licenses and/or certification. A State’s decision to impose specific licensure and/or certification requirements varies depending on the specific licensure and certification categories that exist within the State as well as the relevancy of specific requirements to PACE program operations. Typically, States have chosen to utilize a combination of adult day health care, clinic, and home health/home care licensure.

In August 1998, the State Work Group conducted a survey of nineteen states including eight States operating PACE programs, eight operating pre-PACE programs and three others in a pre-operational phase of development. Of the eighteen States responding to the survey that have now implemented PACE or pre-PACE programs, all require individual practitioners to hold appropriate licenses. Five States do not require any additional program licensure or certification. Eleven of the remaining thirteen States require the PACE programs to hold an adult day care, adult day health or medical day care license or certification. Five require home health or home care licensure. Finally, five require the programs to be licensed as a health care or primary care clinic, or a diagnostic and treatment center.6 (See Attachment C)

To date, no State has developed a distinct licensure category for PACE although several are considering development of such licensure in the future. Such efforts could eliminate the administrative burden of duplicative requirements and provide the benefit of monitoring overall quality of care as opposed to looking at a portion of program operations through the individual components.

Because PACE-specific licensure has not been developed, States have applied existing licensure requirements developed for related provider types. As a consequence, some of the requirements associated with these licensure categories may not be completely consistent with PACE program operations and, in some cases, may result in unintended consequences. For example, several States have chosen to license their PACE programs as home health agencies. In 1998, HCFA required all State-licensed home health agencies to report OASIS (Outcome and Assessment Information Set) data. Beginning in 2002, PACE programs will be required to report OBCQI (Outcome Based Continuous Quality Improvement) information. To a significant degree, these overlapping requirements will impose a significant administrative burden on PACE programs with no apparent benefit in terms of enrollees’ quality of care or HCFA/States’ ability to monitor program effectiveness. States should therefore give careful consideration as to appropriate licensure requirements for PACE.

6 Although housing is not a formal component of the PACE service delivery model, many of the programs have developed housing options for their enrollees. In Wisconsin and South Carolina, the PACE programs hold a license to operate a community-based residential care facility.
C. Determine Licensure Requirements as a Risk Entity  **Policy Decision**

Federal regulation does not require State HMO licensure for PACE organizations. Instead, the regulation specifies financial requirements, beneficiary protections and quality assurance requirements that substitute for the types of consumer protections that HMO licensure would otherwise provide. States must carefully evaluate their own environments to determine how, or if, PACE organizations should be licensed as risk-bearing entities and whether any explicit formal exemptions, either administrative or legislative, from current licensure or specific requirements of licensure should be sought.

Because of unique features of the PACE model and the Federal regulatory requirements noted above that afford enrollees and contract providers protection against a PACE program’s insolvency, most States have considered exempting PACE from State HMO requirements. The rationale for exempting PACE is based on the program’s small scale in terms of numbers of enrollees and the conclusion that financial reserve and other requirements of HMO licensure are inappropriate or overly burdensome for PACE programs, particularly during start-up. The following is the rationale for such exemption:

- **PACE Is Not an Insurance Model.** PACE and HMOs differ in their risk management strategies. HMOs spread the risk of high cost utilization among a large population that includes a majority of relatively healthy members. Benefits are restricted as well. In contrast, all PACE enrollees are “in benefit.” PACE manages risk by targeting a relatively homogeneous population, making estimates of costs more predictable. Costs are controlled, not by benefit limitation, but rather by using a specialized team to manage and provide care directly and employing a service strategy which emphasizes prevention, maximization of functioning, and substitution of lower cost services in the community in place of high cost institutional care.

- **Assurance of Continued Coverage for Beneficiaries.** Unlike HMO enrollees, PACE enrollees are never at risk for complete loss of coverage. Most enrollees are dually eligible for Medicare and Medicaid and are free to disenroll at any time. Upon disenrollment or program termination, enrollees return to the fee-for-service system or another managed care alternative with no loss of coverage of their traditional Medicare and Medicaid benefits (so long as they retain their Medicaid eligibility). Those who are ineligible for Medicaid and are paying privately (or through long-term care insurance) for PACE can continue to purchase long-term care services privately upon disenrollment. In addition, those who had Medigap insurance prior to enrollment in PACE are able to access Medigap coverage, if desired, upon disenrollment from PACE generally under the same conditions as
apply to enrollees of Medicare+Choice plans (42 U.S.C. §1395ss(s)(3)(B)).

- **PACE-Specific Financial Requirements.** §460.80 of the PACE Federal regulation stipulates the requirements related to fiscal soundness for PACE organizations. These include a requirement for a net operating surplus or a financial plan for maintaining solvency that is satisfactory to HCFA and the State administering agency. In addition, the regulation requires PACE organizations to have arrangements to cover expenses in the event of insolvency, i.e. one month’s total capitation revenue to cover expenses the month before insolvency and one month’s average payment to all contractors to cover expenses the month after operations cease.

- **PACE-Specific Quality Management.** The PACE regulation establishes a number of oversight mechanisms that may largely substitute for requirements typically imposed by States’ insurance commissions or other HMO licensing bodies. For instance, the State and HCFA must approve all enrollment, disenrollment, marketing, and grievance and appeals procedures, and closely monitor the program for compliance in these areas. Also, major components of the model, i.e. adult day health, skilled home care, and primary care clinics, may require licensure and/or certification. Finally, HCFA, in cooperation with the State administering agency, conducts a comprehensive review of the operations of the PACE organization. These reviews occur annually during an initial three-year trial period and no less than every two years thereafter per §460.190 of the PACE regulation.

Referring to the State Work Group’s August 1998 survey, virtually no States implementing PACE (17 of 19) required or anticipate requiring PACE programs to be licensed as HMOs or as other types of risk-bearing entities at that time. In some instances, State legislation was required to exempt the PACE or pre-PACE programs from HMO licensure. (Again, please refer to the State Work Group’s Issue Brief #1 for examples.) However, States may revisit the question of HMO or similar licensure now that the Federal regulation has been issued. In addition, in those States where only pre-PACE programs are in operation, many intended to revisit the question of HMO licensure upon these programs’ transition to full PACE status.

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7 In general, issuers of Medigap policies may not deny or condition the availability of a Medigap policy, discriminate in the pricing of such policy or exclude benefits based on a pre-existing condition to individuals who disenroll from PACE for the first time within a 12 month period of initial enrollment. However, it is required that the individual acquire a Medigap policy within 63 days of disenrolling from PACE. Further, individuals who disenroll from PACE due to program termination or as a result of moving outside the program’s geographic catchment area are guaranteed access to Medigap coverage without the application of exclusions related to pre-existing conditions, etc. so long as they seek to enroll under the Medigap policy not later than 63 days following disenrollment.

8 Currently, Missouri is the only State requiring its PACE organization to be licensed as an HMO.
States should address the question of whether to require HMO licensure early in the development phase so that: 1) providers can proceed with what may be a lengthy application process; or 2) adequate time is available to seek a legislative exemption, if desired. As an alternative to applying standard HMO licensure requirements to PACE, States also may consider the following:

- HMO licensure with a waiver of certain requirements, i.e., alternative solvency requirements;
- Licensure as an alternative type of risk bearing entity, e.g., a managed long term care plan or limited health services contract.

D. Determine Financial Requirements ** Policy Decision **

As indicated above, the Federal regulation (§460.80) stipulates minimum financial requirements for PACE organizations. These include requirements for a fiscally sound operation as demonstrated by:

1. Total assets exceeding total unsubordinated liabilities;
2. Sufficient cash flow and adequate liquidity to meet obligations as they come due;
3. A net operating surplus or a financial plan for maintaining solvency that is satisfactory to HCFA and the State; and
4. A documented plan for insolvency, approved by HCFA and the State and arrangements to cover expenses in the event of insolvency.

In the absence of HMO licensure, the State must determine whether it wishes to establish additional financial requirements. The State Work Group provides several recommendations in this area: 1) The PACE organization must provide assurance that it has adequate resources for up-front capitalization in the form of cash to cover any projected losses until achieving breakeven; 2) for organizations which operate businesses in addition to PACE, it is important to treat PACE as a separate line of business for purposes of calculating sufficient reserves; and 3) the State may wish to establish additional requirements in the event the organization becomes insolvent. The Federal regulation (§460.80(c)(1)) requires arrangements to cover the sum of:

1. One month’s total capitation revenue to cover expenses the month before insolvency; and
2. One month’s average payment to all contractors, based on the prior quarter’s average payment, to cover expenses the month after the date it declares insolvency or ceases operations.

Because these requirements are tied to monthly capitation revenues as opposed to being fixed dollar amounts, the initial requirements may be quite low (e.g. less than $100,000) for organizations just initiating operations and, therefore, may provide insufficient protections in the event of the organization’s insolvency. For
this reason, States may wish to establish financial requirements in addition to the Federal requirements for new PACE and/or pre-PACE organizations.

IV. Identification and Selection of Providers ** Policy Decision **

With establishment of PACE as a permanent provider, States may play a much more active role in PACE development than was the case under the demonstration when the total number of authorized sites was limited to 15. Rather than responding to provider-initiated interest, States may actively solicit provider interest in PACE development and/or respond to interest from many more providers than was possible under the demonstration. The policy decisions made during Phase I above may dictate the approach to site selection that States choose to follow.

The State Work Group’s Issue Brief #1, “Site Selection and Application Process for PACE,” describes the processes states have used to identify and select interested providers. These include development of a Request for Information or Request for Proposal to solicit provider interest in PACE development; development of an application process in which interested providers submit an application to the State for review and approval; and designation of prospective PACE sites through the legislative process. Issue Brief #1 also suggests a number of criteria that States may use to evaluate an organization’s capacity to successfully develop PACE.

V. Implementation Activities and Contract Development

The following subsections identify and discuss major areas of State activity necessary to implement the PACE program. These elements must be addressed in detail in the PACE provider application, PACE Program Agreement and the State’s contract with the PACE organization.

A. Determine Basic Eligibility Criteria

The target population for the PACE model is frail older adults. §460.150 of the PACE regulation establishes the basic eligibility criteria for PACE enrollees or participants as follows:

- Age 55 or older;
- Meets the State’s eligibility criteria for nursing home level of care; and
- Resides in the PACE organization’s service area.

In addition, the individual may but is not required to be entitled to Medicare Part A and/or Part B and/or eligible for Medicaid.⁹

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⁹ Under the demonstration, approximately 90% of all PACE enrollees were eligible for both Medicare and Medicaid.
Under the demonstration, some States established more restrictive eligibility criteria than are now included in Federal regulation (§460.150), i.e., the minimum age requirement was set at age 60 or 65, rather than 55; or enrollment was restricted to dual eligibles only, thereby excluding the Medicaid-only population. However, HCFA has stated that once existing demonstration sites transition to provider status, States will not have the option to modify basic eligibility requirements established in statute.

**Additional Eligibility Requirements**

The Federal regulation (§460.150(b)(4)) permits States to establish “additional program-specific” eligibility conditions beyond the three basic eligibility requirements identified in the preceding section. For example, because PACE is intended to serve individuals with a chronic, as opposed to short-term, need for long-term care services, States may choose to impose an additional eligibility criteria that limits enrollment in PACE to individuals projected to have long-term care needs of 120 days or longer. In addition, because PACE is designed to support individuals in the community who would otherwise need institutional care, States may require prospective enrollees to make their intent to remain in the community explicit.

Alternatively, States, in collaboration with PACE providers, may seek to establish a PACE program exclusively for persons with Alzheimer’s disease or for those with physical disabilities only. The State Work Group recommends caution, however, in establishing criteria that would restrict the potential enrollee population to so few individuals that building sufficient census to appropriately spread financial risk becomes exceedingly difficult.

Finally, the regulation states that, at the time of enrollment, an individual must be able to live in a community setting without jeopardizing his or her health or safety (§460.150(c)). Prospective PACE organizations will need to define the criteria used to identify those individuals whom they believe they cannot serve under this section and specify the criteria used in making this determination in their provider applications. These criteria must be reviewed and approved by the State and HCFA prior to being incorporated into the PACE Program Agreement.

**Service Area**

A prospective PACE organization must specify its proposed service area in its provider application. Service areas may be identified by county, zip codes, street boundaries, census tract, block or tribal jurisdiction. The proposed service area must be approved by the State and HCFA.

There are several important considerations related to identification and approval of the PACE organization’s service area. First, all enrollees must receive the complete PACE benefit package through the PACE organization. Because the
PACE interdisciplinary team and many services are based at the PACE center, the maximum size of a PACE organization’s service area is generally defined by the length of time required to transport enrollees to and from the PACE center. This calculation depends less on distance than the particular characteristics of the proposed service area, e.g., road access, traffic congestion. In addition, the PACE organization must establish a catchment area that affords its enrollees access to all contracted providers in addition to PACE center services.

**Policy Decision** Another consideration in approving a prospective PACE organization's proposed service area is whether an existing PACE organization already serves that area. The PACE regulation allows HCFA, in consultation with the State administering agency, “to exclude from designation an area that is already covered under another PACE Program Agreement to avoid unnecessary duplication of services and avoid impairing the financial and service viability of an existing program” (§460.22(b)). These considerations may be important in an area with a limited number of frail elders. On the other hand, there is no prohibition on overlapping service areas; and densely populated urban areas can certainly sustain multiple PACE organizations. Multiple programs enhance consumer choice which can be particularly important when there are differences in organizations’ traditional constituencies and/or differences in language and cultural competencies.

B. Clinical Eligibility Determination Process **Policy Decision**

States must establish clinical eligibility criteria for PACE and a process for determining individuals’ eligibility for enrollment in the program. Because PACE enrollees must meet States’ eligibility requirements for nursing home level of care, States typically utilize the same criteria as are applied to nursing home residents, or to home and community-based waiver (HCBS) clients who also must meet an institutional level of care. In most States, an identical instrument used to evaluate the need for nursing home level of care is applied across all three programs. In a few States, different instruments are used to assess eligibility for nursing home residents, and home and community-based waiver clients. This is the case in New York, for example, and PACE enrollees are assessed using the same instrument as is applied to HCBS clients.

The process for determining whether individuals meet clinical eligibility criteria for PACE varies somewhat from State to State reflecting broader differences in how States assess eligibility for nursing home, and home and community-based waiver services. In some States, in-person assessments are conducted, with or without involvement of the PACE organization. In others, the State (or its contractor) conducts a paper review of the assessment instrument submitted by the PACE organization. If States contract for this function, they must consider whether the contracted agency has a disincentive to refer to PACE, e.g. in cases where the certification agency also is a direct provider of case management or long-term care services. In cases where a conflict of interest is present, i.e. the
contractor is also a provider, the State must develop a conflict of interest policy and conduct periodic reviews of a sample of the denied applicants to verify that the denials are valid.

Once policy decisions have been made regarding clinical eligibility criteria and the eligibility determination process for PACE, clinical eligibility workers must be educated about PACE and its position within the State’s long term care system. This is particularly critical in States that have established a single point of entry into their long-term care systems. Workers must have a clear understanding of who is eligible for PACE so as not to restrict or target enrollment inappropriately.

Under the demonstration, enrollees’ clinical eligibility for PACE was determined only at the time of enrollment. No subsequent reassessment of enrollees’ need for nursing home level of care was performed. Once enrolled in PACE, an individual could not be disenrolled regardless of change in health status. Under provider status, however, the BBA requires PACE enrollees’ eligibility for nursing home level of care to be reassessed at least annually unless the State waives, on an individual basis, the re-certification requirement because there is no reasonable expectation of improvement or significant change in condition (§460.160(b)(1)). In circumstances where an enrollee does not meet level of care requirements upon reassessment, the State also may opt to deem that individual eligible if, in the absence of continued coverage under the program, he/she could reasonably be expected to meet nursing facility level of care within the next six months (§460.160(b)(2)).

**Policy Decision** Consequently, in developing eligibility criteria for the PACE program, States must determine the circumstances under which either of the two preceding conditions are met, i.e., no reasonable expectation of improvement, or deemed eligibility. In the first situation, States may opt to waive the re-certification process. Doing so would minimize the administrative burden at both the State and program levels related to the new re-certification requirement. On the other hand, by requiring all PACE enrollees to be re-certified at the same or similar time intervals as nursing home residents and HCBS clients, the State would acquire assessment data that could be used to compare PACE enrollees to other long-term care populations.

C. Medicaid Financial Eligibility

PACE enrollees are financially eligible for Medicaid if they are eligible under the State plan (examples include those eligible as Categorically Needy or Medically Needy). In addition, States have the option of extending Medicaid financial eligibility to those individuals enrolled in PACE who would be eligible if they were residing in a medical institution and who would be eligible under rules specifically designed to apply to individuals living in such institutions. An example of this option would be those eligible under the special income level group described at section 1902(a)(10)(A)(ii)(VI) and 42 CFR 435.236, sometimes referred to as the
300% rule. This option may be elected only if the State’s plan already covers such institutional groups and only if the same limits are applied to income and assets.

In addition, States have the option to use the spousal impoverishment rules (Section 1924 of the Act) to determine eligibility of those individuals with a spouse. As is the case with home and community-based waiver programs, most States elect to use spousal impoverishment for PACE in addition to institutional services so that no financial disincentive exists for individuals with a community spouse to select a community-based service.

Specific requirements regarding financial eligibility as well as post-eligibility treatment of income are defined in detail in the HCFA’s State plan amendment pre-print pages referenced previously.

Transfer of Assets for Less than Fair Market Value (Look-Back Provisions)

Under Federal Medicaid rules, States are required to penalize individuals in medical institutions who have transferred assets for less than fair market value in the prior 36 months. States also have the option of imposing transfer of assets penalties on non-institutional individuals. PACE enrollees are considered to be institutionalized for transfer of assets purposes if their eligibility is determined using special institutional rules (e.g. 300% of Federal SSI or spousal impoverishment). Thus, PACE enrollees who are eligible under institutional rules may be subject to penalty, which involves the Medicaid program not paying for their care for a period of time if they transfer assets for less than fair market value. PACE enrollees eligible under community rules are subject to penalty only if their State has elected to impose transfer penalties on non-institutional individuals.

PACE enrollees who are actually in a medical institution are always subject to the transfer of assets rules and thus may be penalized if they transfer assets for less than fair market value.

D. Enrollment and Disenrollment Procedures

The Federal PACE regulation (§460.158) requires enrollments in PACE to take effect the “first day of the calendar month following the date the PACE organization receives the signed enrollment agreement.” Consequently, the State must establish procedures for processing enrollments and disenrollments for PACE, including a cutoff date on or before which all enrollments/disenrollments will become effective the first of the following month. In contrast to most other Medicaid managed care programs which do not serve a dually eligible population, enrollment and disenrollment procedures for PACE should, to the greatest extent possible, be consistent with, or at least address, effective dates of Medicare enrollment and disenrollment.
It is critical that enrollment in PACE is processed in a timely manner. Consequently, it is important to establish cutoff dates as late as possible in the month. Because PACE organizations enroll very frail individuals in immediate need of services, many due to a recent change in health status precipitating their eligibility for nursing home level of care, the enrollment process for PACE must facilitate quick access to PACE services. Extended delays in the enrollment process, e.g. due to lags in effective dates of enrollment, delays in processing clinical or financial eligibility, etc., may result in nursing home placement for individuals who cannot maintain their community residence while awaiting enrollment in PACE.

Most PACE organizations begin providing services immediately following an individual’s decision to enroll, often precipitated by an acute episode. Because many of the services provided by the PACE organization are not reimbursable through the Medicare and Medicaid fee-for-service systems, costs of care provided during the period following the enrollment decision and prior to effective dates of Medicare and Medicaid enrollment are often absorbed by the program. Consequently, any delay in enrollment has significant implications for the viability of the PACE program. It is crucial for States to establish an enrollment process for PACE that will facilitate rapid enrollment into the program. Ideally, the process would allow for expedited determinations related to Medicaid eligibility or retroactive enrollments in PACE for individuals awaiting Medicaid eligibility determinations.

Similarly, it is important to expedite disenrollments from other Medicaid managed care plans following an individual’s choice to enroll in PACE. Delays of one or more months may jeopardize the ability of an individual to enroll in PACE, compromise overall coordination of care and cause significant financial hardship for the PACE organization.

Federal statute requires voluntary enrollment and disenrollment from PACE. The same is currently true for Medicare+Choice enrollees through the Year 2001. Beginning in 2002, Medicare beneficiaries may be locked into their Medicare+Choice plan for up to six months of the year, and in 2003 and thereafter, for nine months. This change in Medicare policy may have significant implications for PACE enrollment, particularly in areas of the country where a large proportion of Medicare beneficiaries are enrolled in managed care. For individuals who become eligible for PACE while locked-into their Medicare+Choice plan, disenrollment into PACE may not be feasible. This will potentially impair providers’ ability to grow their census and States’ ability to direct nursing home eligible individuals into PACE.

Finally, any involuntary disenrollment from the PACE organization must be reviewed by the State before it is effective to determine that the PACE organization has adequately documented acceptable grounds for disenrollment.
as provided in the PACE regulation. (§460.164(e)) Again, it is important that this occurs in a timely manner as the enrollee remains "locked-in" and the PACE organization remains financially responsible for all services until such disenrollments are processed.

**Enrollment Brokers.** A few States, particularly those implementing mandatory managed care programs, utilize enrollment brokers to inform consumers of their choices and to conduct actual enrollments. However, use of enrollment brokers may be inappropriate for PACE for the following reasons: 1) clinical eligibility requirements for PACE, i.e. the requirement that enrollees be certified eligible for nursing home level of care, are likely to be different from requirements for other managed care plans; and 2) enrollment in PACE requires an assessment by the PACE interdisciplinary team in order to develop a treatment plan, as well as to assess whether health and safety are in jeopardy in the community. Therefore, the State Work Group suggests it is appropriate to exempt PACE programs from use of enrollment brokers.

**E. Payment Systems and Modifications to MMIS**

Each State must evaluate its Medicaid Management Information System (MMIS) and consider what modifications are required to implement PACE. MMIS modifications may be necessary to: 1) process program enrollments and disenrollments in a timely fashion; 2) prevent PACE enrollees’ access to fee-for-service benefits; and 3) enable capitation payments to be made. In addition, it is also critical that a State’s MMIS recognize PACE enrollees as managed care enrollees, particularly in States where PACE coexists with mandatory managed care programs. If not, PACE enrollees inadvertently may be assigned to mandatory Medicaid managed care programs, effectively ignoring their enrollment in PACE. As a result, the State may not make monthly capitation payments to its PACE program(s).

Implementing systems modifications for a program that serves a relatively small number of individuals, particularly at the point PACE organizations initiate operations, may be cumbersome. In some States, certain functions typically handled by MMIS, e.g. program enrollments and disenrollments, are performed manually to avoid the need for systems redesign.

**F. Capitation Rate Setting**

Like other managed care organizations, PACE organizations are paid on a monthly, capitated basis. In PACE, HCFA establishes and pays the Medicare capitation; and each State establishes and pays the Medicaid capitation. (Enrollees ineligible for Medicaid pay privately an amount equal to the Medicaid capitation.) Medicare, Medicaid, and private capitation payments are combined at the provider level, creating a flexible funding pool for all primary, acute, and long-term care services.
No single methodology exists for the development of a Medicaid capitation rate for PACE. Instead, States have flexibility to develop a rate methodology reflective of each individual State’s environment relative to eligibility criteria for long term care services, the existing long term care service system, and policy decisions as to where PACE should be positioned vis-à-vis institutional and community-based alternatives.

Despite differences among States and their individual long-term care systems, each State must address a set of common issues: 1) establishment of a general approach to rate setting, i.e. formula-based vs. cost-based approach; 2) identification of an appropriate comparison group; 3) calculation of the comparison group’s costs; and 4) assuring cost effectiveness to the State. Some of these are **Policy Decisions** which must be addressed prior to embarking on the rate setting process. How States have addressed these issues under the PACE demonstration is discussed in detail in the State Work Group’s Issue Brief #3, “PACE Capitation Rate Setting.”

States’ rate-setting methodologies are subject to review by HCFA with the intent of assuring the rate method is actuarially sound, i.e. the PACE capitation rate is based on costs of an appropriate comparison group. Further, the rate may not exceed what Medicaid would otherwise have paid had an individual not enrolled in PACE. This review occurs through the HCFA regional office as part of the State plan amendment process.

G. Data Reporting Requirements

States and HCFA require clinical, program, and financial data from PACE and pre-PACE organizations to assure they comply with contractual requirements and to monitor quality of care. Clearly this is an area where States will need to work in partnership with HCFA to establish appropriate requirements and avoid unnecessary duplication.

Under the demonstration, almost all States (12 of the 14 States responding to the 1998 survey in which PACE or pre-PACE programs were then operational) required PACE programs to report DataPACE information. DataPACE was the uniform data collection set for all PACE programs operating under the demonstration and was previously required by HCFA. Pre-PACE sites also have collected DataPACE information and are required to report these data by virtually all States. DataPACE information includes individual enrollees’ demographic; health status; functional and utilization information. Hence, States have utilized DataPACE information to monitor the characteristics of PACE/pre-PACE enrollees as well as to assure that services are being provided. In addition to DataPACE, several States have required PACE and/or pre-PACE programs to report encounter data (MI, MD, WI, OH).
PACE organizations’ data reporting requirements are being modified extensively in the transition from demonstration to provider status. In the future, reporting requirements are likely to more closely resemble those for Medicare+Choice organizations (M+COs). Like M+COs, HCFA requires PACE programs to submit hospital inpatient and physician encounter data and to participate in the Health Outcomes Survey. Hospital outpatient encounter data also will be required of PACE programs as of April 1, 2001 for services rendered on or after January 1, 2001. These requirements apply to existing demonstration programs as well as to PACE organizations approved under provider status.

New data reporting requirements also will evolve out of efforts related to the development of a core comprehensive assessment (COCOA) instrument and Outcome Based Continuous Quality Improvement (OBCQI) system for PACE currently underway at the Center for Health Services and Policy Research at the University of Colorado Health Sciences Center. This project has attempted to address States’ concern that PACE data requirements are not comparable to those for other long-term care populations, e.g., nursing home residents for whom the Minimum Data Set (MDS) is collected. Efforts have been made by researchers at the University of Colorado to review data sets collected on other long-term care populations and, when possible, to incorporate similar data elements into COCOA and OBCQI. To some degree, this may facilitate States’ comparison of patient-level characteristics for long-term care populations across programs. The development of COCOA and OBCQI is scheduled to be completed by Fall, 2002 at which point associated data collection and reporting requirements will be implemented.

In the interim, HCFA has developed a minimum data set which PACE organizations will be required to submit quarterly for purposes of monitoring the program. These data, coupled with financial statements, are intended to alert HCFA and States to potential problems. The data set includes the following elements:

- Number of PACE enrollees receiving flu and pneumococcal immunizations (minimum level of performance for this element is 80%);
- Number and sources (participant, family, caregiver, etc.) of grievances and appeals, and dates of initiation and resolution;
- Number of new enrollees in the program, by payer;
- Number of voluntary and involuntary disenrollments and reason;
- Number of potential enrollees interviewed, but not enrolled;
- Number of unscheduled hospitalizations including diagnosis; number of readmissions with same diagnosis in a 31-day period;
- Number of emergent care visits including diagnosis;
- Number of unusual incidents affecting PACE enrollees and the PACE site (including staff); and
- Number of deaths, by cause and setting.
Financial statements including a balance sheet, statement of revenues and expenses, and a source and use of funds statement, also must be submitted quarterly throughout the trial period and annually thereafter. HCFA and/or the State may require that financial statements be submitted more frequently if more frequent monitoring and oversight are determined to be necessary. Specific data and financial reporting requirements will be included in the PACE Program Agreement.

States must evaluate whether HCFA’s reporting requirements generate data that are consistent with their needs or whether additional State requirements are necessary. In imposing State-specific requirements, States should attempt to strike a balance between: 1) their need to gather data that is comparable to information collected on other long-term care recipients; and 2) the administrative burden facing programs in complying with duplicative and perhaps even conflicting Federal and State requirements.

VI. Federal Provider Approval Process

Although States are solely responsible for initial site selection, approval of an organization as a PACE provider is done in partnership by HCFA and the State and involves a three-part process:

- Review of Provider Application
- On-Site Review
- Three-Way Program Agreement

A. Review of Provider Application

All potential PACE organizations must complete the Federal PACE provider application. Although the provider application is completed by the provider, a number of sections will require prior discussion with the State, e.g. marketing materials, eligibility determination process, site specific eligibility requirements, enrollment/disenrollment procedures, process for review of denials of enrollment, process for review of proposed involuntary disenrollments, and data reporting requirements.

Prior to submission to HCFA, applications are submitted by the provider to the State for review. The State’s role in the process is to review the application to determine that it is in compliance with all State requirements. As part of the review process, States will want to pay particular attention to the review of certain sections of the application. These include:

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10 Again, the PACE provider application is available on HCFA’s website at the following address: www.hcfa.gov/medicaid/pace/pacest.htm.
• Marketing and Enrollment Materials -- HCFA and States must review these for accuracy and to assure they are written in such a way that they will be understood by prospective enrollees and their families.
• Participant Rights -- Must include review of Participant Bill of Rights, and Grievance and Appeals processes.
• Quality Assessment and Performance Improvement Plan.

Once the State has completed its review, it submits the application to HCFA, along with written assurances that: 1) the State is willing to enter into a PACE Program Agreement with the prospective PACE organization if HCFA approves the application; 2) the provider is qualified to be a PACE provider under Federal requirements; and 3) the provider will be limited to a certain enrollment ceiling, if applicable.

(As described previously, HCFA has indicated that it is not necessary for the State’s request to amend its State plan to have been approved at the point the provider application is submitted. The two processes can proceed in parallel. In some instances, the provider application may even be submitted before the request to amend the State plan. Regardless, however, the State plan amendment must be approved before HCFA will enter into a PACE Program Agreement with the State and the provider.)

As provided in Section 460.18 of the regulation, HCFA has 90 days to approve or deny the PACE provider application, or to request additional information. If additional information is requested, the 90-day clock stops. Once the additional information has been submitted to HCFA by the State, HCFA has a second 90-day period in which to approve or deny the application.

B. On-Site Review

Operational Programs. For PACE applicants already operating as either PACE demonstration sites or pre-PACE programs, an on-site review of the applicant will be conducted as part of the provider approval process.

This review is another example of HCFA and States’ joint administration of the program. On-site review teams will consist of four HCFA representatives as well as representatives from the State. HCFA team members will represent both the Medicare and Medicaid offices from each of HCFA’s central and regional offices. Each States must determine the appropriate individual(s) to participate in this site review process.

Non-Operational Programs. For those PACE applicants that are not yet operational as demonstration sites or pre-PACE programs, HCFA will not conduct an on-site review prior to approval and signing of the PACE Program Agreement. Instead, HCFA will rely on the State to conduct an assessment of provider readiness. HCFA has developed a readiness review tool suggested for
use by States in conducting this assessment. In addition to the requirements incorporated in HCFA’s instrument, the State may incorporate additional review criteria. Attachment D is a narrative describing this process in more detail. The suggested tool to be used by States conducting readiness reviews is available on HCFA’s website at the following address: www.hcfa.gov/medicaid/pace/pacest.htm.

Assuming the provider successfully completes the readiness review and initiates operations as a PACE organization, HCFA and the State will conduct a joint on-site review within six months to insure that it is operating in compliance with program requirements.

C. Sign Three-Way PACE Program Agreement

Once approved, a three-way PACE Program Agreement must be signed by HCFA, the State Administering Agency (which, again, may or may not be the State Medicaid Agency), and the provider. It is the signed Program Agreement that authorizes the provider to begin marketing and enrollment activities. It is also the signed Program Agreement that reserves a “slot” for the limited number of PACE providers authorized by the BBA. The template for the Program Agreement is included as Attachment E.11

VII. Program Oversight and Monitoring

Under the demonstration, the Federal government has relied largely on States to assure the quality of care provided by PACE programs. As indicated above, States will continue to establish licensure requirements for their PACE organizations. However, in the future program monitoring will be done jointly by HCFA and the State.

As required by statute, HCFA and the State will conduct comprehensive annual reviews of PACE organizations during their first three years of operation, referred to as the "trial period," to ensure compliance with the requirements of the PACE regulation. As specified in regulation (§460.190), the review will include the following:

- An on-site visit to the PACE organization which may include, but is not limited to:
  - Facility review;
  - Review of participant charts;
  - Interviews with staff, participants and caregivers, and contractors;
  - Observations of program operations, including marketing, participant services, enrollment and disenrollment procedures, and grievances and appeals.

11 The PACE Program Agreement is also available on HCFA website at the following address: www.hcfa.gov/medicaid/pace/pacest.htm.
Operationalizing PACE from the State Perspective

- A comprehensive assessment of the organization’s fiscal soundness.
- A comprehensive assessment of the organization’s capacity to furnish all PACE services to all participants.
- Any other elements that HCFA or the State find necessary.

At the conclusion of the trial period, HCFA and the State will continue to conduct reviews of the PACE organization including an on-site visit at least every two years (§460.192).

**Policy Decision**  The State will need to determine what, if any, additional activities it wishes to pursue to monitor and assure quality provided by PACE programs. Under the demonstration, States have undertaken a range of activities in this area. Based on survey responses from States operating PACE or pre-PACE programs, these activities have included:

- assuring quality through the contract management process;
- surveys to assure compliance with licensing requirements undertaken by licensing agencies within the State;
- review of programs’ grievance and appeals processes;
- assuring that subcontractors are properly licensed and in good standing;
- implementing Medicaid compliance reviews;
- requiring submission of reports and corrective action plans;
- annual auditing of medical records;
- participant satisfaction surveys;
- requirements regarding internal quality assurance systems and Quality Assurance plans;
- implementation of quality improvement projects;
- submission of quarterly complaint and grievance data;
- assuring compliance with PACE Protocol requirements;
- periodic reviews (either quarterly or annually) of program operations, contract compliance, etc.;
- ongoing clinical and financial audits;
- State participation on PACE program’s Quality Council;

No single State requires all of the above; rather, States’ quality assurance activities are a combination of one or more of these activities. At this point there is little consistency across States in their evaluations of quality; whether this will change in response to Federal regulation is an outstanding question.

VIII. Conclusion

Under the Balanced Budget Act and Federal regulation governing PACE organizations, PACE programs will be implemented and administered jointly by HCFA and the States. This issue brief has identified seven phases of development and implementation from the particular perspective of the State.
Because the PACE transition from demonstration to provider status is still in its infancy, many of the issues and processes identified in this brief will continue to evolve.

**Additional Resources:**

“Integration of Acute and Long-Term Care for Dually Eligible Beneficiaries through Managed Care,” prepared by The Muskie School of Public Service, University of Southern Maine, and The National Academy for State Health Policy, Published by the Medicare/Medicaid Integration Program, University of Maryland Center on Aging, August 1997.
## State PACE Development Phases

I. Initial Policy Development
II. Address Federal Requirements
III. State Legislation (If Required) & Regulatory Requirements
IV. Identification/Selection of Providers
V. State Implementation Activities & Contract Development
VI. Federal Provider Approval Process
VII. Program Oversight & Monitoring

## Provider PACE Development Phases

I. Feasibility Study
II. State Application
III. Site & Program Development
IV. Federal Application Process
V. Project Operational
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<th>Planning Quarter</th>
<th>Feasibility Period</th>
<th>Year 1</th>
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I. INITIAL POLICY DEVELOPMENT
   A. Determine Policy Position on PACE
      1. Examine Benefits and Limitations of the Model for the State; Determine Role of PACE Relative to Other LTC Services, Number of Providers Desired, Location
      X--------X

   2. Decision to Proceed with PACE Development
   X

   B. Identify Appropriate State Administering Agency
   X

   C. Determine Start-Up Strategy
   X

II. ADDRESS FEDERAL REQUIREMENTS
   A. Amend State Plan
   X X

III. STATE LEGISLATION & REGULATORY REQUIREMENTS
   A. Determine Need for Legislation
      "Policy Decision"
      1. Review following areas:
         a. Authority to Contract w/ Providers
         b. Budget Authority/Funding
         c. Establishment of Solvency Standards/Modification of State HMO Requirements
         d. Other based on individual state environment
      X

      2. Pass Legislation & expand timeframe accordingly
      X---------X

   B. Determine Licensure &/or Certification Requirements
      "Policy Decision"
      e.g. ADHC, Primary Care Clinic, Home Health

      2. "Policy Decision"

   C. Determine Requirements as a Risk Entity
      "Policy Decision"
      e.g. HMO, Limited Risk, or Exempt

   D. Determine Financial Requirements
      "Policy Decision"
## IV. IDENTIFICATION/SELECTION OF PROVIDERS

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<th>Planning Quarter</th>
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<tr>
<td><strong>A. Determine Procurement Process</strong></td>
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<td><strong>e.g. RFP, RFI, Provider Initiation, State Legislation</strong></td>
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<td><strong>Policy Decision</strong></td>
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<td><strong>B. As Applicable:</strong></td>
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<td>If RFP or RFI Process:</td>
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<td>1. Develop RFP, RFI</td>
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<td>2. Release RFP, RFI</td>
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<td>3. Review Provider Responses</td>
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<td>4. Provider Selected</td>
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<td><strong>or</strong></td>
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<td>If Provider Initiated or Site Identified by Legislation</td>
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<td>1. Develop State Provider Application</td>
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<td>2. Application Made Available to Providers</td>
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<tr>
<td>3. Review Provider's Application</td>
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## V. IMPLEMENTATION & CONTRACT DEVELOPMENT:

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<tbody>
<tr>
<td><strong>A. Determine Basic Eligibility Criteria</strong></td>
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<tr>
<td>1. Any Criteria beyond Age 55+ and NHC?</td>
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<td><strong>Policy Decision</strong></td>
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<td><strong>B. Clinical Eligibility</strong></td>
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<tr>
<td>1. Determine Instrument and Process for Assessment of nursing facility level of care</td>
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<td><strong>Policy Decision</strong></td>
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<tr>
<td>2. Determine Policies &amp; Procedures for Reassessment</td>
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<td><strong>Policy Decision</strong></td>
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<td>3. Inform/Educate Local Eligibility Office</td>
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<td><strong>C. Financial Eligibility</strong></td>
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<tr>
<td>1. Determine Eligibility Rules Under State Plan i.e. categorical eligibility, MNO, 300%, spousal</td>
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<td>2. Determine Rules for Post-Eligibility Treatment of Income</td>
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<td>3. Inform/Educate Local Eligibility Office of Rules as appl.</td>
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<td>Planning Quarter</td>
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<td>D. Enrollment/Disenrollment</td>
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<td>1. Determine Procedures, Cut-off Dates, etc.</td>
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<tr>
<td>E. Payment Systems</td>
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<tr>
<td>1. Determine Procedures</td>
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<tr>
<td>2. Determine System Requirements for Lock-in</td>
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<tr>
<td>a. Modify state MMIS systems as necessary</td>
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<tr>
<td>F. Rate Development</td>
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<tr>
<td>1. Determine Comparison Group for Rate Setting</td>
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<tr>
<td><strong>Policy Decision</strong></td>
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<tr>
<td>2. Determine Services to be Capitated</td>
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<tr>
<td>3. Determine Current Cost Experience for Comparison Grp.</td>
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<tr>
<td>a. In-House vs External Analysis</td>
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<tr>
<td>(if external, add time for analysis &amp; review)</td>
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<tr>
<td>4. Project PACE Rate Relative to Current Cost Experience Options:</td>
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<tr>
<td>-Set rate as percentage of current costs, e.g. 85-95%</td>
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<tr>
<td>-Negotiate rate with provider</td>
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<tr>
<td>5. Finalize Rate for Contract</td>
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<td>G. Determine Data Reporting Requirements</td>
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<tr>
<td><strong>Policy Decision</strong></td>
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<tr>
<td>1. Establish Standards of Performance</td>
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<tr>
<td>2. Establish Process</td>
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<tr>
<td>3. Establish Data Requirements to Support QA/QI Activities</td>
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<tr>
<td>H. Contract Legal Review</td>
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<tr>
<td>1. Review by State Legal Department</td>
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<tr>
<td>2. Review by HCFA Regional Office (?)</td>
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<tr>
<td>3. Provider review</td>
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# STATE WORKPLAN FOR PACE DEVELOPMENT AND IMPLEMENTATION

<table>
<thead>
<tr>
<th>Planning Quarter</th>
<th>Feasibility</th>
<th>Year 1</th>
<th>Year 2</th>
<th>Year 3</th>
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<tr>
<td></td>
<td>Period</td>
<td>1  2  3 4</td>
<td>1  2  3 4</td>
<td>1  2  3 4</td>
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<tr>
<td>VI. FEDERAL PROVIDER APPROVAL PROCESS</td>
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<tr>
<td>A. State Review of Provider Application</td>
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<tr>
<td>1. Review Provider Materials, e.g. Marketing Plan, Enrollment Documents, QA/QI plan, etc.</td>
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<tr>
<td>2. Forward Application to HCFA w/ State Assurances</td>
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<td>X</td>
<td></td>
<td></td>
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<tr>
<td>B. HCFA Review of Application</td>
<td></td>
<td>X</td>
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<tr>
<td>C. Assess Provider Readiness</td>
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<tr>
<td>1. Review HCFA Readiness Criteria</td>
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<td>X</td>
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<tr>
<td>2. Conduct Pre-Operational Site Visit</td>
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<td>X</td>
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<tr>
<td>D. HCFA Approval/Sign Program Agreement</td>
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<tr>
<td>**** PROGRAM OPERATIONAL</td>
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<tr>
<td>VII. PROGRAM OVERSIGHT AND MONITORING</td>
<td></td>
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<tr>
<td>A. Operational Site Visit with HCFA</td>
<td></td>
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<td>X</td>
<td></td>
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<tr>
<td>B. Annual Site Visits with HCFA</td>
<td></td>
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<td>X--&gt;</td>
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</table>
State Plan Amendment Flow Chart

State decides to offer PACE through the State Plan

State submits SPA pre-print pages (or alternative format) to RO

90-day clock begins upon RO receipt

RO analyst forwards copy of SPA to CO PACE Leader for distribution to CO review team

SPA analysis performed in RO, with assistance as necessary from CO team

RAI letter (or approval letter if all requirements are adequately addressed) drafted - with any CO comments as necessary - by 76th day

RAI letter sent to State by RO to stop the 90-day clock

Second 90-day clock begins upon RO receipt of State responses to RAI letter

RO analyst forwards copy of responses to CO PACE Leader for distribution to CO review team

Analysis of RAI responses (and any additional information obtained through subsequent discussion) performed in RO, with assistance from CO as necessary

SPA approveable

SPA approved by RO

Approval letter sent to State by RO with a cc to CO

SPA not approveable

CO/RO notify State to withdraw responses and convert to draft

CO/RO work with State to develop agreed upon responses

Second 90-day clock restarts upon RO receipt of agreed-upon responses
## Licensure & Certification Requirements for PACE Programs by State

<table>
<thead>
<tr>
<th>States w/ PACE</th>
<th>Adult Day/Day Health</th>
<th>Clinic</th>
<th>Home Health</th>
<th>Other – Specify**</th>
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<tbody>
<tr>
<td>CA</td>
<td>X</td>
<td>X</td>
<td>X</td>
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<tr>
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<td>X</td>
<td>X</td>
<td>X</td>
<td>CLIA</td>
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<td>OR</td>
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<tr>
<td>WA</td>
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<td>WI</td>
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<td>None</td>
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</table>

<table>
<thead>
<tr>
<th>States w/ Pre-PACE</th>
<th>Adult Day/Day Health</th>
<th>Clinic</th>
<th>Home Health</th>
<th>Other – Specify**</th>
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<tbody>
<tr>
<td>HI</td>
<td>X</td>
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<td>X</td>
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<tr>
<td>IL</td>
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<td>None</td>
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<tr>
<td>NM</td>
<td></td>
<td></td>
<td>Diagnostic &amp; Treatment Center</td>
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<tr>
<td>PA</td>
<td>X</td>
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<td>X</td>
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<tr>
<td>VA</td>
<td>X</td>
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<td>Primary Care</td>
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</table>

** These are examples of additional licenses which may be held by PACE providers. This list may not be comprehensive.
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 to 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.
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).
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 capitlated 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/enrollment 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

<table>
<thead>
<tr>
<th>Printed Name</th>
<th>Title</th>
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Signature    Date

Address

For (name of the SAA)

<table>
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<tr>
<th>Printed Name</th>
<th>Title</th>
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</table>

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
LIST OF APPENDICES TO PACE PROGRAM AGREEMENT

APPENDIX A: Names and Contact List
APPENDIX B: Organizational Structure
APPENDIX C: Service Area
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
APPENDIX N: State Enrollment/Disenrollment Reconciliation Methodology
APPENDIX O: Termination Phase-Down Plan