The National PACE Association's

State Guide

to

PACE

Programs of All-inclusive Care for the Elderly

December 2008

Part I

How to Use This Guide

• Legal entity

Organizational structure

Introduction to PACE	Page 5
 Background History Emerging opportunities & challenges Benefits to states 	
States' Roles and Responsibilities	Page 8
 Initial policy development Relationship to existing state systems Adding PACE services to state Medicaid benefit Rate setting Stimulating, responding to provider interest 	
Provider Application Review, Processing & Approval	Page 12
 Overview of provider application review process Review of provider application Processing application, timeframes Requests for Additional Information (RAIs) Waivers Onsite review Program agreement, oversight and monitoring 	
Part II	
Review of PACE Provider Application	'n
Chapter 1. General Information and Organization	Page 17
 Organizational summary Service area Transitional care during termination Nonprofit status Organized under state law 	

Chapter 2. PACE Administration	Page 19
 Training Program integrity Contracted services Physical environment 	
Chapter 3. Financial	Page 22
 Fiscal soundness Financial projections Insolvency Financial risk Financial recordkeeping and reporting 	
Chapter 4. Marketing	Page 25
MarketingMarketing projections	
Chapter 5. PACE Services	Page 26
 Required services Service delivery PACE Centers Emergency care Interdisciplinary team (IDT) Participant assessment Reassessments Plan of care 	
Chapter 6. Participant Rights	Page 29
 Bill of Rights Explanation of rights Restraints Grievance and appeal process 	

Governing bodyParticipant Advisory Committee (PAC)

Chapter 7. Quality Assessment & Performance Improvement (QAPI)	Page 31
 QAPI plan Minimum requirements Internal activities Community-input committees Additional activities 	
Chapter 8. Participant Enrollment, Disenrollment	Page 33
 Eligibility Enrollment Process Enrollment Agreement Other procedures Voluntary disenrollment Involuntary disenrollment Reinstatement in other Medicare, Medicaid programs Reinstatement in PACE Documentation of disenrollment 	
Chapter 9. Payment	Page 35
Payment to PACE providersMedicare as secondary payer	
Chapter 10. Data Collection, Record Maintenance & Reporting	Page 35
 Maintenance of records and reporting data Participant health outcomes data Medical records 	
Chapter 11. Medicare Part D	Page 37
States' limited role	
Resources	Page 38

How to Use this Guide

The National PACE Association (NPA) has produced this guide as an introduction and orientation for states to the Programs of All-inclusive Care for the Elderly (PACE) and its provider application review process. Part I presents a brief history of PACE and describes how PACE programs can complement state long-term care services. It also discusses the program's major challenges and opportunities, the states' roles and responsibilities and the provider application review and approval process.

As a reference tool for states, Part II provides a chapter-by-chapter, annotated review of the PACE provider application. The guide references topics that frequently generate requests for additional information (RAIs), summarizes application requirements as amended by final PACE regulations, and describes any CMS-approved waivers related to each chapter.

Part I

Introduction to PACE

Background

Developed to address the needs of long-term care clients, providers and payers, PACE was modeled on the integration of acute and long-term care services envisioned by On Lok Senior Health Services in San Francisco. Conceived in the early '70s, PACE was tested in the 1980s through CMS (then HCFA) demonstration projects that replicated the On Lok model.

PACE features a comprehensive service-delivery system and capitated Medicare and Medicaid financing. Capitated financing allows providers to deliver all services consumers need rather than limiting services to those reimbursable under Medicare and Medicaid fee-for-service systems. PACE providers assume full financial risk for care of each eligible enrollee (participant) without limits on amount, duration or scope of services and receive monthly Medicare and Medicaid capitation payments for each participant.

PACE participants must be 55 years or older, live in a PACE service area and be certified as nursing-home eligible by the appropriate state agency. Medicare-eligible participants ineligible for Medicaid pay monthly premiums equal to the Medicaid-capitation amount, but with no deductibles, coinsurance or other type of Medicare or Medicaid cost sharing.

Once enrolled, participants receive all Medicare and Medicaid services from the PACE program. The PACE service package provides social and medical services, supplemented by in-home and contracted services, determined necessary for the care of the participant by the PACE organization's (PO's) interdisciplinary team (IDT). The IDT, consisting of professional and paraprofessional staff, assesses participants' needs, develops care plans and provides all services either directly or through contracted providers, including acute-care services and nursing-facility services when necessary.

The PACE program integrates these services through the IDT to achieve a seamless continuum of total care. For most PACE participants, the comprehensive service package permits them to receive long-term care services at home rather than being institutionalized.

History

In 1971, San Francisco's Chinatown-North Beach community recognized the pressing long-term care services needs of families whose elders had immigrated from Italy, China and the Philippines. Dr. William L. Gee, a public health dentist in San Francisco, led a committee that hired Marie-Louise Ansak to seek solutions. Along with other community leaders, they formed a nonprofit corporation, On Lok Senior Health Services, to create a community-based system of care.

On Lok received a four-year HHS grant in 1979 to develop a consolidated model of delivering care to frail, elderly persons with long-term care needs. Four years later On Lok was authorized to test a financing system that reimbursed it a fixed monthly amount for each enrollee. Federal legislation in 1986 extended On Lok's new financing system

and allowed 10 additional organizations to replicate its service-delivery and funding model in other parts of the country. These replication sites were identified as PACE.

The first PACE replication site received Medicare and Medicaid waivers to begin operations in 1990. After the other replications were established and operational, Congress authorized PACE as a permanent benefit of the Medicare program in the Balanced Budget Act (BBA) of 1997. The legislation also authorized states to offer PACE services to Medicaid beneficiaries as a state option. CMS issued the first PACE interim regulations on November 24, 1999, establishing requirements for PACE under the Medicare and Medicaid programs.

Alexian Brothers Community Services in St. Louis became the first PACE Organization (PO) to be permanently recognized as part of the Medicare and Medicaid programs in 2001. The second PACE regulations, published October 1, 2002, incorporated revisions to the original rules and established a process through which POs can request waivers of certain regulatory requirements. They also offered flexibility in adapting the PACE service-delivery model to the needs of a particular organization and removed the requirement that POs directly employ the program and medical directors, and all IDT members.

In 2005, Congress created the Rural PACE Provider Grant Program. Subsequently in 2006, CMS awarded \$7.5 million in competitive grants to 15 rural health care provider organizations to support development of rural PACE programs in 13 states. The grant program provided each of the 15 grantees with \$500,000 to support the development of rural PACE programs.

Final PACE regulations, published December 8, 2006 and effective January 8, 2007, include new requirements for providers, states and CMS. In particular, the final rules revise staff experience, training and education requirements to include that a MSW serve on the IDT and that OTs and PTs participate in initial assessments and annual reassessments.

Emerging Opportunities & Challenges

Meeting the needs of growing market demands for PACE services, adapting to pressure from an expanding field of public and private competitors, engaging the for-profit long-term care community to participate and developing strategies to better educate federal, state and local audiences about its benefits are some of the challenges facing the PACE program.

However, the most significant challenge facing PACE providers is reduced reimbursements over the next few years due to the recently revised calculation of the CMS-HCC frailty risk-adjustment factor under Medicare capitation rates. While CMS has subsequently lengthened the timeframe for full implementation of the recalculation from four to five years and limited the size of the first-year decrease, the reduction of future Medicare reimbursements could challenge the ability of future PACE providers to establish financially viable programs.

Working with CMS as it implements and interprets final PACE regulations could also prove challenging. In particular, new requirements that all staff providing personal care have at least one-year experience, that OTs and PTs participate in initial participant assessments and annual reassessments and that a MSW serve on the IDT, could make

it harder for providers to hire sufficient staff. Although, if needed, POs can request waivers based on local job markets.

Program growth presents both opportunities and challenges for CMS and states, especially those states new to the program. Since 2001, the number of PACE programs has increased from one to 55 in 24 states. Additional programs are under development in several new and existing PACE states. By the end of 2008, PACE should be serving more than 20,000 frail and older adults across approximately 60 sites in 28 states. Staff and other federal and state resources likely will be stretched to meet the growing administrative burden posed by the program's growth.

Nevertheless, despite its tremendous growth, PACE only reaches a very small fraction of those who need and qualify for its services. Some states are not participating, many potential participants live in areas not serviced by existing programs, and efforts to serve individuals in rural, sparsely populated areas are in their infancy. Rural expansion, in particular, holds tremendous promise for innovative providers and supportive states. Success for rural PACE, however, will require regulatory and operational flexibility, innovative strategies and partnerships, and the development of a variety of creative models of care and service delivery.

Benefits to States

PACE has proven its ability to deliver highly coordinated, comprehensive care to the frail elderly to support their ability to continue living actively in their community for as long as possible. PACE provides these services with significant cost savings based upon a predictable, capitated payment that combines Medicare and Medicaid funding. Bringing these systems together in PACE not only results in a higher quality of care and life for participants and their families, it also allows states to better predict and control health expenditures for the frail elderly.

PACE benefits states by:

- Serving the dually eligible Medicare and Medicaid population
- Empowering frail elderly to age in place
- Helping comply with Olmstead requirements
- Providing high clinical outcomes and participant satisfaction
- Helping predict costs and save money

Through PACE, today's fragmented health-care financing and delivery systems converge to serve the unique needs of each individual in a way that makes sense to elderly consumers, their informal caregivers, advocates, health care providers and policymakers.

PACE gives states an opportunity to:

Encourage providers to effectively manage comprehensive services for a frail, longterm care population in a community setting Fully integrate the delivery of Medicare and Medicaid acute and long-term care services

Substantially reduce use of inpatient services

Improve outcomes relative to comparable individuals served in traditional settings

Utilize a well-established model of care as a benchmark for other managed long-term care initiatives

Complement other state programs by offering a provider-based alternative to larger, health insurer-based models

States' Roles and Responsibilities

Initial Policy Development

In the initial development phase, states must make key policy decisions including choosing whether or not to include PACE as a Medicaid benefit. State staff should articulate how PACE contributes to their long-term care system in order to determine if the state can make a commitment to the development of PACE programs. Once a state decides to pursue PACE, it must amend its State Plan to offer PACE as a Medicaid benefit.

Identifying the appropriate agency to administer the PACE program is the next step. While state Offices on Aging or managed-care agencies could serve as the PACE state-administering agency (SAA), that role usually is filled by the state Medicaid agency. This differs from Medicare home and community-based waiver programs, which are usually administered by state agencies on aging, and may reflect that PACE also provides medical, acute and nursing-facility care services overseen by state Medicaid agencies.

Relationship to Existing State Systems

After deciding to include PACE in its long-term care system, the state must determine the relationship of PACE with other long-term care and managed-care programs. Decisions made during this phase will impact how the state proceeds with various aspects of program implementation, including decisions regarding the number of PACE sites to be developed, their geographic location, the state's approach to rate setting, etc. In all states with PACE, the program coexists with other institutional and home and community-based services. With a local provider-based approach, PACE complements statewide or regional health insurer-based alternatives by offering:

- Provider-based in-home and community-based services
- Individual integrated care planning and needs assessment
- Comprehensive benefits package including end-of-life care

Adding PACE Services to State Medicaid Benefit

Successful PACE implementation requires sufficient planning and commitment to ensure adequate state support, funding and staffing resources for its development,

management, oversight and growth. Early in the development process, states must establish an operational infrastructure guided by a vision of where PACE fits into a state's spectrum of long-term care services.

In creating this infrastructure, states should focus on:

- Ensuring adequate staff resources and program linkages for PACE
- Providing clear and consistent policies and regulations that build on states' existing long-term care policies and regulations
- Building on CMS requirements and coordinating administrative activities with CMS

Each state that elects PACE as a State-Plan option can choose to develop just one or multiple sites in one or more geographic areas. States 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 operate as efficiently and manage financial risk as effectively as possible.

States also are responsible for:

- Establishing clinical eligibility requirements for PACE enrollees
- Recertifying enrollees' program eligibility on at least an annual basis
- Reviewing all involuntary disenrollments, denials of enrollments, grievances and appeals

Rate Setting

Like other managed-care organizations, POs are paid on a monthly, capitated basis. In PACE, CMS establishes and pays the Medicare capitation and each state establishes and pays the Medicaid capitation. Participants ineligible for Medicaid pay privately an amount equal to the Medicaid capitation. At the provider level, Medicare, Medicaid and private capitation payments are combined, 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 should set 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
- Policy decisions as to where PACE fits relative to institutional and communitybased alternatives

Some of these policy decisions must be addressed prior to embarking on the rate-setting process, which is subject to CMS review to ensure the rate method is actuarially sound (i.e., the PACE capitation rate is based on costs of an appropriate comparison group).

The broad objectives of the rate-setting process are to establish payment rates that:

- Provide POs with revenues to support appropriate and high-quality services to all program participants
- Allow POs to provide services based upon the needs of participants
- Assure that well-run programs can be financially viable
- Provide payers (Medicare, Medicaid and private-pay) with savings relative to what would otherwise be spent for PACE enrollees in fee-for-service

States must develop a payment amount based on the cost of comparable services for the state's nursing facility-eligible population. Generally, the amounts are based on a blend of the cost of nursing home and community-based care for the frail elderly. The monthly capitation payment amount is negotiated between the PO and the SAA and can be renegotiated on an annual basis.

In the application, the state must set forth the upper payment limit (UPL) and capitated-payment rates, describe the methodology used to compute the UPL and rates, specify that the rates do not exceed the UPL and demonstrate that they are reasonable and predictable. The UPL must take into account the comparative frailty of PACE participants, and must be a fixed amount regardless of changes in the participant's health status.

In general, the state must calculate the UPL for the PACE population and make the appropriate calculations after choosing from among the following rate-setting options:

- Open cooperative contracting
- Separate rate calculation
- Competitive procurement

The methodology used to calculate the UPL must be specified in the State Plan amendment. The calculation is a computation method that produces an UPL equal to the costs to the Medicaid program and defines the scope of services that participants would receive if they were not enrolled in PACE.

During the UPL and rate-setting processes, the CMS Regional Office should be consulted to ensure that the state and CMS agree on the final outcome, since the state's specific methodology and calculation of its UPL and capitated rate are reviewed and approved by that office during the application process and each time the state amends the rates. It is also important to ensure that the provider is educated about how the UPL will be set, so the provider can make an accurate assessment about the financial viability of moving forward as a PO.

Note: CMS has developed a "Financial Review Documentation for UPL and Rate Setting" document (also referred to as UPL Checklist) for Regional Offices to utilize in the review process. This document is divided into two separate checklists: one for UPLs and one for rates. In order to ensure that the requirements of CMS are met, states are advised to carefully review this document and the State Plan amendment pre-print pages prior to calculating the UPL and selecting a rate-setting process.

Stimulating, Responding to Provider Interest

Because PACE is a three-way partnership between providers, states and CMS, interest is essential from both states and prospective providers. States, in particular, need to communicate their commitment to PACE within state government and with prospective providers, other health care and aging services providers, legislators, community organizations and consumers.

Successful state communication strategies may include:

- Taking the lead in educating prospective providers, advocates and consumers
- Communicating a long-term commitment to PACE as an essential part of the state's long-term care system
- Assuring the viability of the program with appropriately developed rates
- Providing opportunities for consensus-building
- Ensuring that consumers have equal access to PACE as a long-term care service option within PACE service areas
- Supporting and monitoring PACE programs through start-up and operational phases
- Providing a clear and fair process for provider selection
- Embracing and encouraging innovative PACE approaches designed to respond to community needs

To identify opportunities for PACE development, states should consider PACE as an alternative to new nursing-home bed construction in areas where a state is experiencing a shortage of beds, or areas with limited availability of community-based long-term care services.

In choosing from among several organizations interested in developing PACE, states should weigh the market demand for long-term care services and consider the supply of alternative long-term care services in the proposed service-delivery area. States also should focus on the number of potential eligible PACE participants within specific geographic areas, especially in rural, less-populated regions.

States should develop criteria to evaluate an organization's capacity to successfully develop PACE, which should be a major factor in a state's decision to pursue

development with a particular organization. Factors that can be useful in assessing an organization's ability to implement PACE include:

- Organizational commitment to principles consistent with the PACE model
- Evidence that the organization has the necessary depth in leadership and experience required to develop and implement PACE successfully
- Experience in providing primary, acute and/or long-term care services and in serving the dual eligible population
- Sufficient demand for PACE services in the proposed service area
- Adequate financial capacity and wherewithal to fund program development and start-up, and to assume full financial risk
- Organization's timeline for development

Provider Application Review, Processing & Approval

Overview of Provider Application Review Process

The PACE provider application process can take a significant amount of time and is susceptible to delays as eligibility, rate setting, licensing, monitoring and other issues are resolved by the state. The process is more timely and successful when the state works as a partner with CMS and prospective providers. In fact, the 1997 BBA calls for a cooperative relationship between CMS and states in the development, implementation and administration of the PACE program. In multiple instances the statute specifically instructs CMS to work "in close cooperation with" or "in consultation with" the SAA.

Developing and facilitating three-way communication opportunities between the state, CMS and prospective providers early on and throughout the provider application process helps ensure collaboration, transparency and predictability. In addition, states need to plan adequately for the state resources needed to process the provider application in order to ensure it is processed on a timely and effective basis.

States that demonstrate a commitment to the completion of the PACE provider application and seeing that consumers receive services as soon as possible are more likely to work through difficult issues and complete the provider application process in a timely manner. States demonstrate this commitment when they develop a vision for the new PACE program, work proactively, plan ahead and develop work plans and timelines. States also can demonstrate a commitment by securing technical assistance when needed and collaborating with providers on difficult developmental issues.

Review of Provider Application

Although states are solely responsible for initial site selection, under federal requirements both the state and CMS must review and approve each PACE provider application. The approval process consists of:

• Review of provider application by state

- Review of provider application by CMS
- On-site review by state
- Endorsement of three-way Program Agreement

While the provider completes the application, completing the following sections will require prior discussion with the state:

- Specifications of the provider's service area
- Marketing materials
- Eligibility determination process
- Site-specific eligibility requirements
- Enrollment/disenrollment procedures
- Process for review of enrollment denials
- Process for review of proposed involuntary disenrollments
- Data-reporting requirements

States will want to pay particular attention to certain sections of the application, including:

- Marketing and enrollment materials (Note: CMS and states must review these for accuracy and to assure they are written in such a way to be understood by prospective enrollees and their families)
- Participant rights, including review of Participant Bill of Rights, and grievance and appeals processes
- Quality Assessment & Performance Improvement (QAPI) Plan

Prior to submission to CMS, provider applications are submitted to the state for review to determine that they are in compliance with all state requirements. Once the state begins receiving the application, staff should have a system in place to ensure its timely review. An effective approach might include the following:

- Assignment of a lead to coordinate the review. The lead will review the application to ensure all questions are answered completely and that it appears to be consistent with federal and any state requirements
- The lead distributes any specialty areas in the provider application such as clinical or financial issues that may require review by specific professionals

- The lead coordinates formal feedback to the provider. Written feedback is accompanied by a phone call or in-person meeting to discuss the submitted and reviewed application chapters
- Provider revisions should be reviewed on an ongoing basis until acceptable
- The lead assures that the state assurance pages are signed and forwarded to the provider for mailing to appropriate CMS and Regional Office staff

After the state has completed its review, it submits the application to CMS, along with written assurances that the:

- State is willing to enter into a Program Agreement with the prospective PO if CMS approves the application;
- State expects the provider to be qualified to be a PACE provider; and
- Provider will be limited to a certain enrollment ceiling, if applicable.

Note: The provider application may be submitted to CMS before the State Plan is amended to include PACE as a Medicaid benefit. However, the State-Plan amendment must be approved before CMS will enter into a Program Agreement with the state and the provider to enable operations to begin.

Processing Application, Timeframes

Once CMS receives an application from the state, a determination is made within two weeks on the completeness of the package. CMS will notify the state and applicant in writing about whether the package is acceptable. Prospective POs should have secured a site for the PACE Center so it can be inspected for local, state and federal compliance and they must have written policies and procedures to become operational.

CMS has up to 90 days from the date the acceptable application is received in the Central Office to submit written requests for additional information (RAIs). States should conduct a readiness review and CMS should conduct its onsite review during this non-operational timeframe. Once the applicant receives the RAIs, including information from either the state's readiness review or the CMS on-site review, the second and final 90-day clock starts. CMS will decide on the application within this second 90-day period and if approved, a three-party Program Agreement will be signed.

While circumstances differ within each submission, a conservative estimate of the average time needed to process an application by CMS is nine months. As the program has grown, however, some states in conjunction with providers are employing innovative strategies to successfully move the application more quickly through the approval process. Experience indicates such innovations expedite the process.

Note: To help encourage innovation, NPA has created an installment model Provider Application Development, Review and Approval process specifically for rural applications. NPA's rural model (see Attachment I) suggests an 18-month timeframe from the time of a provider's decision to apply to the signing of the Program Agreement.

Requests for Additional Information (RAIs)

As states and CMS review the application, RAIs play an integral role in the application review process and help CMS, states and applicants fine-tune the application to give the provider every opportunity to be approved for PACE. Because most applications trigger numerous RAIs, states work with applicants to respond to the RAIs in an accurate and timely fashion. Providers should expect RAIs for nearly every chapter.

Note: Examples of RAIs issued by CMS are listed after each chapter section of the following application summary.

Waivers

CMS advises applicants and POs to communicate with their SAA regarding requests for regulatory waivers prior to submitting them for formal CMS review to help ensure mutual understanding and support for the requested waiver by both the SAA and the PO. All waiver requests must be approved by the SAA.

Final PACE regulations explicitly recognize the ability of both currently operating POs and new applicants to submit waiver requests through the State Administering Agency. CMS is required to notify in writing of denials and approvals of waiver requests. (See, 42 CFR Part 460.26 and 42 CFR Part 460.28)

A waiver-request submission package should include:

- Identification that the submitted document is a waiver request
- Identification of regulatory section the PO is requesting to have waived
- Rationale behind the request
- Process that will be followed to ensure participant care is not compromised

The following provisions may not be waived:

- Focus on frail elderly qualifying individuals who require skilled-nursing care
- Delivery of comprehensive, integrated acute and long-term care services
- The IDT approach to care management and service delivery
- Capitated, integrated financing that allows providers to pool payments received from public and private programs and individuals
- The assumption by the provider of full financial risk

Waiver requests should be placed in their own envelope labeled "waiver request" and must be submitted to the CMS Central Office and relevant Regional Office by the SAA along with any concerns or conditions identified. CMS has 90 days from the date of receipt to make a determination on a waiver request.

Note: CMS has granted a range of waivers for various reasons; those waivers are listed at the end of each applicable provider application chapter in the following summary.

On-Site Review

An on-site review will be conducted as part of the provider application approval process before the Program Agreement is signed. On-site review teams will consist of four CMS representatives as well as representatives from the state. CMS team members will represent both the Medicare and Medicaid offices from CMS and its relevant Regional Office. Each state determines the appropriate individuals to participate. For those PACE applicants not yet operational programs, CMS will rely on the state to conduct an assessment of provider readiness.

Note: CMS has developed a readiness review tool suggested for use by states in conducting this assessment. In addition to the requirements incorporated in CMS' instrument, the state may incorporate additional review criteria.

Program Agreement, Oversight & Monitoring

Once the application is approved, CMS, the SAA and the PO must sign a three-way Program Agreement, authorizing the PO to begin marketing and enrollment activities.

Final PACE regulations [42 CFR Part 460.180(b)(1)] require that the Program Agreement include the methodology used to calculate the Medicare capitation rate rather than the rate itself. This change reflects transition to CMS-HCC risk adjustment that generates different capitation rates for each participant (See, Emerging Opportunities & Challenges in Part I and Chapter 9 of Provider Application Summary in Part II)

Assuming the provider successfully completes the readiness review and initiates PO operations, CMS and the state will conduct a joint on-site review within six months to ensure that it is operating in compliance with program requirements. As required by statute, CMS and the state will conduct comprehensive annual reviews of POs during their first three years of operation, or "trial period," to ensure compliance with PACE regulation requirements. The review will include:

- On-site visit to PO including (but not limited to):
 - Facility review
 - Participant charts review
 - Interviews with staff, participants, caregivers and contractors
- Observations of program operations, including marketing, participant services, enrollment/disenrollment procedures, and grievances and appeals
- Fiscal soundness assessment
- Capacity to furnish all PACE services to all participants
- Any other elements that CMS or the state find necessary

At the conclusion of the trial period, CMS and the state will continue to conduct PO reviews including an on-site visit at least every two years.

Part II

The PACE Provider Application

Chapter 1. General Information and Organization

Section I. Organizational Summary—The initial section of the application includes an organizational summary with a brief history of the provider organization, a description of present operations, its most significant aspects and a description of its experience working with the Medicare and Medicaid programs and serving their participants.

Sample CMS RAIs:

- Detail eligibility criteria in describing sites' capacities to serve the population
- Describe how PO integrates affiliated organizations into program

Section II. Service Area (42 CFR Part 460.22)—The application should map out a proposed service area using county, zip code, census track, and block or street boundaries. The map should include geographical barriers, location of PACE Centers and any satellites. Travel time from the six farthest points in the service-area map to the nearest ambulatory or institutional service site must be denoted.

States must approve the PO service area and ensure that if it includes an area already covered by another PO, it does not create duplication of services or undermine the financial and service viability of an existing program.

RAIs:

- Specify travel times to all PACE Centers from the six farthest points identified in the map
- Show locations of all facilities with which PO contracts and clarify if it serves an entire county or set of zip codes

Section III. Transitional Care During Termination (42 CFR Part 460.52)—This section includes a written plan for phase down that describes in writing how the PO will inform participants, their families, the community and state and federal agencies about termination and transition plans. It also should clarify how the PO will assist participants to be reenrolled in conventional Medicare and Medicaid programs, transition care to other providers, terminate marketing and enrollment activities, and through appropriate referrals and cooperation, assist each participant in obtaining necessary care.

States must ensure the plan contains detailed procedures as specified in the federal PACE regulations.

RAIs:

- Note termination of marketing
- Describe assistance with reinstatement of Medicare/Medicaid benefits and transfer to other providers

Section IV. Nonprofit Status (42 CFR Part 460.60)—Under this section, the application should include evidence of nonprofit status and any applicable IRS

documentation, usually a 501(c)(3) letter of tax exemption. The entity may be a corporation, a subsidiary of a larger corporation or a department of a corporation.

RAIs:

 Provide current, official documentation of incorporation and nonprofit status (can use the Official Catholic Directory as evidence of status if applicable)

Section V. Organized Under State Law (42 CFR Part 460.60)—This section should include the PO's "doing business as" (DBA) designation and state approval of a DBA if applicable.

Section VI. Legal Entity (42 CFR Part 460.60)—This section should include the articles of incorporation.

Section VII. Organizational Structure (42 CFR Part 460.60)—An organizational chart for the PO should detail its relationship to the sponsor (if not an independent organization), the PACE program and its key positions, a description of its Board and Committee structures and how information flows throughout the organization.

Position descriptions of all key staff (and their names, if known) should be included. In the case of a corporate entity the organizational chart must indicate the PO's relationship to the corporate board and to any parent, affiliate or subsidiary corporate entities.

The key position responsibilities of "program director" and "medical director" must be detailed and states must ascertain that the positions have been hired or a contractual agreement has been signed or assure that the positions will be filled and staff in place prior to the effective date of the Program Agreement.

The application also needs to provide assurances of HIPPA privacy compliance, which designates a privacy officer and is documented in the Board minutes. States must ensure the privacy officer has a job description and verify that a contact person for handling all HIPPA privacy complaints is named.

RAIs:

- Detail Board's oversight role relative to the PO's critical functions beyond minimum requirements
- Clarify the medical director's responsibility for clinical outcomes

Section VIII. Governing Body (42 CFR Part 460.62)—This section should ensure that the PO is operated by a governing body or a designated person functioning as a governing body with full legal authority and responsibility for:

Governance and operation

Policy development and implementation, including personnel and health and safety policies

Management and provision of all services including those provided by contractors Fiscal operations

PO's quality assessment and performance improvement (QAPI) Plan Personnel policies

Development of policies regarding participant health and safety

RAIs:

 Specify if participant liaison to governing body is a participant, family member or community member

Final PACE regulations require the PO's governing body to include a participant liaison to present issues from the Participant Advisory Committee (PAC). The liaison can be a member of the Participant Advisory Committee (PAC), a participant representative or a participant. 42 CFR Part 460.62(c) specifically states "(1) A PACE organization must ensure participant representation on issues related to participant care. This shall be achieved by having a participant representative on the governing body. (2) The participant representative is a liaison of the participant advisory committee to the PACE organization governing body."

Section IX. Participant Advisory Committee (PAC) (42 CFR Part 460.62)—Under this section the application must describe how the PO will ensure participant representation on issues related to participant care, including a participant representative serving as liaison to the governing body to present issues of participant concerns. The PO also must establish a PAC to act as liaison to and advise the governing body on matters of concern to participants. Participants and/or their representatives must comprise a majority of this committee and its minutes reflecting participant issues must be forwarded to the governing body. If the PO is non-operational, it needs to explain how this goal will be accomplished.

RAIs:

- Detail how committee members are selected, their duties, committee-meeting frequency and its role relative to the PO
- Address interaction of PAC across multiple sites, if applicable
- Describe how PO ensures participant representation on issues related to participant care
- Describe how often committee meets and how Board is apprised of issues and recommendations

Waivers granted for Chapter 1 allow for:

- Allowing PO's legal entity to serve as governing body member
- Joint-venture arrangements

Chapter 2. PACE Administration

Section I. Training (42 CFR Part 460.66)—This section should describe and explain the training programs for the PO, including a detailed plan for performing initial competencies and ongoing skills reviews. The description should include the minimum skills necessary to perform a job, how skills are assessed and ongoing training plans. It also should include a detailed training program for personal care attendants and assure that personal care attendants demonstrate competency prior to working independently.

RAIs: Describe

- Initial and ongoing skills and competency testing
- Who is responsible
- Measures used

- How drivers are trained (may be described in detail in Section V of this Chapter)
- System for continuing education
- How training program involves contractors
- How competency of in-home, direct participant care contractors is determined and who determines it
- How personal-care assistants' skills will be tested
- Which if any professional certifications are required

Final PACE regulations (42 CFR Part 460.64) require all staff providing direct patient care:

- have a minimum of one-year experience working with the frail or elderly population (CMS has indicated this can be waived for drivers and personal care attendants)
- be medically cleared for communicable diseases
- be up to date on all immunizations
- demonstrate competency prior to working independently

Section II. Program Integrity (42 CFR Part 460.68)—This section should clearly indicate the process the PO uses to run criminal background checks on its employees, including conviction of physical, sexual, drug or alcohol abuse, and Medicare/Medicaid fraud and ensure that contractor/contracted organizations comply with appropriate regulations. This process, through use of CMS tracking lists, also should ensure no employees have been excluded from participation in Medicare/Medicaid or debarred from federal agencies.

The application should clearly define policies and procedures established by the PO for handling conflicts of interest to assure that no member of the governing body or its Board, or any of their immediate family members has direct or indirect interest in any contract that supplies administrative or care-related services or materials to the PO. These policies must make clear that members of the governing body are required to disclose any conflicts and recuse themselves from discussing, negotiating or voting on any matter that involved any inappropriate conflict of interest.

The policies and procedures should clearly define the process to disclose such conflicts of interest, including what information is disclosed, how it's disclosed, who receives the information and how management would handle such a disclosure.

The application also should describe the formal process in place to ensure continuing compliance with criminal background and program debarment checks as well as for conflicts of interests.

RAIs: Describe:

 Sources used to check criminal backgrounds, program fraud and to address state requirements

- How frequently checks are made for staff and contractors
- Whether or not staff needs to sign a disclosure form and clarify:
 - If conflicts of interest can apply to staff
 - · How conflicts of interest are identified and addressed
 - Process for reporting conflicts of interest

Final PACE regulations (42 CFR Part 460.68) require that:

- POs establish policies and procedures for handling conflicts of interest
- Members of the governing body must disclose any conflicts
- Members must recuse themselves from discussing, negotiating or voting on any matter that involves a conflict

Section III. Contracted Services (42 CFR Part 460.70)—The application should provide the position description of the employee who will serve as official liaison to coordinate activities between contractors and the PO. It should include a list of all contract providers and provide sample contracts for all administrative and service-related contractors (i.e., nursing home, specialty care, hospital and home care).

The PO must ensure that all contract staff providing direct patient care demonstrate the necessary skills for the performance of their position and provide all contracted staff with PACE orientation, including mission, philosophy, policies on participant rights, emergency plans, ethics, the PACE benefit and any other policies related to the job duties of specific staff.

The PO also should provide a copy of a sample contract for all administrative and carerelated contracts (including inpatient, nursing facility, home care, and specialty care) that is inclusive of HIPAA language.

Section IV. Oversight of Direct Participant Care (42 CFR Part 460.71) —The application must describe the process the PO will use to ensure its competency evaluation program that identifies those skills, knowledge and abilities that must be demonstrated by direct participant care staff, whether employed or contracted. The PO also must assure that before performing direct patient care, contracted staff are free of communicable diseases and are current with immunizations.

Evidence of completion of the competency program must be provided for each employee or contractor before they provide participant care and on an ongoing basis. The PO must designate a staff member to oversee these activities and work with PO contractor liaison to ensure compliance by contracted staff.

Section V. Physical Environment (42 CFR Part 460.72)—Applications should describe how each Center (if multiple centers, address each) is designed (including square footage) and equipped, how each is licensed by the state, the licensing requirements, and how the PO complies with ADA and HIPPA.

It also should describe a plan to ensure that all equipment is maintained in accordance with manufacturers' recommendations. The plan should include the following:

Identifying equipment

- How manufacturers' recommendations will be met
- Maintenance schedules
- How FDA injuries are reported (see <u>www.fda.gov</u> for "medical device" definition and reporting requirements)

The narrative should include evidence of compliance with regulations governing the Life Safety Code and National Fire Protection Association and describe how the PO complies with them. This section also should include the occupancy capacity of each Center.

Policies and procedures for emergency readiness should include a plan for non-medical emergencies and disasters, any emergency equipment and drugs, and staff responsibilities. A detailed description of how the PO handles emergency in-home or after-hours events must be included.

The PO's infection control policy, based on CDC and OSHA regulations, should be spelled out, making clear they apply to Centers, homes, staff and contract providers. A detailed description of how staff infections are managed and how they are recorded should be included. Also included should be a description of how communicable diseases are reported to state and local authorities, how laundry is handled and how waste is handled and disposed.

A transportation program description should include an inventory of vehicles, vehicle maintenance policies, staff and contractor training programs and requirements, and how information concerning transportation is communicated to and from the IDT, both while in transit with participants and regarding the status of individual participants.

A description of the PO's dietary services should indicate how meals are provided at the Centers, how meals, if indicated as needed, are provided at home by the IDT, meal-planning procedures, and how special diets are planned, including enteral and parenteral supplements. Procedures for assessing and care planning for participants should be included.

Waivers granted for Chapter 2 waive

- Conflict of interest requirements
- Requirement that drivers and personal care attendants have one year of experience with a frail or elderly population.

Chapter 3. Financial

Section I. Fiscal Soundness [42 CFR Part 460.80(A)]—The application must describe how the PO will meet any reserve and other financial requirements set by CMS and the state in which the PO operates. If the state requires HMO licensure or surety bonds, the PO should describe compliance with insurance commission and other applicable regulations. Any supporting documentation should be included.

In the Documents part, the PO must provide: three most recent fiscal-year periods, or if operational for a shorter period of time, for each operational fiscal year. If the PO is an applicant's line of business, it must provide:

- 1) Audited statements relating to the legal entity. Audits must include:
 - Opinion of a certified public accountant
 - Statement of revenues and expenses
 - Balance sheet
 - Statement of cash flows
 - Explanatory notes
 - Management letters
 - Statements of changes in net worth
 - Actuarially certified statement of incurred but not reported claims, if applicable
- 2) A copy of the most recent year-to-date, unaudited financial statement of the entity
- 3) Independently certified audited financial statements of guarantors and lenders (organizations providing loans, letters of credit or other similar financing)

If the PO is a public corporation or subsidiary of a public corporation, it must include the most recent Annual Report pursuant to Section 13 or 15(d) of the Securities Exchange Act of 1934, Form 10-K.

RAIs:

- Specify any formal financial arrangements
- Include applicable capitation methodology and rates

Section II. Financial Projections— The PO must provide financial projections for a minimum of one year from the date of the latest submitted financial statement and from this date through one year beyond break-even. Financing arrangements must be described, including all documents supporting these arrangements for any projected deficits, along with evidence of financing arrangements for any projected deficit. The financial projections should be prepared using the accrual method of accounting in conformity with generally accepted accounting principles (GAAP) and using the *proforma* financial statement methodology.

Projections must include quarterly:

- Balance sheets for the applicant, using accrual accounting in conformity with GAAP. The National Association of Insurance Commissioners (NAIC)
 Financial Report #1 format may be used if also required for state licensure
- Statements of revenues and expenses for the legal entity. Projections should include enrollment and utilization in gross dollars as well as on a permember, per-month basis. Quarters should be consistent with standard calendar year quarters, including year-end totals. If an organization has a category of revenue and/or expense not included in the present definitions, provide an explanation
- Statements of cash flows

Note: For a line of business, the applicant should also complete a statement of revenue and expenses for the line.

Major assumptions must be stated in sufficient detail to allow an independent financial analyst to reconstruct projected figures using only the stated assumptions and should be justified to the extent that a knowledgeable reviewer would be convinced that they are reasonable. Assumptions should address all periods for which projections are made, including inflation assumptions; details of minor assumptions will be verified on site.

Note: For a line of business, assumptions need only be submitted to support the projections of the line.

Justifications should include operating and capital budget breakdowns and be based on such factors as the applicant's experience and the experience of other health plans; hospital and health professional costs, and utilization should be described in detail.

RAIs:

 Compare actual to projected performance for most current, complete year and explain differences

Section III. Insolvency [42 CFR Part 460.80(b)]—This section must describe the PO's provisions for the event of insolvency, including:

- Continuation of benefits for the duration of the period for which capitation payment has been made
- Continuation of benefits to participants who are confined in a hospital on the date of insolvency until their discharge
- Protection of participants from liability for payment of fees that are the legal obligation of the PO

In the Documents part, the PO must demonstrate that in the event it becomes insolvent, it can cover expenses of:

- At least the sum of one month's total capitation revenue to cover expenses the month prior to insolvency
- One month's average payment to all contractors, based on the prior quarter's average payment, to cover expenses the month after the date insolvency is declared or operations cease

Note: Arrangements to cover expenses may include but are not limited to insolvency insurance or reinsurance, hold-harmless arrangements, letters of credit, guarantees, net worth, restricted state reserves or state law provisions.

RAIs:

- If using cash reserves, describe other uses
- Note where required reserves are held
- Describe current reserve level
- Note hold-harmless agreements in place

Section IV. Financial Risk (42 CFR Part 460.80(c)—Using the Insurance Table the PO must summarize insurance or other arrangements for major types of loss and liability. The table should be completed in *paceinsu.doc* in its file on the disk with the hard copy placed in the Documents part.

RAIs:

Provide copies of reinsurance policies

Section V. Financial Record Keeping and Reporting (42 CFR Part 460.204-208)— The PO should describe how its financial records and reports meet the regulatory requirements and how it will ensure submission of quarterly and annual certified financial statements in a format acceptable to CMS and the state. Also describe who is responsible for generating reports.

Chapter 4. Marketing

Section I. Marketing (42 CFR Part 460.82)—Copies of all marketing materials to be distributed by the PO as a permanent provider must be included in the Documents part. The PO should identify in which languages marketing materials will be available and assure that once marketing materials have been approved by CMS and the SAA, they will be translated into all identified languages, including translations into Braille for visually impaired participants.

Marketing materials should describe:

- Enrollment and disenrollment policies and processes, specifying enrollment effective dates relative to signing enrollment agreement
- Spend-down and premium obligations for different payer status (dual, Medicaid, Medicare, private)
- Benefits and additional services participants may receive, clearly stating that
 acute and emergency services are covered; and clarifying that all services,
 except for urgent care and emergency care, must be received through the PO's
 staff or contracted providers
- Any premium information and explain access to services, including emergencies (using the prudent layperson definition of an emergency)
- Training, oversight and enforcement the PO will use to ensure that its employees or agents do not use prohibited marketing practices
- Liability to potential participants, caregivers and other health care providers

Once approved marketing materials have been translated they must be submitted along with an attestation of accurate translation to the SAA, which will forward them to the CMS Regional Office. POs may NOT utilize the English version of marketing materials until translated materials and the accompanying attestation are received by the CMS Regional Office.

Note: ALL marketing materials must clearly state that PACE participants may be fully and personally liable for the costs of unauthorized or out-of-network services.

RAIs:

- Address non-English and visually impaired versions of materials
- Participants should be informed that they can attend any Center they wish
- Describe marketing department, including position description of person in charge
- Provide scripts used when discussing PACE with participants
- Submit mailings, flyers, print, radio, television, slide presentations and videos for approval before use
- Explain enrollment and disenrollment process
- Specify enrollment effective dates in relation to date of enrollment agreement signing
- Describe spend-down and premium obligation for Medicaid, Medicare, dual and private

Section II. Marketing Projections [42 CFR Part 460.82(f)]—Provide in the Documents part a marketing plan and outreach efforts with measurable enrollment objectives and a system for tracking effectiveness. Projected and actual enrollment levels need to be verified. The plan should in no way discriminate against populations who might reside in a particular service area or purposely target more healthy individuals.

RAIs:

- Should be based on realistic assumptions
- Explain if targeting hospitals outside the service area
- Describe how inquiries are tracked
- Provide monthly census and referral projections/experience
- Be more specific about premium costs for Medicare-only and private-pay participants

Chapter 5: PACE Services

Section I. Required Services (42 CFR Part 460.92 - 94)—Application must include a completed table for how the PO will provide required health services, ensuring names and titles in organizational chart in Chapter 1 are consistent with the table. Services should include all Medicare-covered items and services, all Medicaid-covered items and services, and other services determined medically necessary by the PO's IDT.

Section II. Service Delivery (42 CFR Part 460.98)—PO should describe how it will establish and implement a written plan to provide everyday, around-the-clock, medical, health and integrated social services that meet the acute and long-term care needs of each participant whether at the PACE Centers, alternative delivery sites, the participants' homes or inpatient facilities.

Application should review the roles of IDT members in formulating care plans and describe how the IDT monitors care during temporary or permanent nursing-home placements. It also should explain policies and procedures for participant transfers to other treatment settings and the process for accessing medical assistance and non-emergency services when Center is closed or, for example, when weather is bad (on-call procedures). Describe how on-call system is communicated to caregivers and participants and how inpatient care is coordinated for participants not admitted by the PO physician.

Policies must make clear that PO cannot discriminate against any participant in the delivery of required PACE services based on race, ethnicity, national origin, religion, sex, age, sexual orientation, mental or physical disability or payment source.

RAIs:

- Provide copies of clinical practice guidelines and formularies
- Describe role of IDT in formulating care plans
- Describe on-call system
- Describe how inpatient care is coordinated for participants not admitted by the PO physician

Final PACE regulations add sexual orientation to list of populations against which POs cannot discriminate. [See, 42 CFR Part 460.112(a)]

Section III. PACE Centers (42 CFR Part 460.98)—Describe locations of PACE Centers in relationship to the defined service area and whether there is sufficient capacity to allow routine attendance by participants. Explain expected attendance and how smokers are accommodated.

Describe PO's plan to increase number of Centers, staff or other PACE services when necessary to provide for accessible and adequate participant services. Describe how IDT determines the frequency of each participant's attendance at the Center based on his or her needs.

RAIs:

- Estimate number of participants in Center at any given time
- Estimate capacity for routine attendance
- Assure capacity is adequate in case of a 24-hour emergency (i.e., when no one leaves in the course of a day)

Final PACE regulations revise definition of "PACE Center" as "the focal point for coordination and provision of most PACE services." Specifically, 42 CFR Part 460.6 states the "PACE center is a facility which includes a primary care clinic, and areas for therapeutic recreation, restorative therapies, socialization, personal care, and dining, and which serves as the focal point for coordination and provision of most PACE services."

Section IV. Emergency Care (42 CFR Part 460.100)—Provide written emergency care plan that addresses PO's capacity to handle post-stabilization requirements and includes hold-harmless and prudent layperson standard provisions. Describe procedures used to explain to participants how to recognize the need for emergency care and include the explanation given to each participant. Also describe procedures used to ensure that each participant, caregiver or both understand how to access emergency care, urgently needed care and out-of-network services.

RAIs:

- Address capacity to handle post-stabilization requirements
- Describe how the PO will coordinate care if a non-PACE hospital is used
- Address the PO physician's role in emergencies

Section V. Interdisciplinary Team (IDT) (42 CFR Part 460.102)—The application should describe process for assigning each participant to an IDT at the Center and identify all IDT members. Provide in the Documents part a position description for each IDT member.

Final regs require that Social Workers on IDT hold Master's degrees. [See, 42 CFR Part 460.102 (b)(3)]

The PO should describe how it assures each IDT member, including contractors:

- Regularly inform the IDT of the medical, functional and psychological condition of each participant
- Remain alert to pertinent input from IDT members, participants and caregivers

 Ensure that documentation and other communications about changes in a participant's condition are included in his or her medical record

The application should describe the procedures that ensure confidentiality in exchange of information between IDT members, contractors, participants and caregivers. These procedures must address all forms of communication, who has access, conditions for releasing information, who is allowed to document on record and how the record will be safeguarded.

RAIs:

Discuss how meeting records are incorporated into a participant's record Define recreational therapy assistant duties Explain how staff who miss meetings are informed of changes

Section VI. Participant Assessment (42 CFR Part 460.104)—The PO should describe a clear assessment policy ensuring that an IDT member will conduct an initial comprehensive assessment of each participant. Include a timeframe for completing the assessment during enrollment process and include disciplines and criteria specified in the regulation.

Describe how PO consolidates discipline-specific assessments into a single plan of care for each participant. Plans of care must be ongoing, current and must include input from participant and caregiver.

Note: Ensure that female participants are entitled to choose a qualified specialist for women's health services from the PO's provider network to furnish routine or preventative care.

RAIs:

- Detail how home environment is assessed, specifying participant's role
- Allow for a full range of disciplines that could be relevant
- Explain how disciplines involved in assessment are determined
- Be specific about timeframes for responding to a reassessment request
- Describe criteria that determines who participates in three-month reassessment

The Final PACE regulations require that both PTs and OTs participate in initial assessment and annual reassessment. [See, 42 CFR Part 460.104(a)(2)(iv) and (v)]

Section VII. Reassessments (42 CFR Part 460.104)—Explain procedures that assure that in addition to regularly scheduled reassessments, participants will be reassessed whenever their health or psychological status changes or at the request of the participant or a designated representative. Describe which IDT members participate in periodic, annual and semiannual reassessments. Each reassessment should:

- Reevaluate the participant's plan of care
- Discuss any changes with IDT members
- Obtain approval of revised plan from IDT members, the participant or their designated representative
- Document all information in the participant's medical record

- Furnish any service included in the revised care plan to the participant when he
 or she needs it
- Explain procedures for denying request of participant or designated representative
- Determine when additional disciplines will be included in reassessment

As stated in the preceding section, the final PACE regulations require that both PTs and OTs participate in initial assessment and annual reassessment. [See, 42 CFR Part 460.104(a)(2)(iv) and (v)]

Section VIII. Plan of Care (42 CFR Part 460.106)— Explain process the IDT will use to implement, coordinate and monitor a participant's plan of care, including health and psychosocial status, whether PO employees or contractors furnish services. Explain process IDT members will use to reevaluate plans of care at least on a semiannual basis and document the plan of care or any changes made to it in the participant's medical record.

Also describe how plans of care will be consolidated among disciplines and how the participant, caregiver or both are brought into the care-planning process. Include a sample plan of care in Documents part.

Waivers granted for Chapter 5 allow for and waive:

- Use of community-based primary care physician(s)
- Primary care physician to meet the needs of participants outside the PACE center and not to serve primarily PACE participants
- Nurse practitioner to operate in role of primary care provider
- Social Worker without a Master's Degree
- IDT members not to primarily serve PACE participants
- Requirement for IDT to include dietician and home care coordinator
- Certain IDT (primarily transportation drivers and personal care attendants) priorexperience requirements

Chapter 6: Participant Rights

Section I. Bill of Rights (42 CFR Part 460.110-112)— The PO should provide a copy of the Participant Bill of Rights in the Documents part, utilizing the Participant Rights template found at www.cms.hhs.gov/pace/prtemp.pdf.

Section II. Explanation of Rights (42 CFR Part 460.112 and 116-118)—The applicant should summarize policies and procedures for informing participants of their rights in easy-to-understand language to ensure they understand those rights; avoid using the term "complaint." Application should include "long version" of the enrollment agreement and describe Medicare and Medicaid appeal processes (if not described in detail in this section, the appeals processes are likely explained in detail in Section IV of this chapter).

Posted version should be the same as included in the participant handbook and translated into the same languages as identified by the SAA for service area, including into Braille for visually impaired participants. The application must explain how translator

services will be obtained for these languages and how any additional translator/interpreter services will be obtained as needed.

The application should summarize policies and procedures for staff education, including contract staff, regarding participant rights to ensure that staff understands those rights and how to report violations, and policies and procedures for promoting participant rights. It also should describe the process for identifying, responding to and rectifying violations.

RAIs:

- Explain how participant responsibilities, rules and regulations governing participation will be conveyed to participants
- Make sure written materials are available in all applicable languages
- Explain how additional translator/interpreter services will be obtained if needed
- Explain how PO promotes the right to vote, autonomy, making choices, voicing suggestions, and participating in care-planning decisions

Section III. Restraints (42 CFR Part 460.114)—Describe the PO's policies and procedures regarding the use of chemical or physical restraints, including:

- Circumstances under which they may be used
- Requirements for documentation
- Symptoms that led to their consideration
- Less-restrictive approaches utilized
- Evaluation of participant responses
- Specific goals to be achieved by the use of restraints
- Definition and examples of restraints allowed
- Staff training regarding the use of restraints, care of participants while restrained, hazards of restraints and alternative approaches, reduction or elimination in restraint use, and care-plan requirements

RAIs:

- Describe criteria for use of restraints
- Describe staff training on use of restraints
- Describe how restraints are documented in care plan

Section IV. Grievance and Appeal Process (42 CFR Part 460.120 – 124)—Provide in the Documents part a copy of the formal written grievance process and a copy of the information on grievances that will be provided annually to participants.

Describe how grievance data will be collected, aggregated, analyzed, trended and included in the QAPI plan, and the process for informing participants of their additional appeal rights under Medicare and/or Medicaid, including the process for filing further appeals. Explain how the PO will ensure participant, family and staff understand policies and process, including additional appeal rights, and identify who is responsible for maintaining confidentiality how it will be maintained.

RAIs:

- Process must be detailed and specific
- Language must be easily understood and consistent
- Must include explanation of participant's right to additional appeals

- Must specify what information on appeals is provided to participants upon enrollment and annually thereafter
- Clarify how oral and written grievances will be handled
- Differentiate processes for dealing with medical and non-medical issues
- Detail how grievances will be coordinated between all departments
- Include process for tracking and trending grievances for the QAPI plan
- Include who is responsible for initiating response or follow up for grievances and appeals
- Clarify whether the PO internal process must be exhausted before participant may pursue additional appeals

Chapter 7. Quality Assessment & Performance Improvement (QAPI)

Section I. QAPI Plan (42 CFR Part 460.132)—Application must include a copy of the PO's QAPI Plan in the Documents part. It also must specify how the QAPI plan:

- Receives approval and revisions annually from the Board
- Identifies areas which to improve or maintain the delivery of services and patient care
- Develops and implements plans of action to improve or maintain quality of care
- Documents and disseminates to PO staff and contractors QAPI Plan results.

RAIs:

- Address how QAPI reports will be communicated to the Board
- Describe confidentiality for QAPI activities
- Explain process for communicating QAPI results to contractors

Section II. Minimum Requirements for QAPI (42 CFR Part 460.134)—In this section the PO must describe the methodology it will use to demonstrate improved performance with regard to:

- Utilization of PACE services, such as decreased inpatient hospitalizations and emergency room visits
- Caregiver and participant satisfaction
- Outcome measures derived from data collected during assessments, including data on participants' physiological well being, functional status, cognitive ability, social/behavioral functioning and quality of life
- Effectiveness and safety of staff-provided and contracted services, including competency of clinical staff, promptness of service delivery, achievement of treatment goals and measurable outcomes
- Non-clinical areas, such as grievances and appeals, transportation services, meals, life safety and environmental issues

It also must specify clinical practice guidelines and professional practice standards on which outcome measures and standards of care are based. (Note: Clinical practice guidelines are those national, regional or statewide scientifically derived tools recognized as best practice patterns. Professional practice standards are defined by each state for each licensed group and also may be defined by professional organizations).

Describe how PO ensures it meets or exceeds minimum levels of performance established by CMS and the state on standardized quality measures specified in the Program Agreement, and that all data used for outcome measures are accurate, complete and collected in a timely manner. Also describe the standard codes and formats utilized.

RAIs:

- Describe process for selection of objective measures
- Describe outcome measures derived from collected data
- Describe clinical practice guidelines on which outcome measures are based
- Specify data collection, storage, analysis, reporting and oversight.

Section III. Internal QAPI Activities (42 CFR Part 460.136)—The application must describe how the PO:

- Uses a set of outcome measures to identify areas of exemplary or problematic performance
- Takes actions targeted at maintaining or improving care
- Incorporates actions resulting in performance improvement into standards of practice for the delivery of care and periodically tracks performance to ensure improvements are sustained over time
- Sets priorities for performance improvement and gives priority to improvement activities that affect clinical outcomes
- Immediately corrects any identified problem that directly or potentially threatens the health and safety of a participant

The PO should explain how it ensures that all IDT members, employees and contract providers are involved in developing and implementing QAPI activities and are aware of their results. It also should identify a person designated to coordinate and oversee implementation of QAPI activities and explain how he or she encourages participants and their representatives to be involved in QAPI activities, including providing information about their satisfaction or dissatisfaction with provider services.

RAIs:

Specify:

- Priorities for improvement
- Contractors' involvement
- Feedback loop
- How quality assurance committee will assess contracted entities and services
- Participant and caregiver involvement in process

Section IV. Community-Input Committees (42 CFR Part 460.138)—Describe any committees established by the PO that use community input to:

- Evaluate data collected pertaining to quality outcome measures
- Address the implementation of and results from the QAPI plan
- Provide input related to ethical decision-making, including end-of-life issues and implementation of the Patient Self-Determination Act

Section V. Additional Quality Activities (42 CFR Part 460.140)—The PO should describe how it will meet external quality assessment and reporting requirements as specified by CMS or the SAA. This should include the health care data system and data-

entry processes, both manual and electronic, utilized to ensure data are collected in standardized formats.

Chapter 8: Participant Enrollment and Disenrollment

Section I. Eligibility to Enroll (42 CFR Part 460.150)—The application should describe how the PO will ensure that participants meet PACE eligibility requirements and specify any additional site-specific eligibility conditions proposed. It should specify the criteria used to determine whether a participant's health or safety would be jeopardized by living in a community setting and how the level-of-care determination conducted by the SAA or its delegate is communicated to the PO.

RAIs:

- Describe criteria for determining nursing-home level of care
- Specify potential participant screening process
- Describe process for ensuring eligibility for Medicaid-only potential participants
- Specify criteria for determining if participant is safe to live in community setting

Section II. Enrollment Process (42 CFR Part 460.152)—Describe enrollment and intake processes, including:

- Staff responsible for explaining the program to potential enrollees
- Obtaining appropriate medical and financial information releases
- The requirement that the PO be the sole-service provider and guarantee access to all services, but not to a specific provider
- Timeframes for providing the participant a list of employees and contractors who furnish care
- Applicable premium or Medicaid spend-down requirements
- Explanation of the post-eligibility treatment of income to potential participants and their representatives or caregivers
- Effective date of enrollment

The PO should provide a copy of all enrollment policies and procedures and interview and/or enrollment scripts, assessment criteria and other assessment forms utilized by appropriate staff during the enrollment process.

It should describe the process used to inform prospective enrollees that they have been denied enrollment and the procedures to inform CMS and the state of enrollment denials. Copies of form letters and procedures should be included in Documents part. The application also should describe procedures the PO uses to direct prospective enrollees to other sources of care after determining they are ineligible for PACE.

RAIs:

- Detail enrollment process and timeframes
- Describe notification of denial of enrollment timelines
- Describe what happens if state and PO disagree on denial of enrollment

Section III. Enrollment Agreement (42 CFR Part 460.154)—Submit a copy of the proposed enrollment agreement that includes all items referenced in the regulations in the Documents part.

RAIs:

- Clarify that enrollment in PACE results in disenrollment from any other Medicaid prepayment plan and, conversely, that enrolling in any other Medicare or Medicaid prepayment plan or optional benefit after enrolling in PACE will cause voluntary disenrollment from PACE
- Include in enrollment agreement appropriate lock-in language, timelines for enrollment process, out-of-area access to care and consequences of prolonged out-of-area stay

Section IV. Other Enrollment Procedures (42 CFR Part 460.156)—Submit copies of the following in the Documents part:

- The PACE membership card (if used)
- Emergency information to be posted in participants' homes
- Stickers to be applied to the Medicare/Medicaid cards (if used)
- · Any other relevant materials that are distributed

Describe the process for ensuring that if there are changes in the enrollment agreement information at any time during the participant's enrollment, the PO will provide an updated copy of the information and explain the changes to participants and their designated representatives in a manner they understand.

The Final PACE regulations:

- Require that the applicant or his or her representative sign and date the enrollment agreement [See, 42 CFR Part 460.154(t)]
- Disallow Medicare participants from enrolling in or disenrolling from PACE at Social Security offices [See, 42 CFR Part 460.154 (h)]
- Require that intake process includes explanation of post-eligibility treatment of income [See, 42 CFR Part 460.152 (a)(1)(vi)]

Section V. Voluntary Disenrollment (42 CFR Part 460.162)—Provide a copy of the policies and procedures for voluntary disenrollment and explain the process used to notify CMS and the state of the effective date of the voluntary disenrollment.

Section VI. Involuntary Disenrollment (42 CFR Part 460.164)—Provide a copy of the policies and procedures for involuntary disenrollment. Identify staff members involved in involuntary disenrollment decisions and any safeguards in place to protect the rights of participants in these circumstances. Describe how the state is notified of a potential disenrollment and the process for providing reasonable advance notice to the participant.

RAIs:

• Detail reasons for involuntary disenrollment

Section VII. Reinstatement in Other Medicare or Medicaid Programs (42 CFR Part 460.168)—Describe procedures the PO uses to direct voluntarily or involuntarily disenroll participants to other sources of care. Describe procedures the PO uses to make appropriate referrals and ensure medical records are made available in a timely manner to new providers.

Describe process to reinstate the participant in other Medicare or Medicaid programs for which the participant is eligible.

Section VIII. Reinstatement in PACE (42 CFR Part 460.170)—Describe the procedures to reinstate participants who have been disenrolled.

RAIs:

- Avoid using the word "voluntary" in this section
- Clarify that reinstatement also is available to participants who were involuntarily disenrolled.

Section IX. Documentation of Disenrollment (42 CFR Part 460.172)—Describe the documentation to verify a participant's voluntary and involuntary disenrollment. Include a copy of any forms used in the disenrollment process in the Documents part. Describe how disenrollments are analyzed in the QAPI Plan.

Waivers for Chapter 8 have been granted to allow for involuntary disenrollment for:

- threatening or disruptive behavior of a participant's family member,
- noncompliance to the plan of care by the participant's family or caregiver, and
- failure to pay Medicaid spend-down amounts or share of costs relating to nursing facility placement

Chapter 9: Payment

Section I. Payment to PACE Providers (42 CFR Part 460.180-182)—The Medicare and Medicaid monthly capitation payments will be payment in full for services rendered to participants, with the exception of premiums under certain circumstances. The PO must have procedures to assure that all forms are signed and dated by responsible parties, including payment information form and Medicare contractor data.

Section II. Medicare as a Secondary Payer (42 CFR Part 460.180)—Describe the systems/procedures the PO will implement under the Medicare Secondary Payer provisions. Describe the systems/procedures the PO will use to avoid duplicate payment of health care services.

Final PACE regulations recognize that the CMS-HCC risk-adjustment payment model for Medicare Advantage plans is also the basis for Medicare payment to POs. (See, 42 CFR Part 460.180)

Waiver granted for Chapter 9 allows PO to continue to receive retrospective payment of premium for PACE services.

Chapter 10: Data Collection, Record Maintenance & Reporting

Section I. Maintenance of Records and Reporting Data (42 CFR Part 460.200)—PO should describe procedures to collect data, maintain records and submit reports as required by CMS and the state, including who has access to data and records. PO also should submit policies on safeguarding data and records, including those of disenrolled participants, against loss, destruction or unauthorized use for period of time specified in state law or six years from the last entry date in the record, whichever is longer.

RAIs:

- Describe where and how participant medical and financial records, personnel records and health-outcome data are stored
- Describe process for safeguarding data

The PO should describe how all data are checked for accuracy, under what circumstances the original medical record would be released from the center, timeframes for completing medical record documentation (filing and authorized discipline documentation), and processes to evaluate the completeness, logic and consistency of data on an ongoing basis.

Written policies and procedures on protecting the confidentiality of all data and records also should be described, including:

- What information may be copied and released to authorized individuals
- How the PO will comply with federal (HIPAA) and state law regarding the release of participant medical information
- The process for identifying Protected Health Information (PHI)
- The process for granting participants timely access to reviewing, copying and requesting amendments to their medical records

Section II. Participant Health Outcomes Data (42 CFR Part 460.202)—Describe the PO's health information system designed to collect outcomes data. The PO must assure it will furnish data and information pertaining to its provision of participant care in the manner and at the time intervals specified by CMS and the state. These data are specified in the Program Agreement.

RAIs:

 Describe the health information system that will be designed to collect outcome data

Section III. Medical Records (42 CFR Part 460.210)—Describe how the PO ensures that a comprehensive, complete and accurate medical record is maintained in accordance with accepted professional standards and housed by the Center providing services to the participant.

Participant records should include:

- A list of what is contained in the medical record
- The PO's acceptable forms of documentation
- Storage procedures if the medical record becomes too large

FinalPACE regulations (42 CFR Part 460.210)w no longer require medical records to contain accident and incident reports. Instead, accident and incident reports should be maintained in a secure confidential location and available for review by the SAA and CMS.

The PO should describe how copies of medical record information will be promptly transferred between treatment facilities, how the primary author will authenticate the medical record entries and how the electronic data are held confidential.

The PO also should explain how all required documentation will be incorporated into one medical record at point of care or promptly thereafter (from other settings), how medical staff receive results of tests in a timely manner and how the system is evaluated for improvements.

In the Documents part the PO should provide a copy of the participant consent form used before releasing any participant information.

Chapter 11: Medicare Part D Application and Approval Process

States' limited role—The PACE application's newest chapter concerns PO Medicare Part D bid submission and the CMS approval process. States will be notified when the provider receives an "H" number from CMS' Health Plan Management System (HPMS) when it submits the Part D bid and when CMS approves it, but states are not required to play a review role in the Part D submission and approval process.

Resources

National PACE Association (NPA) www.npaonline.org

- NPA Summary of Changes in PACE Final Rule published on December 8, 2006
- NPA Summary of CMS-Approved Waivers, as of January, 2005
- Accelerating State Access to PACE (ASAP) Guidebook
- Report on Model State Practices for PACE, Accelerating State Access to PACE, February, 2004
- NPA Core Resource Set for PACE (CRSP), "CMS Requests for Additional Information," Dec. 2002
- PACE Provider Application Pre-conference Workshop, from NPA annual conference, Oct. 13, 2002

Centers for Medicare and Medicaid Services (CMS) http://www.cms.hhs.gov/PACE

- Provider Application and Appendices
- PACE Fact Sheet
- BIPA 903 Waiver Request information
- CMS PACE Application Review Guide Desk Review Tool, March 2004
- CMS (then HCFA) Nov. 9, 2000 letter to State Medicaid Directors