10 - Introduction to PACE
(Rev. 2, Issued: 06-09-11; Effective: 06-03-11; Implementation: 06-03-11)

In the 1970's the federal and state governments became increasingly interested in the development of community-based services. As a result, waivers of federal Medicaid requirements allowed state governments to experiment with fee-for-service programs for frail elderly and disabled beneficiaries. One such program was the Programs of All-Inclusive Care for the Elderly (PACE), which was developed at On Lok Senior Health Services in San Francisco through a series of demonstration projects. On Lok enrollees were among the frailest elderly in the community, those considered most at risk or otherwise needing institutional placement to receive long-term care services. With a one-year grant from The Robert Wood Johnson Foundation (RWJF), On Lok initiated a project to determine the feasibility of replicating the model in other parts of the country. In 1986, Congress authorized waivers for ten replication sites. In 1987, the RWJF authorized start-up grants for replication sites and a grant to On Lok to provide technical assistance. The first replication sites initiated three-waiver demonstrations in 1990 and by 1994 there were ten replication sites operating under waivers. The PACE demonstration operated until PACE was established as a permanent Medicare program by the Balanced Budget Act of 1997 (BBA).

The PACE Protocol was first developed in 1990 as part of a cooperative effort involving staff from CMS, then the Health Care Financing Administration Office of Research Development and Information, States participating in the PACE replication, and PACE sites, including On Lok Senior Health Services. Most of the features of PACE continued from the demonstration into the permanent program, including the focus on the targeted population, the frail elderly, and the capitated funding mechanism.

In September 2006, CMS awarded $7.5 million in grant funds to organizations developing PACE in rural service areas. Fourteen organizations each received over $500,000 for the establishment of a PACE program in their area. This grant program was initiated through the Deficit Reduction Act of 2005. The funding was available through September 30, 2008, and was provided to all fourteen grantees that met the requirements as a PACE provider as demonstrated through the PACE provider application approval process.

10.1 - Demonstration Project History
(Rev. 2, Issued: 06-09-11; Effective: 06-03-11; Implementation: 06-03-11)

Section 603(c) of the Social Security Amendments of 1983 (Pub. L. 98–21), as extended by Section 9220 of the Consolidated Omnibus Budget Reconciliation Act (COBRA) of 1985 (Pub. L. 99–272), authorized the original demonstration waiver for On Lok Senior Health Services in San Francisco. Section 9412(b) of the Omnibus Budget Reconciliation Act (OBRA) of 1986, Pub. Law 99–509, as amended by Section 4118 of the OBRA of 1987 (Pub. L. 100-203, authorized the Secretary of HHS to grant waivers to organizations under a PACE demonstration project to determine whether the model of care developed by On Lok Senior Health Services could be replicated across the country (the number of
sites was originally limited to 10, but Section 4744(a)(1) of OBRA of 1990 (Pub. L. 101-508) authorized an increase to 15 demonstration sites. The PACE demonstration replicated a unique model of managed care service delivery for a small number of very frail community-dwelling elderly, most of whom were dually eligible for Medicare and Medicaid coverage and all of whom were assessed as being eligible for nursing home placement according to the standards established by their respective States. The model of care included as core services the provision of adult day health care and interdisciplinary team case management, through which access to and allocation of all health services was controlled. Physician, therapeutic, ancillary and social support services were furnished in the participant’s residence or on-site at the adult day health center, unless those locations were not feasible. Hospital, nursing home, home health, and other specialized services were furnished under contract. Financing of this model was accomplished through prospective capitation of both Medicare and Medicaid payments. Demonstration sites had been permitted by Section 4118(g) of OBRA of 1987 (Pub. Law 100–203) to assume full financial risk progressively over the initial three years, but that authority was removed by Section 4803(b)(1)(B) of the BBA.

10.2 - Legislative History
(Rev. 2, Issued: 06-09-11; Effective: 06-03-11; Implementation: 06-03-11)

Section 4801 of the BBA (Pub. L. 105–33) authorized the establishment of PACE under the Medicare program by adding Section 1894 to Title XVIII of the Social Security Act (the Act) which addresses Medicare payments to, and coverage of benefits under, PACE. Section 4802 of the BBA authorized the establishment of PACE as a State option under Medicaid by adding Section 1934 to Title XIX of the Act, which directly parallels the provisions of Section 1894 and addresses Medicaid payments to, and coverage of benefits under, PACE. Section 4803 of the BBA addresses the timely issuance of regulations, expansion and transition for PACE demonstration project waivers, priority and special consideration in processing applications, and repeal of current PACE demonstration project waiver authority.

In addition, Sections 1894(a)(3)(B) and 1934(a)(3)(B) of the Act allowed private, for-profit entities to participate in PACE, subject to a demonstration waiver described in Sections 1894(h) and 1934(h) of the Act. For-profit entities wishing to participate in PACE applied for a demonstration waiver under Section 1894(h) and 1934(h) of the Act. While participating in the PACE for-profit demonstration, they must meet all requirements set forth in PACE regulations. The PACE organization is expected to retain all key administrative functions including marketing and enrollment, quality assurance and program improvement, and contracting for institutional providers and other key staff. On July 24, 2009, CMS issued a Federal Register Notice announcing a closing date of July 26, 2010 for submission of proposals for the PACE for-profit demonstration project.

20 - Statutory and Regulatory Overview
(Rev. 2, Issued: 06-09-11; Effective: 06-03-11; Implementation: 06-03-11)
As discussed previously, Section 1894 of the Act addresses Medicare payments to, and coverage of benefits under, PACE. Section 1934 of the Act addresses PACE as a State option under Medicaid for States electing PACE as an optional Medicaid benefit under Section 1905(a)(26) of the Act. The regulations implementing these PACE statutory requirements are set forth in 42 CFR Part 460. This manual provides further guidance on the PACE program.

[42 CFR § 460.2]

20.1 - State Medicaid Plan Requirement
(Rev. 2, Issued: 06-09-11; Effective: 06-03-11; Implementation: 06-03-11)

The State Medicaid plan is the contract between the States and the Federal government under which States agree to administer the Medicaid program in accordance with Federal law and policy. The State plan preprint sets forth the scope of the Medicaid program, including groups covered, services furnished, and payment policy. When a State wants to change its State Medicaid plan, the State submits a “State Plan Amendment” (SPA), which must be approved by CMS in order for the State to receive Federal matching funds for the amended plan.

Section 1905(a)(26) of the Act, as added by Section 4802(a)(1) of the Balanced Budget Act (BBA), provides authority for States to elect PACE as an optional Medicaid benefit. The State plan electing the optional PACE program must be approved before CMS can approve an application for a PACE organization in that State.

To aid States in modifying their State plans, the CMS Center for Medicaid and State Operations developed an interim State plan preprint for PACE. A State Medicaid letter dated March 23, 1998, provided information and guidance to State Medicaid agencies on how to satisfy the SPA requirement. Additional directions for completing the SPA were provided in a State Medicaid Director letter that was issued November 9, 2000. The most current version of the State Plan preprint is available on the CMS PACE homepage: http://www.cms.hhs.gov/PACE/04_InformationforStateAgencies.asp.

20.2 - Consultations with State Agency on Aging
(Rev. 2, Issued: 06-09-11; Effective: 06-03-11; Implementation: 06-03-11)

Under the Older Americans Act, State Agencies on Aging were charged with the responsibility of promoting comprehensive, coordinated services and systems for older persons in their States. Consistent with this responsibility, State Agencies on Aging oversee important programs for home and community-based services, which are funded through Title III of the Older Americans Act, State revenues, and the Medicaid home and community-based waiver program. The State agencies also implement and oversee important planning, referral, case management, and quality assurance functions. In addition, State agencies are responsible for administering the State Long Term Care Ombudsman Program through which service quality in nursing homes and board and care
homes are monitored in every State. Each State agency that administers the PACE program should regularly consult with their respective State Agency on Aging in order to avoid service duplication in the PACE service areas and to assure the delivery and quality of services to PACE participants.

**20.3 - Interaction with Medicare Advantage**  
*(Rev. 2, Issued: 06-09-11; Effective: 06-03-11; Implementation: 06-03-11)*

Although the PACE program has certain fundamental similarities to Medicare Advantage and managed care organizations, PACE is not a Medicare Advantage plan. The Balanced Budget Act (BBA) established distinct requirements for the PACE program. PACE is similar to some Medicare Advantage options in these ways: it is capitated; it is risk-based; it provides managed care; and it is an elective option. However, PACE differs significantly from a Medicare Advantage plan in other ways such as: it is not available nationwide (only in a limited number of states); it includes statutory waivers that expand the scope of Medicare covered services; it is not available to all beneficiaries (only to a defined subset of frail elderly); and it is a joint Medicare/Medicaid program. The BBA in sections 1894(f)(3)(A) and 1934(f)(3)(A) of the Act directed CMS to consider some of the requirements established for Medicare Advantage programs while developing regulations for the PACE program relating beneficiary protections and program integrity.

**20.4 - Interaction with Medicare Part D**  
*(Rev. 2, Issued: 06-09-11; Effective: 06-03-11; Implementation: 06-03-11)*

PACE organizations offer Medicare Part D prescription drug coverage. Persons who join a PACE program will get Part D-covered drugs and all other necessary medication from the PACE program. Persons in a PACE program do not need to join a separate Medicare Part D prescription drug plan. Joining a separate Medicare drug plan will cause a person to be disenrolled from the PACE program. For more information, refer to: [http://www.cms.gov/PrescriptionDrugCovContra/Downloads/PACEApplication.pdf](http://www.cms.gov/PrescriptionDrugCovContra/Downloads/PACEApplication.pdf).

**20.5 - Flexibility**  
*(Rev. 2, Issued: 06-09-11; Effective: 06-03-11; Implementation: 06-03-11)*

The PACE regulation which established the requirements for PACE organizations is based on the On Lok, Inc. Protocol. The Protocol provided authority for CMS and the State Administering Agency (the State Agency designated to administer the PACE program), to waive specific requirements of the Protocol, if, in their judgment, the following criteria were met:

- The intent of the requirements were met by the proposed alternative and safe and quality care would be provided;
- Written requests for waivers were required to be approved by CMS and the State Administering Agency before implementation of the proposed alternative.
CMS incorporated the requirement under the Protocol in the PACE regulations to the extent consistent with the BBA provisions in Sections 1894 and 1934 of the Act. The intention was to allow some flexibility to promote PACE in rural and Tribal areas while maintaining consistency with the requirements for other PACE programs. The rationale for limited view of the flexibility provisions was based on our belief that all PACE demonstration programs were in compliance with the PACE protocol and, therefore, would need to make only minor changes in their operations to meet the PACE regulatory requirements. CMS intended to provide more flexibility to all PACE organizations once sufficient experience in administering the PACE program was achieved. However, CMS learned that although the early PACE demonstration programs initially complied with the Protocol, most of them modified the Protocol requirements as they expanded, using the flexibility authorized in the Protocol. While many of these modifications were related to the allowable areas of service coverage and arrangement provisions, many others were not authorized by the flexibility clause in the Protocol. Furthermore, many of the later PACE demonstration programs also inappropriately exercised the flexibility clause in the Protocol, especially with regard to direct employment of staff. Finally, very few of the waivers were requested in writing or approved by CMS or the State Administering Agency before implementation. Subsequently CMS revised regulations on the waiver process in accordance with the requirements of the Medicare, Medicaid, and SCHIP Benefits Improvement and Protection Act of 2000 (BIPA) (Pub. L. 106-554).

[64 FR 66302 (Nov. 24, 1999) and 67 FR 61496 (Oct. 1, 2002)]

30 - Overall Objective of PACE Model

(Rev. 2, Issued: 06-09-11; Effective: 06-03-11; Implementation: 06-03-11)

The Programs of All-Inclusive Care for the Elderly (PACE) is an innovative model that provides a range of integrated preventative, acute care, and long-term care services to manage the often complex medical, functional, and social needs of the frail elderly. PACE was created as a way to provide clients, family, caregivers and professional health care providers the flexibility to meet a person’s health care needs while continuing to live safely in the community.

The purpose of a PACE program is to provide pre-paid, capitated, comprehensive health care services that are designed to:

- Enhance the quality of life and autonomy for frail, older adults;
- Maximize dignity of and respect for older adults;
- Enable frail, older adults to live in their homes and in the community as long as medically and socially feasible; and
- Preserve and support the older adult’s family unit.
30.1 - Overview of the PACE Program
(Rev. 2, Issued: 06-09-11; Effective: 06-03-11; Implementation: 06-03-11)

PACE is a capitated benefit for frail elders authorized by the Balanced Budget Act of 1997 (BBA) that features a comprehensive service delivery system and integrated Medicare and Medicaid financing. The program is modeled on the system of care developed by On Lok Senior Health Services in San Francisco, California and was tested through demonstration projects that began in the mid-1980s. The BBA established PACE as a permanent entity within the Medicare program and enables states to provide PACE services to Medicaid beneficiaries as a state plan option. Operationally, the PACE program is unique as a three-way partnership between the Federal government, the State, and the PACE organization.

30.2 - PACE Organizations
(Rev. 2, Issued: 06-09-11; Effective: 06-03-11; Implementation: 06-03-11)

A PACE organization is a not-for-profit, for-profit private or public entity that is primarily engaged in providing PACE services. For-profit entities operating PACE organizations do so under demonstration authority. The following characteristics also apply to a PACE organization. It must:

- Have a governing body or a designated person functioning as a governing body that includes participant representation;
- Be able to provide the complete service package regardless of frequency or duration of services;
- Have a physical site and staff to provide primary care, social services, restorative therapies, personal care and supportive services, nutritional counseling, recreational therapy, and meals;
- Have a defined service area;
- Have safeguards against conflict of interest;
- Have demonstrated fiscal soundness;
- Have a formal Participant Bill of Rights; and
- Have a process to address grievances and appeals.

The PACE organization must not discriminate against any participant in the delivery of required PACE services based on race, ethnicity, national origin, religion, sex, age, mental or physical disability, sexual orientation, or source of payment.
30.3 - Eligibility and Benefits
(Rev. 2, Issued: 06-09-11; Effective: 06-03-11; Implementation: 06-03-11)

Participants must be age 55 or older; reside in the PACE organization’s service area; be certified as eligible for nursing home care by their state and be able to live safely in a community setting at the time of enrollment. Eligible beneficiaries who choose to enroll in PACE agree to forgo their usual sources of care and receive all their services through the PACE organization. (Additional information on Eligibility and Enrollment can be found in Chapter 4 of the PACE Manual).

PACE provides participants all the care and services covered by Medicare and Medicaid, as authorized by the interdisciplinary team (IDT), as well as additional medically-necessary care and services not covered by Medicare and Medicaid. There are no limitations or condition as to amount, duration or scope of services and there are no deductibles, copayments, coinsurance, or other cost sharing that would otherwise apply under Medicare or Medicaid. The IDT assesses the participant’s needs and develops a comprehensive care plan that meets the needs of its participants across all care settings on a 24 hour basis, each day of the year. Social and medical services are provided primarily in an adult day health care center, but are supplemented by in-home and referral services as needed.

The benefit package for all PACE participants includes: Primary Care, Hospital Care, Medical Specialty Services, Prescription Drugs (including Medicare Part D drugs), Nursing Home Services, Nursing Services, Personal Care Services, Emergency Services, Home Care, Physical Therapy, Occupational Therapy, Adult Day Health Care, Recreational Therapy, Meals, Dental Care, Nutritional Counseling, Social Services, Laboratory/X-Ray, Social Work Counseling, End of Life Care and Transportation. Hospital, Nursing Home, Home Health, and other specialized services are generally furnished under contract. In most cases, the comprehensive service package permits participants to continue living at home rather than be institutionalized.

30.4 - Payments to PACE Organizations
(Rev. 2, Issued: 06-09-11; Effective: 06-03-11; Implementation: 06-03-11)

PACE services are financed by combined Medicare and Medicaid prospective capitation payments, and, in some instances, through private premiums. PACE organizations receive a monthly capitation payment for each eligible enrollee, and combine these funds into a common pool from which providers pay health care expenses. This capitated financing allows PACE organizations to deliver all services participants need rather than be limited to those reimbursable under the Medicare and Medicaid fee-for-service systems. In exchange, PACE organizations assume full financial risk for all the health care services enrollees need.

As a Medicare program and a Medicaid state plan option, PACE organizations receive two capitation payments per month for dually eligible participants.
Medicare eligible participants who are not eligible for Medicaid pay monthly premiums equal to the Medicaid capitation amount and a premium for Medicare Part D drugs, but no deductibles, coinsurance, or other type of Medicare or Medicaid cost-sharing applies. For those participants eligible for Medicaid, but not Medicare, the state will pay the full cost to the PACE organizations. PACE providers assume full financial risk for participants' care without limits on amount, duration, or scope of services.

30.5 - Quality of Care
(Rev. 2, Issued: 06-09-11; Effective: 06-03-11; Implementation: 06-03-11)

The PACE organization is required to develop, implement, maintain, and evaluate an effective data-driven quality assessment and performance improvement (QAPI) program. It is important that the QAPI program take into consideration the wide range of services furnished by the PACE organization. PACE organizations have the flexibility to develop the QAPI program that best meets their needs in order that they may fully meet the obligations of care for its participants. It is CMS’ expectation that PACE organizations will operate a continuous QAPI program that does not limit activity to only selected kinds of services or types of patients. The desired outcome of the QAPI requirement is that data-driven quality assessment serves as the engine that drives and prioritizes continuous improvements for all PACE organizations services.
## Transmittals Issued for this Chapter

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