DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

42 CFR Parts 460, 462, 466, 473, and 476

[CMS–1201–F]

RIN 0938–AN83

Medicare and Medicaid Programs; Programs of All-Inclusive Care for the Elderly (PACE); Program Revisions

AGENCY: Centers for Medicare & Medicaid Services (CMS), HHS.

ACTION: Final rule.

SUMMARY: This rule finalizes the interim final rule with comment period published in the **Federal Register** November 24, 1999 (64 FR 66234) and the interim final rule with comment period published in the **Federal Register** on October 1, 2002 (67 FR 61496). The November 1999 interim final rule implemented sections 4801 through 4803 of the Balanced Budget Act of 1997 (Pub. L. 105–33) and established requirements for Programs of All-inclusive Care for the Elderly (PACE) under the Medicare and Medicaid programs. The interim final rule with comment period published on October 1, 2002 (67 FR 61496) implemented section 903 of the Medicare, Medicaid, and SCHIP Benefits Improvement and Protection Act of 2000 (BIPA) (Pub. L. 106–554).

DATES: *Effective Date:* These regulations are effective on January 8, 2007.

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SUPPLEMENTARY INFORMATION:

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ACRONYMS for the PACE Final Rule

ADLs Activities of Daily Living
BBA Balanced Budget Act of 1997
BIPA Medicare, Medicaid and SCHIP Benefits Improvement and Protection Act of 2000
CAP Corrective Action Plan
CBRR Consumer Bill of Rights and Responsibilities
CMS Centers for Medicare & Medicaid Services
COBRA Consolidated Omnibus Budget Reconciliation Act of 1985
COP Condition of Participation
CHSPR Center for Health Services and Policy Research
CMS–HCC CMS Hierarchical Conditions Category
ESRD End-Stage Renal Disease
FFP Federal Financial Participation
HOS Health Outcomes Survey
HPMS Health Plan Management System
IDT Interdisciplinary Team
IRE Independent Review Entity
LCS Life Safety Code
MA Medicare Advantage (formerly Medicare + Choice(M + C))
MA–PDP Medicare Advantage—Prescription Drug Plan
M + C Medicare + Choice (now Medicare Advantage (MA))
MMA Medicare Prescription Drug Improvement andModernization Act of 2003
NF Nursing Facility
NPA National PACE Association
OBCQI Outcome-Based Continuous Quality Improvement
PACE Programs of All-inclusive Care for the Elderly
PCA Personal Care Attendant
PCP Primary Care Physician
PHS PACE Health Survey
PO PACE Organization
QAPI Quality Assessment and Performance Improvement
RAI Request for Additional Information
SAA State Administering Agency
SFH State Fair Hearing
SPA State Plan Amendment
SSA Social Security Administration

Requirements for Issuance of Regulations

Section 902 of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (MMA) (Pub. L. 108–173 enacted on December 8, 2003, amended section 1871(a) of the Social Security Act (the Act)) requires the Secretary, in consultation with the Director of the Office of Management and Budget, to establish and publish timelines for the publication of Medicare final regulations based on the previous publication of a Medicare proposed or interim final regulation. Section 902 of the MMA states that the timelines for these regulations may vary among different regulations but shall not exceed 3 years after publication of the preceding proposed or interim final regulation except under exceptional circumstances. Section 902 also directs the Secretary to establish an appropriate period for finalizing those interim final regulations that were published before the enactment of MMA on December 8, 2003. Pursuant to this requirement, we published a notice in the **Federal Register** (69 FR 78442) establishing a publication deadline of 3 years from MMA enactment, that is December 8, 2006, for finalizing interim final rules published prior to MMA enactment.

This final rule finalizes provisions set forth in the November 24, 1999 and October 1, 2002 interim final rules with comment. These interim final regulations will be finalized within the 3-year period after MMA enactment that was established under section of the MMA 902. Therefore, we believe that this final rule is in accordance with the Congress' intent to ensure timely publication of final regulations.

I. Background

A. Program Description

The Program of All-inclusive Care for the Elderly (PACE) program is a unique model of managed care service delivery for the frail community-dwelling elderly, most of whom are dually eligible for Medicare and Medicaid benefits, and all of whom are assessed as being eligible for nursing home placement according to the standards established by their respective States.

B. Legislative History

1. Demonstration Project

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 of 1985 (COBRA) (Pub. L. 99–272) authorized the original demonstration PACE program for On Lok Senior Health Services (On Lok) in San Francisco. Section 9412(b) of Pub. L. 99–509, the Omnibus Budget Reconciliation Act of 1986 (OBRA, 1986), authorized us to conduct a PACE demonstration program to determine whether the model of care developed by On Lok could be replicated across the country. The number of sites was originally limited to 10, but the Omnibus Budget Reconciliation Act of l990 (Pub. L. 101–508) authorized an increase to 15 PACE demonstration programs.

The PACE model of care includes as core services the provision of adult day health care and interdisciplinary team (IDT) care management, through which access to and allocation of all health services is managed. Physician, therapeutic, ancillary, and social support services are furnished in the participant's residence or on-site at a PACE center. Hospital, nursing home, home health, and other specialized services are generally furnished under contract. Financing of the PACE demonstration model was accomplished through prospective capitation of both Medicare and Medicaid. PACE demonstration programs had been permitted by section 4118(g) of Pub. L. 100–203 (OBRA 1987) to assume full financial risk progressively over the initial three years. As such authority was removed by section 4803(b)(1)(B) of the Balanced Budget Act of 1997 (BBA) (Pub. L. 105–33), PACE demonstration programs approved after August 5, 1997 had to assume full financial risk at start-up.

The PACE demonstration program was operated under a Protocol established and published by On Lok, Inc. on April 4, 1995.

2. Balanced Budget Act of 1997 (BBA) (Pub. L. 105–33)

The BBA built on the success of the PACE demonstration program. Section 4801 of the BBA, authorized coverage of PACE under the Medicare program. It amended title XVIII of the Act by adding section 1894, which addresses Medicare payments and coverage of benefits under PACE. Section 4802 of the BBA authorized the establishment of PACE as a State option under Medicaid. It amended title XIX of the Act by adding section 1934, which directly parallels the provisions of section 1894. Section 4803 of the BBA addresses implementation of PACE under both Medicare and Medicaid, the effective date, timely issuance of regulations, priority and special consideration in processing applications, and transition from PACE demonstration program status.

As directed by section 4803 of BBA, we published an interim final rule on November 24, 1999, permitting entities to establish and operate PACE programs under section 1894 and 1934 of the Act (64 FR 66234).

The 1999 interim final rule was a comprehensive rule that addressed eligibility, administrative requirements, application procedures, services, payment, participant rights, and quality assurance.

a. Use of the PACE Protocol

Throughout the 1999 interim final rule, when we referred to ''the Protocol'' we meant the PACE Protocol, as published by On Lok, Inc., the parent company of On Lok Senior Health Services. A copy of the Protocol was included as an attachment to the 1999 interim final rule with comment period.

We were directed by sections 1894(f)(2) and 1934(f)(2) of the Act to incorporate into regulation the requirements applied to PACE demonstration programs under the Protocol, to the extent consistent with the provisions of sections 1894 and 1934 of the Act. We also were authorized to modify or waive certain provisions of the Protocol in the development of the regulation, if the modification or waiver were not inconsistent with and would not impair the essential elements, objectives, and requirements of sections 1894 and 1934 of the Act.

b. Consultation With States

Sections 4801 and 4802 of Pub. L. 105–33 clearly dictate a cooperative relationship between the Secretary and the States in the development, implementation and administration of the PACE program. In order to fulfill these requirements, we utilized the American Public Human Services (formerly, the American Public Welfare Association) as the conduit to solicit States for volunteers to consult with CMS staff. The participating State staff members represented States with a range of PACE experience. Each State staff volunteer selected a specific target area to provide information.

In order to efficiently and effectively obtain a large amount of feedback in a short period of time, CMS staff arranged a series of conference calls to discuss a wide range of issues pertaining to PACE including requirements on the application process, enrollment, and payment and related financial data collection. Each subject area discussion included CMS staff and two to three State representatives. The feedback obtained during these meetings was an invaluable source of information in understanding State operational concerns and in constructing the regulation. We believed that this approach would minimize operational barriers that are frequently inherent when new programs are initiated. For this reason, CMS continues to regularly consult and receive feedback from States regarding PACE policy by means of teleconferences and forums.

c. Consultation With State Agency on Aging

Under the Older Americans Act, State Agencies on Aging were charged with the responsibility of promoting comprehensive and coordinated service 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. In our 1999 interim final rule, we indicated we were considering the extent to which the State Long Term Care Ombudsman Program would be useful in promoting the rights of PACE participants and in monitoring the quality of care provided by PACE organizations (POs). We received a number of comments on this issue that we discuss in Subpart G ''Participant Rights'' of this final rule.

d. State Medicaid Plan Requirement

The State Medicaid plan is a comprehensive written statement submitted by the State and approved by CMS describing the nature and scope of the Medicaid program and giving assurance that the Medicaid program will be administered according to 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 completes a new State plan preprint page because of changes in its Medicaid program (called a ''State plan amendment (SPA)''), the preprint page must be approved by CMS in order for the State to receive Federal matching funds.

Section 1905(a)(26) of the Act, as added by section 4802(a)(1) of the BBA, provided authority for States to elect PACE as an optional Medicaid benefit. The State plan electing the optional PACE program must be approved before CMS and the State enter into a program agreement with a PO. 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 State plan amendment requirement. Additional directions for completing the State plan amendment 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.*

e. Interaction With Medicare+Choice (Now Medicare Advantage)

The BBA also established the Medicare+Choice (M+C) program, which expanded the health care options available to Medicare beneficiaries. Under the M+C program, beneficiaries could elect to receive Medicare benefits through enrollment in one of several private health plan choices beyond the original (fee-for-service) Medicare program or choose a plan previously available through managed care organizations under section 1876 of the Act.

The BBA set forth the requirements for M+C organizations in a new Part C of title XVIII of the Act. The interim final rule that implemented the M+C program was published June 26, 1998 (63 FR 34968). The final regulation addressing comments was published on February 17, 1999 (64 FR 7968).

Significant changes were made to the M+C program by the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (MMA) (Pub. L. 108–173, enacted on December 8, 2003). The two final regulations that implemented the MMA were published January 28, 2005 (70 FR 4194 and 4588). The first regulation established the Medicare Prescription Drug Benefit or Medicare Part D and the second regulation established the Medicare Advantage (MA) program which replaced the M+C program.

In this final rule, we are finalizing our regulations that implement the PACE provisions of the BBA and BIPA statutes. We are limiting our discussion of the effects of MMA provisions to those issues that have been addressed in other MMA rulemaking. We think our regulations on Part D and MA provide sufficient and appropriate guidance to all affected entities, including POs. However, we believe it is essential to highlight the impact of MMA, particularly with respect to how Medicare Part D relates to a PO. Specifically, the MMA provides that POs electing to provide Part D coverage to their enrollees shall be treated in a manner similar to Medicare Advantage Prescription Drug Plans (MA–PDPs). A more detailed discussion of the relevant MMA provisions is provided later in this section.

Although the PACE program has certain fundamental similarities to M+C (now MA), PACE is not a M+C plan. The BBA established separate and distinct requirements for the PACE program. PACE is similar to some M+C 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 M+C plans in other ways such as: it is not available nationwide (only in a limited number of sites); statutory waivers 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. However, the BBA directed us to consider some of the requirements established for the M+C program as we developed regulations for POs in certain areas common to both programs, for example, beneficiary protections, payment rates, and sanctions.

f. Flexibility Under the BBA

As noted above, the PACE demonstration program was operated pursuant to a Protocol developed by On Lok, Inc. The Protocol provided authority for CMS and the State Administering Agency (SAA) (that is, 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 was met by the proposed alternative and
- Safe and quality care would be provided.

In addition, written requests for waivers were required to be approved by CMS and the SAA before implementation of the proposed alternative.

Flexibility was limited to the requirements in the section on service coverage and arrangement. That section includes the following requirements:

- POs must provide all Medicare and Medicaid services and provide care 7 days per week, 365 days per year;
- A listing of required and excluded services and minimum services;
- Each participant be assigned to an IDT;
- The composition and duties of the IDT;
- The assessment and reassessment requirements.

Flexibility was not authorized for other sections of the Protocol, such as participant rights, enrollment and disenrollment, and administration.

Sections 1894(f)(2)(B) and 1934(f)(2)(B) of the Act give the Secretary the authority to waive regulatory provisions as follows:

> In order to provide for reasonable flexibility in adapting the PACE service delivery model to the needs of particular organizations (such as those in rural areas or those that may determine it appropriate to use non-staff physicians according to State licensing law requirements) * * * the Secretary (in close consultation with State administering agencies) may modify or waive provisions of the PACE protocol as long as the modification or waiver is consistent with and would not impair the essential elements, objectives, and requirements of this section * * *.

The statute also specifies the following essential elements that may not be waived:

- The focus on frail elderly qualifying individuals who require the level of care provided in a nursing facility.
- The delivery of comprehensive, integrated acute and long-term care services.
- The multidisciplinary team approach to care management and service delivery.
- Capitated, integrated financing that allows the provider to pool payments received from public and private programs and individuals.
- The assumption by the provider of full financial risk.

To implement sections 1894(f)(2)(B) and 1934(f)(2)(B) of the Act, in the 1999 interim final rule, we identified specific waivers that were intended to encourage the development of PACE programs in rural and Tribal areas. The waivers included the following three requirements:

- A prohibition on members of the governing body and their family members from having a direct or indirect interest in contracts with the organization (see § 460.68(c));

• A requirement that members of the IDT primarily serve PACE participants (see § 460.102(g)); and

• A requirement that the primary care physician (PCP) must be employed by the PO (see § 460.102(g)).

The regulation included specific criteria for each waiver related to whether the PO's service area is rural or Tribal, the accessibility of individuals who meet the three regulatory requirements listed above, and a requirement that the proposed alternative does not adversely affect the availability or quality of care furnished to PACE participants.

Our rationale for this initial, limited view of the flexibility provision was based on our belief that all PACE demonstration programs were in compliance with the Protocol, necessitating only minor changes in their operations to meet the PACE regulatory requirements. Our intention was to allow some flexibility to promote PACE in rural and Tribal areas while maintaining consistency of the requirements for other PACE programs. We intended to provide more flexibility to all POs once we had gained sufficient experience in administering the PACE program.

However, after publication of the 1999 interim final rule, we 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 SAA before implementation.

We subsequently revised our regulations on the waiver process in response to comments on the 1999 interim final rule and in accordance with the requirements of section 903 of the Medicare, Medicaid, and SCHIP Benefits Improvement and Protection Act of 2000 (BIPA) (Pub. L. 106–554, enacted on December 21, 2000), as discussed below. A detailed discussion of waivers and the waiver process is located in section III, subpart B of this final rule.

3. The Medicare, Medicaid, and SCHIP Benefits Improvement and Protection Act of 2000 (BIPA)

a. Background

BIPA modified the PACE program in the following three ways:

• Section 901 extended the transition period for the PACE demonstration programs to allow an additional year for these organizations to transition to the permanent PACE program.

• Section 902 gave the Secretary the authority to grandfather in the modifications these programs had implemented as of July 1, 2000. This provision allowed the PACE demonstration programs to continue program modifications they had implemented and avoid disruptions in participant care where these modifications were determined to be consistent with the PACE model. These sections were implemented administratively.

• Section 903 specifically addressed flexibility in exercising the waiver authority provided under sections 1894(f)(2)(B) and 1934(f)(2)(B) of the Act. It authorized CMS to modify or waive PACE regulatory provisions in a manner that responds promptly to the needs of POs relating to the areas of employment and the use of community-based PCPs. Section 903 of BIPA also established a 90-day review period for waiver requests. As the flexibility language is part of the statutory section dealing with regulations (sections 1894(f) and 1934(f) of the Act), we believed it was intended that waiver requirements be incorporated into the PACE regulations. In order to implement section 903 of BIPA, we published the 2002 PACE interim final rule.

b. Contracting for IDT Members and Administrative Staff

In the 2002 interim final rule, we amended the PACE regulations to replace the term ''multidisciplinary'' with ''interdisciplinary'' to more accurately reflect the interactive and collaborative approach of the PACE care team.

In the 2002 interim final rule, we responded to public comments regarding flexibility, including comments on § 460.102(f) of the 1999 interim final rule, which required that the PACE IDT members be employees of the PO or PACE center. In the 2002 interim final rule, we deleted § 460.102(f) and revised § 460.60 to allow the PO to employ or contract with the program director and the medical director. We also added requirements at § 460.70 that must be met when the PO is contracting for services.

A more detailed discussion of § 460.60 and § 460.70 is located in section III, subpart E of this final rule.

c. Contracting With Another Entity To Furnish PACE Center Services

After publication of the 1999 interim final rule, we learned that in 1995, On Lok, Inc. had changed the Protocol to reflect a contractual arrangement they entered into with another organization to provide all PACE center services. Under this arrangement, the IDT was employed and managed by the contracting organization but On Lok retained responsibility for all care provided to and all risk entailed in meeting the healthcare needs of the participants attending the center. Through this contractual relationship, On Lok was able to expand PACE services within their service area. As this approach was reflected in the PACE Protocol, we amended the PACE regulations in the 2002 interim final rule to allow POs to provide PACE center services through contractual arrangements. We also revised § 460.70 to identify the criteria that a PO must meet to contract out PACE center services. A more detailed discussion of § 460.70 is located in section at IV.B. of this final rule.

d. Oversight of Direct Patient Care Services

As discussed above, in the 2002 interim final rule, we revised the requirements of the 1999 interim final rule to allow for the contracting of IDT members, program director, medical director, and all PACE center services. For this reason, we believed it was essential to establish oversight criteria that POs must implement for all employees and contracted staff who furnish direct patient care. This was accomplished with the addition of § 460.71. A more detailed description of § 460.71 is located in section IV, subpart E of this final rule.

e. Waiver Process

To implement section 903 of BIPA, we established a process for submission and approval of waiver requests. The 2002 interim final rule amended the 1999 interim final rule by adding § 460.26, which specifies the requirements for submission and evaluation of waiver requests and § 460.28, which addresses requirements related to CMS review of waiver requests. In the 2002 interim final rule, we also removed the restrictive waiver provisions for rural and Tribal

organizations that were included in the 1999 interim final rule.

A more detailed description of § 460.26 and § 460.28 is located in section III, subpart B of this final rule.

4. Medicare Prescription Drug Improvement and Modernization Act of 2003 (MMA)

On December 8, 2003, the Congress enacted the MMA of 2003 (Pub. L. 108–173). Several sections of the MMA impact POs. Most notably, section 101 of the MMA affected the way in which POs are paid for providing certain outpatient prescription drugs to any Part D eligible participant. As specified in sections 1894 and 1934 of the Act, POs shall provide all medically necessary services including prescription drugs, without any limitation or condition as to amount, duration, or scope and without application of deductibles, co-payments, coinsurance, or other cost sharing that would otherwise apply under Medicare or Medicaid. Up until January 1, 2006, payment for drugs covered under Medicare parts A and B was included in the monthly Medicare capitation rate paid to POs for Medicare beneficiaries, while payment for outpatient prescription drugs was included in the monthly Medicaid capitation rate paid to POs for Medicaid recipients, or as a portion of the amount equal to the Medicaid premium paid by non-Medicaid recipients.

Consequently, in order for POs to continue to meet the statutory requirement of providing prescription drug coverage to their enrollees, and to ensure that they receive adequate payment for the provision of Part D drugs, beginning January 1, 2006, POs could begin to offer qualified prescription drug coverage to their enrollees who are Part D eligible individuals. The MMA did not impact the manner in which POs are paid for the provision of outpatient prescription drugs to non-part D eligible PACE participants.

Section 1860D–21(f) of the Act, added by section 101 of the MMA, provides that POs may elect to provide qualified prescription drug coverage to enrollees who are Part D eligible individuals.

This section also provides that in the case of a PACE program that elects to provide qualified Part D prescription drug coverage, the requirements under Part D apply to the provision of such coverage in a manner that is similar to the manner in which those requirements apply to the provision of such coverage under an MA–PD local plan. However, because we did not believe that Congress intended for the MMA to alter the way in which PACE services, including outpatient prescription drugs are provided to PACE enrollees, we indicated in the final rule that implements Part D (70 FR 4194) that POs would not be deemed to be MA–PD local plans, but rather, would be treated in a manner similar to an MA–PD local plan for purposes of payment under Part D. We stated that this approach is consistent with section 1894(d)(1) of the Act, which provides that payments will be made to POs ''in the same manner and from the same sources'' as payments are made to a MA organization.

The MMA allows CMS the flexibility to deem POs as MA–PD plans or to treat POs that elect to provide qualified drug coverage in a manner similar to MA–PD plans. Due to inconsistencies in the PACE and MMA statutes, we chose to treat POs in a similar manner as MA–PD plans avoiding conflicting requirements. The requirements that apply to POs that elect to provide qualified prescription drug coverage to Part D eligible enrollees are set forth in subpart T of the preamble to the Part D final rule (70 FR 4194). To the extent that we need to address additional issues regarding Part D as it applies to POs, we will do so in a future rulemaking.

In addition, section 236 of the MMA amended the Act to extend to POs the existing statutory Medicare and Medicaid balance billing protections that had previously applied to POs under PACE demonstration program authority. Specifically, provisions of the Act that limit balance billing against MA organizations by non-contract physicians, providers of service, and other entities with respect to services covered under title XVIII now include PACE providers. Similarly, Medicaid billing limitations specified in the Act now apply to providers participating under the State plan under title XIX that do not have a contract or other agreement with a PACE provider. Both MMA provisions apply to services furnished on or after January 1, 2004.

Section 301 of the MMA amends the Medicare Secondary Payer (MSP) provisions in section 1862(b) of the Act. These amendments clarify the obligations of primary plans and primary payers, the nature of the insurance arrangements subject to the MSP rules, the circumstances under which Medicare may make conditional payments, and the obligations of primary payers to reimburse Medicare. To implement section 301 of the MMA, we issued an interim final rule with comment period (71 FR 9466), published on February 24, 2006, revising our MSP regulations at part 411. Our PACE regulations at § 460.180(d) specify that Medicare does not pay for PACE services to the extent that Medicare is not the primary payer under part 411. The MSP interim final rule establishes our current policies regarding the obligations of other payers. If there are any provisions specific to PACE organizations that result from issuance of the final MSP rule, we will address those provisions in a future PACE rulemaking.

Finally, as discussed above, under the rulemaking requirements of section 902 of the MMA and our notice in the **Federal Register** on December 30, 2004 (69 FR 78442), interim final regulations issued before enactment of MMA on December 8, 2003 must be finalized within 3 years of the date of enactment or the regulations shall not continue in effect. This rule finalizes both the PACE interim final rule with comment period published in the **Federal Register** November 24, 1999 (64 FR 66234) and the PACE interim final rule with comment period published in the **Federal Register** on October 1, 2002 (67 FR 61496).

II. Analysis of and Response to Public Comments

This final rule responds to public comments received on both the November 24, 1999 interim final rule with comment (64 FR 66234) and the October 1, 2002 interim final rule with comment (67 FR 61496).

A. Summary of Comments on the 1999 Interim Final Rule

We received 34 items of correspondence containing more than 500 specific comments on the 1999 interim final rule. In this document, we will refer to this regulation as the 1999 interim final rule. Commenters included representatives of professional associations, State and county governments, PACE demonstration programs, potential PACE programs, various health care providers, and advocacy organizations.

Consistent with the scope of the 1999 interim final rule, most of the commenters addressed multiple issues, often in great detail. Some commenters expressed concerns about Medicare and Medicaid issues that do not pertain to the PACE program.

Numerous commenters disapproved of the limited flexibility provided in the regulation, stating that the regulation restricts programs from developing innovatively and responsively to participant preferences, community needs, and the healthcare marketplace. They asked for operational and service delivery flexibility, while permitting

liberal exceptions for established programs that have proven success in furnishing the PACE benefit. Commenters also noted the regulatory language was too prescriptive in several key areas (personnel qualifications) and too vague in others (Medicare rate-setting), saying that prescriptive language also reduces flexibility in organizational design and limits innovative strategies for service delivery.

Commenters indicated that the application of M+C requirements was often made without considering the differences between the PACE program and M+C plans and that the differences between PACE and nursing facilities should be recognized in the final requirements.

In addition, commenters indicated that the numerous written notices required by the 1999 interim final rule were unduly burdensome.

Comments also indicated that in some instances requirements from other programs (for example, the Outcome Assessment Information Set (OASIS) for home health agencies) have been applied to PACE, thereby disregarding the differences between the programs and adding the burden of information collection.

Finally, commenters opposed the prescriptive language that they thought limited State discretion and usurped traditional State regulatory activities rather than optimizing the opportunity to encourage cooperation with the States. We respond to the particular comments as they relate to specific provisions discussed in section III of this final rule.

Listed below are the six areas of the 1999 interim final rule that generated the most concern:

Subpart D: Sanctions, Enforcement Actions and Termination including civil money penalties;

Subpart E: PACE Administrative Requirements including organizational structure, personnel qualifications, contracted services and marketing;

Subpart F: PACE Services including the interdisciplinary team and participant assessment;

Subpart G: Participant Rights including the appeals process;

Subpart I: Participant Enrollment and Disenrollment which includes eligibility to enroll, enrollment process, continuation of enrollment, and involuntary disenrollment;

Subpart J: Payment including Medicare payment.

B. Summary of Comments on the 2002 Interim Final Rule

We received 4 letters of public comment on the October 1, 2002 interim final rule (67 FR 61496) containing more than 17 specific comments. Commenters included representatives of professional associations, a State government, and an advocacy organization. In this document, we will refer to this regulation as the 2002 interim final rule.

Commenters expressed opposing opinions on the flexibility permitted in the 2002 interim final rule. In general, commenters expressed concerns about flexibility related to all aspects of the program, including waivers and the waiver process, contracted services including staff and contractors, and oversight of direct participant care. Listed below are the three areas that generated the most concern:

Subpart B: PO Application and Waiver Process;

Subpart D: Sanctions, Enforcement Actions and Termination;

Subpart E: Administrative Requirements.

III. Provisions of the 1999 Interim Final Rule With Comment and the 2002 Interim Final Rule With Comment, Analysis of and Responses to Comments and Final Rule Actions

The purpose of this final rule is to respond to public comments and finalize the regulations established in the 1999 and 2002 interim final rules. Below we will list each PACE regulation, note any comments and responses, and then note our final action.

Subpart A—Basis, Scope, and Purpose

This subpart provides the basis for this regulation, the scope and purpose, and defines terms specific to the PACE benefit.

Section 460.2 Basis

As stated in the 1999 interim final rule, the regulations set forth in 42 CFR part 460 are based on Sections 1894, 1905(a), and 1934 of the Act. Section 1894 of the Act authorizes Medicare payments to and coverage of benefits under PACE. Sections 1905(a) and 1934 of the Act authorize the establishment of PACE as an option under the State Medicaid plan to provide for Medicaid coverage of services furnished by the PACE program.

No comments were received on this section.

Final rule actions:

This final rule will finalize § 460.2 as published in the 1999 interim final rule.

Section 460.4 Scope and Purpose

We stated in the 1999 interim final rule that the purpose of the regulation was to set forth the requirements that an entity must meet in order to be approved as a PO under Medicare and Medicaid. It also sets forth how individuals may qualify to enroll in PACE, how Medicare and Medicaid payment will be made for PACE services, provisions for Federal and State monitoring of PACE programs, and procedures for sanctions and termination.

We stated 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.

This philosophy is based on Part I, section A, of the Protocol. Adopting a mission or philosophy statement that includes these elements indicates that an entity is guided by a set of values that influence its structure, planning, and day-to-day operations that is consistent with the purpose of PACE.

No comments were received on this section.

Final rule actions:

This final rule will finalize § 460.4 as published in the 1999 interim final rule.

Section 460.6 Definitions

This section of the 1999 interim final rule included the following definitions based on those in sections 1894(a) and 1934(a) of the Act and other terms determined necessary by CMS.

Contract year means the term of a PACE program agreement, which is a calendar year, except that a PO's initial contract year may be from 12 to 23 months, as determined by CMS.

Medicare beneficiary means an individual who is entitled to Medicare Part A benefits or enrolled under Medicare Part B, or both.

Medicaid participant means an individual determined eligible for Medicaid who is enrolled in a PACE program.

Medicare participant means a Medicare beneficiary who is enrolled in a PACE program.

PACE stands for Programs of All-inclusive Care for the Elderly.

PACE center means a facility operated by a PO where primary care is furnished to participants.

PACE organization (PO) means an entity that has in effect a PACE program agreement to operate a PACE program under this part.

PACE program agreement means an agreement between a PO, CMS, and the State administering agency for the operation of a PACE program.

Participant means an individual who is enrolled in a PACE program.

Services include both items and services.

State administering agency means the State agency responsible for administering the PACE program agreement.

Trial period means the first 3 contract years in which a PO operates under a PACE program agreement, including any contract year during which the entity operated under a PACE demonstration program.

In developing the definition of PACE organization, we explained in the 1999 interim final rule that sections 1894(a)(3) and 1934(a)(3) of the Act defined a ''PACE provider.'' We changed that term to ''PACE organization'' (PO) because we believed that the term ''PACE provider'' would be confusing. Medicare regulations (at 42 CFR 400.202) and Medicaid regulations (at 42 CFR 400.203) define the word ''provider,'' but the definitions are different and neither applies to entities that operate PACE programs. Those definitions denote individual providers of individual services under conventional fee-for-service systems. We selected the alternative term, PO, since ''organization'' is a term used in both titles XVIII and XIX when referring to managed care organizations, which are more similar to entities under PACE. In the few places where we use the term ''provider'' in this regulation, we are using it in the broad generic sense to refer to an individual or an entity that furnishes health care services. Our use of the term is not limited to the narrower Medicare definition in § 400.202.

Also, in defining contract year, we explained that a PO's initial (start-up) contract year may be from 12 to 23 months, as determined by CMS, to enable us to adjust the length of the initial (start-up) contract year so that subsequent years are on a standard annual calendar year cycle.

Comment: One commenter suggested that we clarify the term ''center'' by replacing it with the term ''PACE center.''

Response: We agree and have replaced the term ''center'' with ''PACE center'' throughout the regulation.

Comment: We received several comments requesting that we clearly define PACE, what constitutes a PO, and what constitutes a PACE center including clarification that a PACE provider is considered a PACE program and may have more than one center.

It was also recommended that we adopt the definition of PACE center as contained in the Protocol, which explicitly addresses the full range of services and benefits available at the PACE center.

Response: In response to these comments, in this final rule, we are redefining ''PACE center'' to be more consistent with the definition provided in the Protocol and the statute by defining it as a facility which includes a primary care clinic, 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.

In addition, as noted below we are adding a definition of ''PACE program''. However, we disagree with the commenter who requested that we adopt the definition of ''PACE center'' as contained in the Protocol which explicitly identifies the full range of services and benefits available at the PACE center. We believe that our modification is more appropriate and less cumbersome than including every required service in the definition. We also believe that by expanding the definition of ''PACE center'' that was published in the 1999 interim final rule, we are clarifying that a PACE center is a facility where most PACE services are provided, not just primary care.

As noted earlier in this section, in the 1999 interim final rule, we defined *PACE center* as ''a facility operated by a PO where primary care is furnished to participants.'' This definition was based on section IV. B. 2 of the Protocol, which states: ''The PACE center is the focal point for coordination and provision of most PACE services. The PACE center is a facility which includes a primary care clinic, and areas for therapeutic recreation, restorative therapies, socialization, personal care and dining.'' The Protocol identified other requirements for a PACE center, which were included in other sections of the 1999 interim final rule. Those requirements are included in the following sections: The list of required services is at § 460.98; the requirement that POs operate at least one PACE center is in § 460.98(d)(1); the requirement that the frequency of attendance is determined by the IDT based on each participant's needs is at § 460.98(e); and the requirement that the PACE center is designed, equipped, and maintained to provide for the physical safety of participants, personnel, or visitors and to ensure a safe and sanitary environment is at § 460.72.

We believe the list of explicit services and benefits belongs in § 460.98 which relates to ''Service delivery,'' and in § 460.72, which relates to ''Physical environment.''

Comment: A commenter requested that we add a definition of a ''PACE program'' and use the following language ''all centers and service provision by an approved PACE provider in an approved service area.''

Response: ''PACE program'' is defined in the Act at sections 1894(a)(2) and 1934(a)(2) as an entity that meets the statutory requirements to be a PACE provider and provides comprehensive health care services to PACE program eligible individuals in accordance with the PACE program agreement and regulations. We have not included a definition for ''PACE program'' in our regulations at § 460.6. However, we agree with the commenter that doing so would help to clarify and standardize PACE terminology. As noted above, we changed the term ''PACE provider'' to ''PACE organization'' and defined that term in the 1999 interim final rule.

Based on sections 1894(a)(2) and 1934(a)(2) of the Act, we are defining a PACE program as a program of all-inclusive care for the elderly that is operated by an approved PACE organization and that provides comprehensive health care services to PACE enrollees in accordance with a PACE program agreement. As noted above, we are defining a PACE center as a facility which includes a primary care clinic, 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. We do not think the commenter's language would be needed to ensure that PACE centers are included within the definition of a PACE program.

Final rule actions:

In this final rule we are:

- Replacing the term ''center'' with the term ''PACE center'' throughout the regulation.
- Redefining the term ''PACE center'' as ''a facility which includes a primary care clinic, 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.''
- Defining ''PACE program'' to mean a program of all-inclusive care for the elderly that is operated by an approved PACE organization and that provides

comprehensive health care services to PACE enrollees in accordance with a PACE program agreement.

Subpart B—PO Application and Waiver Process

Section 460.10 Purpose

We established in the 1999 interim final rule, that this subpart sets forth application requirements for an entity that seeks approval from CMS as a PO. In the 2002 interim final rule, we amended § 460.10 to clarify that subpart B also establishes a process by which a PO may request a waiver of certain regulatory requirements in order to provide for reasonable flexibility in adapting the PACE service delivery model to the needs of particular organizations (such as those in rural areas).

PACE Under Both Medicare and Medicaid

We require that each PO must enter into a program agreement under both sections 1894 and 1934 of the Act, that is, that each organization participate in both Medicare and Medicaid. Most of the text in those two sections is identical and our analysis indicates that key language contemplates entities acting as POs under both programs.

Sections 1894(f)(2) and 1934(f)(2) of the Act require that we incorporate in our regulations the requirements applied to PACE demonstration programs under the PACE Protocol, to the extent consistent with the provisions of sections 1894 and 1934 of the Act. Under the Protocol, PACE demonstration programs operated under both Medicare and Medicaid. We believe that the directive to incorporate the requirements in the Protocol reflected an expectation by the Congress that all POs would participate in both Medicare and Medicaid. This view is reinforced by paragraph (f)(2)(B) of these sections, which permits us to modify or waive provisions of the PACE Protocol ''so long as such modification or waiver is not inconsistent with and would not impair the essential elements, objectives, and requirements'' of sections 1894 and 1934 of the Act, but which forbids modifying or waiving, among others, the following provisions:

- Capitated, integrated financing that allows the organization to pool payments received from public and private programs and individuals; and
- The assumption by the organization of full financial risk.

We concluded that both of these provisions preclude the possibility of a Medicare-only or Medicaid-only PACE program. For example, if a program could collect capitation payments from Medicare but bill fee-for-service under Medicaid, not all financing would be capitated, nor would financing be integrated, nor would the organization assume full financial risk.

However, the law does not require that States offer the PACE benefit under Medicaid. As indicated by its title, section 4802 of BBA provides for the ''Establishment of PACE Program as Medicaid State Option.'' If an entity attempted to become a PO under Medicare in a State which has not included PACE program services as an option under its Medicaid program, it would not be possible for that entity to be both a Medicare and a Medicaid PO. While this would curtail the availability of PACE programs in those States, we have concluded that this result was intended because a Medicare-only program could not meet the fundamental concept of an all-inclusive, integrated, capitated, full-risk program.

Moreover, both sections 1894 and 1934 of the Act contemplate the active collaboration of Federal and State governments in the administration of PACE. Each State must have a SAA that is responsible for administering PACE program agreements in their State under sections 1894 and 1934 of the Act. The SAA closely cooperates with CMS in establishing procedures for entering into, extending, and terminating PACE program agreements. The SAA cooperates with CMS and the PO in the development of participant health status and quality of life outcome measures. The SAA also cooperates with us in conducting oversight reviews of PACE programs and has the authority to terminate a PACE program agreement for cause. If Medicare-only programs had been contemplated in a State that does not elect the PACE option, there would have been no reason to assign such a significant role to an SAA. We believe that a State which has not chosen PACE as an optional service would be ill-prepared or unable to perform this role.

As mentioned earlier, most of the text of section 1894 of the Act is identical to text in section 1934 of the Act. Portions of both text reflect the concept of entities acting as POs under both programs. The scope of Medicare PACE program benefits includes ''all items and services covered under this title (for individuals enrolled under this section [section 1894]) and all items and services covered under title XIX.'' Similarly, section 1934 of the Act, defines the Medicaid benefit package as ''all items and services covered under title XVIII (for individuals enrolled under section 1894) and all items and services covered under this title.'' In addition, to be eligible for PACE, an individual must require the nursing facility (NF) level of care covered under the State Medicaid plan.

Section 1894(e) of the Act provides that ''CMS, in close cooperation with the SAA'' will establish program agreements for ''entities that meet the requirements for a PO under this section, section 1934, and regulations.'' A corresponding provision is found at section 1934(e) of the Act, referring to ''entities that meet the requirements for a PO under this section, section 1894, and regulations.'' We believe that the use of the correlative ''and'' indicates that PACE entities would have to meet all three sets of requirements.

A parallel provision provides for termination of PACE program agreements (see paragraphs (e)(5) of sections 1894 and 1934 of the Act). Termination of an agreement under both sections 1894 and 1934 of the Act may be accomplished by either ''CMS or a SAA.''

Nonetheless, it is highly unlikely that any entity could be a viable PO without approval under both Medicare and Medicaid. The majority of potential participants are Medicare beneficiaries who also are eligible for Medicaid. Those who are not currently Medicaid-eligible may eventually exhaust their financial resources and become eligible. Medicare participants who are not enrolled in PACE under Medicaid must pay premiums equal to the Medicaid capitation rate. Aside from the technicality that there would not be an established Medicaid capitation rate in a State that does not elect the PACE option, most of these participants would lack the ability to pay these significant premiums.

As the above citations illustrate, some provisions of the law are conflicting and thus ambiguous. We therefore interpreted them to give effect to many of the provisions and policy objectives that they advance. Furthermore, in keeping with the congressional intent that the Protocol guide our implementation of the PACE program, we determined that POs must be approved under both Medicare and Medicaid.

Based on this interpretation, if a State should choose not to amend its State Medicaid plan to adopt PACE as an optional Medicaid service, we would not accept PACE applications from entities in that State. Also, if a State has elected the optional benefit but declines to recommend a particular entity as a PO, we would not accept an application from that entity.

We stated in the 2002 interim final rule that to implement section 903 of BIPA, we amended the PACE regulation by adding § 460.26 and § 460.28 to establish a process for a PO to request waiver of regulatory requirements. This process allows for variations while achieving the intent of the regulatory provision and responding to the needs of POs to develop and expand within their States' long-term care delivery system.

Waivers will be discussed in detail under § 460.26 and § 460.28.

Comment: Another commenter recommended that social support services and participant care be more clearly defined so beneficiaries and caregivers may make informed decisions about the type and level of care to be provided.

Response: In response to the comment regarding a more defined regulation where social services and participant care is concerned, we disagree with this commenter, as required services are participant specific. After the IDT determines a participant requires a service and it is included in their plan of care, those services become required for that participant for that specific need. Therefore, it would not truly represent the PACE model to constrain the benefit by defining it in regulatory language.

Final rule actions:

This final rule will finalize § 460.10, as published in the 2002 interim final rule.

Section 460.12 Application Requirements

We established § 460.12 to set forth the application requirements for the PACE program. In order for CMS to determine whether an entity qualifies as a PO, an individual authorized to act for the entity must submit an application that describes thoroughly how the entity meets all the requirements specified in this regulation. In recognition of the 90-day review timeframe specified in the statute and described below and the numerical limit on the number of PACE program agreements, we will review and take action to approve, deny, or request additional information only on complete applications; those applications that address all elements of the PACE program agreement. We will send a letter to each applicant indicating whether or not the application is complete and specifying when the 90-day review period ends.

We require in § 460.12(b) that applications for PO status be accompanied by an assurance from the SAA indicating that it considers the entity to be qualified to be a PO and that the State is willing to enter into a PACE program agreement with the entity. We will not accept applications from entities that have not obtained these assurances.

To enable a SAA to make these assurances, an entity would have established to the satisfaction of the State that it is committed to the PACE model of care, that there is sufficient funding for program development and facilities, that there is adequate demand for PACE services as shown by demographic analysis.

Entities that are interested in developing a PACE program agreement should contact their SAA to determine whether the State has submitted or plans to submit a SPA to elect PACE as an optional benefit under its State Medicaid plan and if the State has established additional requirements for POs. Section 1905(a)(26) of the Act provides authority for States to elect PACE as an optional Medicaid benefit. The State plan electing the optional PACE program must be approved before we can approve an application for a PO in that State. We received three comments related to application requirements.

Comment: Commenters questioned the requirement that POs must be approved by their SAA. Further, they requested that we specify an absolute role for SAA, and revise the regulatory language to reflect the SAAs' responsibility to submit the program application and the States' role in the application process.

Response: As we explained in the 1999 interim final rule, States have played a significant role in the development of the PACE demonstration program as well as other community-based alternatives to institutionalization. Most States have implemented home and community based programs that provide comprehensive coordinated services to various groups of Medicaid recipients. As a result, States have gained extensive experience in demographic analysis and contracting with entities that are capable of delivering a specified range of services.

Although the PACE statute does not specify the States' role in the application approval process, many aspects of implementing PACE in Medicare and Medicaid will necessitate extensive involvement of the SAAs and the State Medicaid Agencies. The State must elect to provide PACE services as an option under the Medicaid State plan and PACE applications must be accompanied by an assurance from the SAA that the State considers the entity to be qualified to be a PO and is willing to enter into a program agreement with them.

With regard to applications, we continue to believe the States are in the best position to work with potential organizations to develop programs that meet our requirements and are integrated into the States' overall long-term care delivery system.

Comment: One commenter asked us to clarify the regulatory provision related to the hiring requirements of non-operational programs before submission of their program application. The commenter stated that it is unreasonable to expect the applicant would have hired core staff before application submission.

Response: Although hiring requirements for non-operational PACE programs do not appear in our regulations at § 460.12, we addressed these requirements in the preamble of the 1999 interim final rule (64 FR 66238). We stated, ''To enable a State to make such assurances, an entity would have established to the satisfaction of the State that it is committed to the PACE model of care, that there is sufficient funding for program development and facilities, that there is adequate demand for PACE services as shown by demographic analysis, and that the entity has hired core PACE staff and has developed contracts for referral arrangements and other program services that the site will not furnish directly.''

When the 1999 interim final rule was developed, there were several PACE demonstration programs that needed to transition to permanent provider status. As they were operational and had key staff members in place before submitting their PACE provider applications, this requirement was not an issue.

However, as all PACE demonstration programs have transitioned to permanent provider status, applications will now be primarily from non-operational providers. We acknowledge that start-up costs are extensive and paying salaries for top management staff without a revenue stream is unrealistic. We do not believe that it is appropriate to hold non-operational applicants to the same standard as POs that had been fully operational under the PACE demonstration program. Therefore, we are not requiring that core staff be hired before application approval. However, at the time of an organization's Readiness Review, we do expect documentation that core staff have been chosen and accepted those specific key positions. Language related to staff contracts of non-operational organizations has been included on page ix of the Provider Application, which

can be found on the PACE Web site under Provider Application and Appendices at *www.cms.hhs.gov/pace/.* This signed certification guarantees us, among other things, that the SAA will verify that the PO has qualified staff employed or under contract before furnishing services. This document must be signed by the SAA and included as part the PACE provider application.

In the 2002 interim final rule, we revised § 460.12 by removing and reserving paragraph (a)(2) to clarify that although we may begin review of PO applications, we may sign a program agreement only with a PO located in a State with an approved SPA electing PACE as an optional benefit under its Medicaid State plan. We are finalizing this provision by deleting § 460.12(a)(2) entirely. For the sake of continuity we are redesignating § 460.12(a)(3) as § 460.12(a)(2).

Final rule actions:

In this final rule we are redesignating § 460.12(a)(3) to § 460.12(a)(2).

Section 460.14 Priority Consideration

Section 4803(c) of the BBA directed us to give priority in processing applications, during the 3-year period following enactment of the BBA on August 5, 1997, to PACE demonstration programs and then to entities which had applied to operate a PACE demonstration program as of May 1, 1997.

In the 1999 interim final rule, we established § 460.14 to address priority applications and stated that to give priority in processing applications from entities that met the criteria, we would accept applications only from those entities beginning on the effective date of the 1999 interim final rule and continuing for 45 days. Applications from other entities would not be accepted during this period. Moreover, during the subsequent 45 days, extending to 90 days after the effective date of that regulation, we stated we would continue to accept applications from entities that met the priority processing criteria and we would also accept applications from entities that qualify for special consideration as described in the following section.

We did not receive any requests for priority consideration.

Comments related to § 460.14 also address § 460.16 and will be addressed at the end of § 460.16.

Section 460.16 Special Consideration

Section 4803(c) of the BBA required that we give special consideration in the processing of applications during the 3 years following enactment, to any entity that, as of May 1, 1997, had indicated specific intent to become a PO through formal activities such as entering into contracts for feasibility studies.

In § 460.16, we established a process for special consideration of a PACE application. Similar to the process for priority consideration, to give special consideration in processing applications from entities that meet the criteria in the 1999 interim final rule, we indicated we would accept applications from these entities beginning 45 days after the effective date of the 1999 interim final regulation. We further noted that during the 45-day period that extends from 45 days after the effective date to 90 days after the effective date, we would accept applications only from entities that met the priority processing criteria or entities that qualified for special consideration. Applications from other entities would not be accepted during this period.

Applications from entities that believed they were entitled to special consideration were to include information regarding the formal activities they were engaged in towards becoming a PO. If we agreed that special consideration was appropriate for applications submitted after the special 45-day window, we would identify those applicants and factor in the entity's special status in the event that we had a greater number of applications under review than available capacity for PACE program agreements.

We did not receive any requests for special consideration.

Comment: Six commenters requested clarification regarding the criteria and process applied to applications under the BBA mandate providing priority and special consideration in processing PACE applications.

Response: We believe the 2002 interim final rule provided sufficient information as to the criteria and process needed for priority and special consideration for PACE applications. More importantly, however, we note that as the authority to provide these considerations expired on August 5, 2000, it is no longer necessary to retain these regulations.

Final rule actions:

In this final rule we are deleting § 460.14 and § 460.16.

Section 460.18 CMS Evaluation of Applications

We established the information used to evaluate a PO application in the 1999 interim final rule. We approve entities based upon a review of the materials submitted as part of the application, as well as information obtained from the SAA or through onsite visits.

No comments were received on § 460.18.

Final rule actions:

This final rule will finalize § 460.18 as published in the 1999 interim final rule.

Section 460.20 Notice of CMS Determination

Sections 1894(e)(8) and 1934(e)(8) of the Act require us to approve or deny an application for PO status within 90 days after the date of the submission of the application unless additional information is requested. Applications are deemed approved unless we deny PO status in writing or request additional information within the 90-day timeframe. In the 1999 interim final rule, we established procedures for implementing these requirements at § 460.20. We clarified that, for purposes of the 90-day time limit described in this section, the date that an application is considered to be submitted to CMS is the date on which the application is delivered to the address designated by CMS.

These statutory sections also provide that we may request in writing additional information as may be required in order to make a final determination regarding the application and, after the date we receive that information, the application shall be deemed approved unless, within 90 days of that date, we deny the request.

Based on this authority, we may take up to 90 days to request additional information and, once the information is received, may take an additional 90 days to complete processing of the application. It is important to note that there is no corresponding requirement that the SAA or the PO respond to our request for additional information (RAI) within a specified timeframe.

If the additional information proves insufficient to approve the application, the application will be denied. We will notify each applicant of our determination and the basis for the determination in writing. If the application is denied, we will provide the basis for the denial and the process for requesting reconsideration of the application.

No comments were received on § 460.20.

Final rule actions:

This final rule will finalize § 460.20 as published in the 1999 interim final rule.

Section 460.22 Service Area Designation

Sections 1894(e)(2(B) and 1934(e)(2)(B) of the Act permit the Secretary, in consultation with the SAA, to exclude from a service area designation an area that is already

covered under another PACE program agreement. In the 1999 interim final rule, we specified in § 460.22 that each applicant must designate the service area of the program. We stated that CMS (in consultation with the SAA) may exclude from the proposed service area designation any area that is already covered under another PACE program agreement. Consistent with the statute, we believe this was required to avoid unnecessary duplication of services and impairing the financial and service viability of an existing PO.

No comments were received on § 460.22.

Final rule actions:

This final rule will finalize § 460.22 as published in the 1999 interim final rule.

Section 460.24 Limit on Number of PACE Program Agreements

This provision implements sections 1894(e)(1)(B) and 1934(e)(1)(B) of the Act establishing a limit on the number of PACE program agreements that may be in effect on August 5 of each year, that is, the anniversary of the enactment of the PACE statute. Those sections state that we shall not permit the number of POs with which agreements are in effect under those sections or PACE demonstration programs under section 9412(b) of the OBRA of 1986 to exceed—

- Forty as of August 5, 1997, the date of the enactment of the PACE statute, or
- As of each succeeding anniversary of that date, the numerical limitation for the preceding year plus 20. The annual increase in the number of PACE program agreements is not tied to the actual number of agreements in effect as of a previous anniversary date.

Based on this statutory language, we may enter into up to 80 PACE program agreements as of August 5, 1999, and the limit on the number of PACE program agreements increases by 20 each year thereafter.

No comments were received on § 460.24.

Final rule actions:

This final rule will finalize § 460.24 as published in the 1999 interim final rule.

Section 460.26 Submission and Evaluation of Waiver Requests

Section 460.28 Notice of CMS Determination on Waiver Requests

These sections were established in the 2002 interim final rule to implement section 903 of BIPA. As we explained in that rule, we considered amending the 1999 interim final rule to identify each requirement that is eligible for waiver and provide separate waiver criteria for each requirement. However, we were concerned that amending the regulation for each waiver would: (1) Create a regulatory level of specificity that might make it difficult to apply to future requests for similar but not identical waivers; and (2) cause a significant delay between when the need for a waiver is identified and when it may be implemented.

As an alternative, we amended the PACE regulation by adding § 460.26 and § 460.28 to establish a process for a PO to request waiver of regulatory requirements.

As noted previously, the PACE Protocol and the 1999 interim final rule have been proven effective as POs grow and reach financial solvency. We have learned a great deal about variations in the model through the information we received in processing grandfathering requests under section 902 of BIPA and numerous discussions with the National PACE Association (NPA), POs, and States. Allowing for waivers provides a unique opportunity for POs, the States, and CMS to experiment with new approaches within the structure of the PACE model. This process allows for variations while achieving the intent of the regulatory provision and responding to the needs of POs to develop and expand their States' long term care delivery system. The POs will serve as an ongoing laboratory that over time will establish best practices that may ultimately replace the current regulatory requirements.

We realize that in order to foster innovation and creativity within the PACE program, POs must be granted some degree of flexibility in their operation and service delivery. However, we must balance this need for flexibility with our responsibility to ensure quality, cost effective care for all beneficiaries.

Based upon our experience and review of grandfathering requests under section 902 of BIPA, we established two types of waivers in the 2002 interim final rule, that is, general waivers and conditional waivers subject to evaluation. We discuss the waiver types below:

1. General Waivers

A general waiver may be granted to a PO that has successfully implemented a specific operating arrangement, for example, an operating arrangement approved under section 902 of BIPA. General waivers continue indefinitely; however, approval may be withdrawn for good cause if periodic monitoring of the organization's operations and policies indicates participant care is being jeopardized, there is fiscal instability, or the goals of the PACE model are not maintained.

2. Conditional Waivers

A conditional waiver, subject to evaluation, is a provisional waiver we would approve for a specific period of time to a new or experienced organization. During the conditional period, the PO would need to submit specific data, that we prescribed, that would allow us to monitor and evaluate the conditional waiver to determine whether the waiver may become permanent. This category of waiver may include the following scenarios:

(a) A request for waiver without which a PO would be prevented from entering the program. For example, if a prospective PO has been unable to hire or contract with a social worker with a Master's degree, we may consider approving a conditional waiver request to allow a social worker with a baccalaureate degree to operate in this capacity until a qualified social worker is hired. This waiver would only be in effect until the PO could hire or contract for an appropriate staff member.

(b) A request for approval of an arrangement with which a PO does not have any experience. We want to encourage creative approaches to improving the PACE model and view conditional waivers as a responsible way to balance the need of a PO with protection of participant health and safety. We need to be cautious in approving arrangements in which the PO does not have a proven record of success. In approving a conditional waiver request, we may limit the number of participants exposed to the waiver or approve the waiver for a limited period of time or at a specific PACE center until we are assured through evaluation that (1) the intent of the regulation is met; and (2) the approach is not inconsistent with nor impairs the essential elements, objectives, and requirements of PACE. At that time, we may approve a general waiver so that the PO may expand the arrangement to other PACE centers it manages without jeopardizing participant care.

Each of the conditional waivers is subject to periodic monitoring. A PO approved for a conditional waiver must submit any prescribed data at specified intervals. We have learned that, in most cases, conducting a detailed review of a waiver request allows us to implement waiver approvals without having to require data submission. This evaluation serves a dual purpose. It allows us to monitor the impact on participant care as well as enable us to determine if any permanent changes to

PACE should be implemented through regulations. In addition, it allows us to provide technical assistance to other POs requesting a similar waiver.

In the 2002 interim final rule, we discussed the process necessary to obtain any waiver. To obtain either a conditional or general waiver, a PO must provide a detailed description of how its proposed modification differs from the regulatory requirement and how it meets the intent of the regulatory provision. The burden is on the PO to explain why a waiver is needed to start up or expand their program. Where a PO has not completed the trial period, attained financial solvency, and demonstrated competence with the PACE model as evidenced by successful CMS and State onsite reviews and monitoring activities, it will be necessary for the organization to explain how the waiver is necessary to meet those objectives. For a new organization, it will be necessary for the organization to explain why a waiver is needed for the organization to begin serving participants.

Consistent with the process developed for initial PACE provider applications, all waiver requests must be submitted to the SAA for initial review. The SAA forwards the waiver request to CMS along with any concerns or conditions they may have regarding the waiver. We will not accept waiver requests directly from POs. Waiver requests submitted with an initial application process must be prepared as a separate document. These requests are reviewed simultaneously and in conjunction with the application. Where an existing PO is requesting a waiver, the request must be submitted through the State to the CMS address for BIPA 903 waiver requests indicated on the PACE home page (*http://www.cms.hhs.gov/PACE*). We intend to process waiver requests as expeditiously as possible in order to be responsive to the needs of new organizations to develop their programs and to the needs of mature organizations as they expand.

Section 903 of BIPA directs us to approve or deny a request for a modification or waiver no later than 90 days after the date of receipt. We clarified in § 460.28(b) that the date of receipt is the date the request is delivered to the address designated by CMS. We note that there is no statutory authority to stop the 90-day clock if additional information is necessary to make a determination on a waiver request. Thus, it is in the PO's best interest to provide all pertinent information relevant to their request. Where additional information is necessary, the CMS PACE Team Leader will inform the PO as early as possible in the review process. The PO will then be responsible for submitting the additional information in a timely enough manner to allow us to evaluate the additional information and make a determination on the waiver request within the allotted 90 days. If the reply from the PO is not received in a timely manner, we would have to deny the request. The PO may then reapply for the waiver, starting a new 90-day clock.

Consistent with sections 1894(f)(2)(B) and 1934(f)(2)(B) of the Act, we specified in § 460.26(c) the following requirements that would not be waived:

(1) A focus on frail elderly qualifying individuals who require the level of care provided in a nursing facility;

(2) The delivery of comprehensive, integrated acute and long-term care services;

(3) The IDT approach to care management and service delivery;

(4) Capitated, integrated financing that allows the provider to pool payments received from public and private programs and individuals; and

(5) The assumption by the provider of full financial risk (we note that assuming full financial risk does not preclude an organization from utilizing reinsurance, stop-loss protection, or other mechanism to meet its financial obligations).

In addition to these five provisions, we will not grant waivers that we believe are inconsistent with or would impair the essential elements, objectives, and requirements of sections 1894 and 1934 of the Act.

In addition to the requirements specified in sections 1894(f)(2)(B) and 1934(f)(2)(B) of the Act, we believe there are other requirements that must not be waived. For example, health care is focused at a PACE center; the IDT is composed of certain health care professionals that manage all of the health care provided to participants; a comprehensive assessment by the IDT is conducted before admission into the PACE program; and reassessment occurs at least every 6 months or whenever there is a significant change in a participant's health status. Further, we believe that PACE participants are entitled to the same patient rights' protection available in the Medicare or Medicaid fee-for-service or managed care programs. Therefore, we will not approve waiver or significant modification of these requirements.

Two waiver issues specifically mentioned in section 903 of BIPA are requirements related to employment and the use of community-based primary care physicians (PCP). In this approach, the PCPs work out of their offices rather than from the PACE center and do not primarily serve PACE participants.

The 2002 interim final rule removed the restrictive waiver provisions at § 460.68(c) regarding direct or indirect interest in contracts, which was limited to rural and Tribal organizations. In addition, the 2002 interim final rule also removed the two waivers in § 460.102(g) related to employment of the PCP and the requirement that the IDT primarily serve PACE participants. These waivers were available if CMS and the SAA determined that there was ''insufficient availability in the PO's service area of individuals who meet the requirement, or State licensing laws make it inappropriate for the organization to employ physicians.'' Although we deleted the specific waivers that were intended to encourage development of PACE in rural or Tribal or other medically underserved areas, we continue to recognize the special need for flexibility in these areas and remain committed to allowing waivers to promote PACE in medically underserved areas. Deletion of the specific waiver language was intended to provide greater flexibility within the overall PACE regulatory structure. We remain committed to working with rural and Tribal communities to help them address the challenges of developing successful PACE programs. Organizations that seek waiver of these or any other regulatory requirements must follow the requirements specified in § 460.26.

We note that a PO requesting a waiver of the prohibition on direct or indirect interest in contracts must develop policies and procedures for disclosure of financial interest to the governing body, establish recusal restrictions, and a process to record recusal actions for review by CMS and the SAA in its waiver request.

Comment: We received two comments expressing concern about compromising the integrity of the PACE model by providing expanded flexibility.

One commenter offered assistance in evaluating PACE policy, program, and practice on a continuing basis. The second commenter was concerned that the PACE regulations lack sufficient safeguards to preserve the model as established by the Protocol. The commenter indicated that maintaining the PACE center as the focal point for delivery of services and retaining the central role of the IDT in managing the health care and other services provided to PACE participants were critical to the PACE model. The commenter also emphasized the important role of the PCP in the Protocol, stating, ''the

ultimate responsibility for managing participant medical care rests with the PCP; therefore, if this team member is not present during team meetings the ability to fulfill this obligation will be compromised.''

Response: We share the commenter's concerns regarding the integrity of the PACE model, and thank the commenter who offered assistance in evaluating the PACE program. We believe the flexibility permitted by the 2002 interim final rule has sufficient safeguards to ensure the integrity of the model. We instituted contracting and oversight requirements we believe will ensure quality of care for PACE participants. During the development of the 2002 interim final rule, we made a concerted effort to develop a waiver process that would allow modification of the model without excessive controls, while at the same time not being too burdensome for POs. We believe we achieved that balance.

The PACE model has been proven successful when the PACE center is the focal point for delivery of services and when the IDT's central role of managing the health care and other services provided to PACE participants is retained. Therefore, we believe there are few circumstances when it would be appropriate to waive these elements of the PACE model without substantial justification by a PO or potential PO, for example, the entity being a rural or Tribal organization. However, according to sections 1894(f)(2)(B) and 1934(f)(2)(B) of the Act, we do not have the authority to waive the provision requiring the IDT's central role managing the health care and other services provided to PACE participants, since it is statutorily mandated.

Although we have permitted the use of community-based PCPs, we require that effective and consistent communication be maintained. Whenever we have received a request for waiver pertaining to use of community-based PCPs, the PO has had to provide in-depth justification and meet our conditions for waiver. Among other conditions for waiver approval, the community-based PCP must perform all the requirements of the staff PCP including but not limited to participation in IDT meetings related to their participants' participation in Quality Assurance and Performance Improvement (QAPI) activities and agree to PO oversight by the medical director.

Comment: One commenter submitted comments related to the submission and evaluation of waiver requests. This commenter supported reasonable waiver requests for community-based PCPs for flexibility and innovation within PACE which will allow the program to grow. The commenter also supported conditional waivers, which would allow CMS to monitor the performance of organizations utilizing community-based PCPs as well as participant outcomes. The commenter recommended that we focus on processes for integrating care while utilizing community-based PCPs.

Response: In general, we are not inclined to approve waiver requests allowing POs to utilize community-based PCPs without identifying a substantial need. However, we believe there are circumstances when the use of community-based PCPs may be appropriate. For example, it is important for a participant to have a physician that speaks their language and understands their culture's mores and traditions, which can improve participant compliance with their plans of care and, therefore, their health outcomes. We have approved a limited number of waiver requests allowing community-based PCPs contingent on their compliance with specific requirements. We plan to monitor and review the impact of the interactions between the community-based PCPs and the IDT and participant care before we alter the conditions currently applied to these waiver requests.

Comment: Commenters asked whether PACE programs which are operating under grandfathering arrangements would be required to request a waiver in order to continue operations. They believe having to request waiver of operational arrangements grandfathered under BIPA 902 will be administratively burdensome, and they recommend POs be allowed to expand grandfathering arrangements ''organization wide'' provided the expansion is ''* * * reasonably consistent with the objectives of the PACE program.'' They suggested the PO could file a notice with CMS describing the expansion arrangement and how it is consistent with program objectives.

Response: PACE demonstration program sites were granted BIPA 902 ''grandfathering'' of certain operational arrangements that did not meet the 1999 interim final rule, if the identified practice was in place before July 1, 2000. As the approved ''grandfathering'' was effective, only to the extent it existed on July 1, 2000, we believe it was not intended to cover a new or expanded site. As a result, POs need to submit BIPA 903 waiver requests of grandfathered practices for expansion sites.

Based on our experience with the waiver process, we believe there is value in CMS and SAA review and approval of waivers. The consultations involved in the waiver process allows CMS and the SAA to discuss the PO's ability to implement the requested waiver, any concerns either agency has regarding the waiver request, request further information or clarification of the PO's operations, and determine any requirements or conditions that will be included in the waiver approval. CMS and the SAA collaborate in the review and approval of waivers. We have found that the SAA generally has a better knowledge and understanding of the PO and its operations and relevant State laws and requirements.

Comment: One commenter indicated that the regulatory language fails to address entities that are not already a PO, saying that prospective POs (as well as established POs) should be eligible for waivers of regulatory requirements. The commenter requested clarification regarding whether PACE demonstration programs transitioning to permanent provider status, pre-PACE programs, and previously ''non-operational'' entities are eligible to request waivers of regulatory requirements.

Response: Any entity submitting a PACE provider application may submit a request for waiver. The PO demonstration programs had been operating in some cases for years and the implementation of the 1999 interim final rule could have disrupted operations and care to the participants as the demonstration programs transitioned to permanent provider status and were required to be in compliance with the 1999 interim final rule. BIPA provided flexibility for those transitioning demonstration programs to continue their existing operational arrangements and a waiver process for those organizations that did not meet the grandfathering criteria but were unable to comply with the 1999 interim final rule. We believe the intent of the waiver provision in BIPA was to assist organizations to participate in the Medicare and Medicaid PACE benefit program.

We believe that there may be circumstances when applicants are not able to comply with the regulations. The BIPA section 903 waiver process allows developing organizations to work with CMS and the SAA to develop an appropriate alternative rather than abandon their efforts to become a PACE program when they discover they can not meet the regulatory requirements. Therefore, we have allowed these entities to submit waiver requests. A waiver request must be submitted as a

separate document from the provider application and must contain substantial justification for the request. Pre-PACE organizations are Medicaid pre-paid health plans that provide Medicare services under Medicare fee-for-service rules and certain Medicaid services paid by Medicaid on a capitated basis. These organizations may submit a waiver request and their PACE provider application simultaneously but as separate documents.

We will accept waiver requests from non-operational entities and pre-PACE applicants, in an attempt to assist new organizations that would otherwise be unable to meet regulatory requirements. All waiver requests must be submitted through the SAA, who will review and forward to CMS. Regardless of the prior status of the entity, a request for a waiver is reviewed on a case-by-case basis.

Comment: Commenters also requested that we make information regarding approved waiver requests available to current and potential POs.

Response: At this time, we do not agree that making information on particular PACE programs available is warranted. We believe it would be more beneficial for each PO to develop their own unique waiver request and rationale. Each PO is a unique operational entity that has specific circumstances and experience that influence the appropriateness for approving a waiver. Therefore, approving all similar requests for a waiver of a specific requirement is inappropriate. Our intention is that all POs comply with the PACE regulations.

Final rule actions:

In this final rule, we are expanding the regulatory requirements of § 460.26 to permit POs and entities applying to become POs to submit waiver requests.

Section 460.28 Notice of CMS Determination on Waiver Requests

Comment: One commenter requested clarification as to whether an entity submitting a PACE application is permitted to submit a waiver request separate from the provider application, as prompt CMS determination will be important to the organization's ability to move forward with PACE development. The commenter also asked whether the CMS timeframe for responding to waiver requests is affected by the status of the request, or whether the applicant is an operational or a prospective PO.

Response: Waiver requests may accompany an application, but must be prepared and submitted as a separate document. Requests will be reviewed simultaneously and in conjunction with the application. Alternatively, waiver requests can be submitted independently of the application by POs that are currently operational.

The timeframe for our response to a waiver request is the same regardless of the operational status of the requestor. We have a statutory 90-day timeframe to approve or deny waiver requests. As a result, when we request additional information, regarding a waiver request, it is incumbent upon the organization to respond as expeditiously as possible to provide CMS and the SAA time to review their responses. We provide a written approval or denial letter to the PO or PACE applicant with the determination and any additional conditions.

Final rule actions:

In this final rule, we are amending paragraph (a)(2) by adding ''or PACE applicant,'' thereby requiring CMS to notify the PO or PACE applicant in writing of the decision to deny the submitted waiver request.

Subpart C—PACE Program Agreement

The purpose of subpart C is to establish requirements for the PACE program agreement establishing the entity as a provider of PACE benefits under Medicare and the Medicaid State plan.

Section 460.30 Program Agreement Requirements

In accordance with sections 1894(a)(4) and 1934(a)(4) of the Act, we established § 460.30 to require that each PO have an agreement with CMS and the SAA for the operation of a PACE program by the organization under Medicare and Medicaid. This three-party agreement must be signed by an authorized official of the organization, as well as by an authorized CMS official and an authorized State official.

We received no public comments on § 460.30 of the 1999 interim final rule.

In the 2002 interim final rule, we revised the regulatory language to reflect that the PACE program agreement is a three-party agreement that is signed by CMS, the SAA, and the PO. Also, we added regulatory language to clarify that CMS may sign a program agreement only with a PO that is located in a State with an approved SPA electing PACE as an optional benefit under its Medicaid State plan.

We received no comments on this section of the 2002 interim final rule.

Final rule actions:

This final rule will finalize § 460.30 as published in the 1999 and 2002 interim final rules.

Section 460.32 Content and Terms of PACE Program Agreement

In § 460.32(a), we stipulate the required content of a PACE program agreement.

We require that each PACE program agreement designate the service area of the program, specifically identifying the area by county, zip code, street boundaries, census tract, block, or tribal jurisdictional area, to the extent that those identifiers are appropriate. Any changes in the designated service area would require advance approval by CMS and the SAA. This requirement implements the provisions of sections 1894(e)(2)(A)(i) and 1934(e)(2)(A)(i) of the Act and reflects Part I, section D of the Protocol.

Each PO must agree to meet all applicable requirements under Federal, State, and local laws and regulations, including provisions of the Civil Rights Act, the Age Discrimination Act, and the Americans with Disabilities Act. These requirements include, but are not limited to, all requirements contained in the regulations implementing those Acts. This requirement implements in part the provisions of sections 1894(e)(2)(A)(iv) and 1934(e)(2)(A)(iv) of the Act.

We require that the program agreement indicate the effective date and term of the agreement as well as information related to: Organizational structure of the PO; participant rights; processes for grievances and appeals; eligibility; enrollment and disenrollment policies; service description; QAPI; capitation rates; names and numbers of administrative contacts in the organization; and program agreement termination procedures. These requirements are based on sections 1894(b)(2) and 1934(b)(2) of the Act and on Part X, section A of the Protocol.

Each PACE program agreement includes a statement of the levels of performance that we require the organization to achieve on standard quality measures and the data and information on participant care that CMS and the State require the organization to collect. A detailed discussion of the levels of performance and the standard quality measures are contained in the preamble discussions for § 460.134 and § 460.202(b) in the 1999 interim final rule.

In § 460.32(b), we specify that a PACE program agreement may provide additional requirements for individuals to qualify as PACE program eligible individuals. This provision implements sections 1894(e)(2)(A)(ii) and 1934(e)(2)(A)(ii) of the Act. However,

the eligibility criteria in § 460.150(b)(1)–(3) cannot be modified. In addition, a PACE program agreement may contain additional terms and conditions as the parties agree to, if the terms and conditions are consistent with sections 1894 and 1934 of the Act and with these regulations. This provision implements sections 1894(e)(2)(A)(v) and 1934(e)(2)(A)(v) of the Act.

We received five comments on the 1999 interim final rule related to the program agreement, which are listed below.

Comment: One commenter requested that we clarify whether the program agreement content is meant as a substitute for all provisions or only some of the provisions of the State Medicaid contract requirements in 42 CFR part 434. The commenter also asked whether additional terms and conditions could be included in the PACE program agreement to meet specific State law requirements.

Response: The PACE program agreement is a three-way contract between the PO, the SAA and CMS, and contains the PACE requirements from the Federal statute and regulations. If the SAA has requirements beyond those in the three-way PACE program agreement, those requirements should be addressed in a separate contract between the State and the PO. The PACE three-way program agreement can be an attachment to the State-PO contract. As we stated above, each PO must agree to meet all applicable requirements under Federal, State, and local laws and regulations.

States may implement additional or more stringent requirements if they are consistent with sections 1894 and 1934 of the Act and with Federal laws and regulations. However, if there is a conflict between the State and Federal requirements, the Federal requirements would generally take precedence.

Comment: We were asked to describe the mechanism for revising a signed program agreement.

Response: We will provide the PO and the SAA with written notification of any revisions and include updated pages of the program agreement. The PO and the SAA have 30 days to send written notification to us of any disagreement with the revisions. We have provided information on the program agreement on the PACE home page, in the PACE Fact Sheet, which is located at *http://www.cms.hhs.gov/PACE/Downloads/PACEFactSheet.pdf.*

Comment: One commenter asked that we define the procedure for expanding a service area.

Response: The procedure for expanding a service area differs depending on whether a new PACE center is also being opened. The abbreviated PACE expansion application and additional information regarding the procedures for expanding a service area on the PACE home page, in the PACE Fact Sheet, which is located at *http://www.cms.hhs.gov/PACE/Downloads/PACEFactSheet.pdf.*

Comment: Two commenters asked when we would provide the requirements on standard quality measures, the requirements for participant care data and information and asked whether the requirements are the same for all PACE programs. A number of commenters inquired when the data would be collected and what the specific measures would be.

Response: The program agreement identifies the data elements for monitoring that must be submitted quarterly by all POs. A further discussion on standard quality measures, Outcome-Based Continuous Quality Improvement (OBCQI), and COCOA–B is in section III subpart H of this final rule.

Comment: Commenters asked when CMS would provide the Medicare capitation rates.

Response: Section 1894(d) of the Act directs the Secretary to make prospective monthly payments of a capitation amount for each PACE program eligible individual enrolled under the agreement under this section in the same manner and from the same sources as payments are made to the Medicare+Choice (formerly M+C, now MA) organizations and to specify the capitation amount in the PACE program agreement. Therefore, in the 1999 interim final rule, we required that the Medicare capitation rates be included in the program agreement. The Balanced Budget Act of 1997(BBA) mandated that a risk adjustment payment methodology incorporating information on beneficiaries' health status be implemented in the M+C program. The resulting PACE payment methodology that began in 2004 includes a risk adjusted methodology that results in a unique payment for each participant. As a result, it is not possible to include the Medicare capitation rates in the program agreement. Therefore, we are amending our regulation to remove the requirement that the program agreement include the Medicare capitation amount and to require, instead, that the program agreement must include the Medicare payment methodology. This requirement is included in Appendix ''M'' of the program agreement, which can be found at *http://www.cms.hhs.gov/pace/Downloads/programagreement.pdf.* Medicare rates are annually updated, published, and posted on the CMS Web site. Current Medicare payment rates can be found at *http://www.cms.hhs.gov/healthplans/rates/default.asp.*

Final rule actions:

This final rule will amend § 460.32 to indicate that the program agreement must include the ''Medicare payment methodology'' which replaces the ''Medicare capitation rate.''

Section 460.34 Duration of PACE Program Agreement

In § 460.34, we specify that each program agreement will be effective for a contract year, but may be extended for additional contract years in the absence of a notice by a party to terminate, in accordance with the requirements of sections 1894(e)(2)(A)(iii) and 1934(e)(2)(A)(iii) of the Act.

Comment: It was recommended that we extend the program agreement's designated 1-year contract period to a longer period of time with an automatic extender.

Response: As noted above, the statute specifies a 1-year contracting period. We provided for a flexible initial contract year that could be as long as 23 months to allow us to adjust the length of the initial or start-up contract year so that subsequent years are on a standard calendar year cycle.

PACE program agreements are considered to be ''evergreen'' meaning they will be automatically renewed without having to be re-signed. We believe the term of the program agreement is appropriate and consistent with overall Medicare policy, as well as in compliance with the requirements of the Act.

Final rule actions:

This final rule will finalize § 460.34 as published in the 1999 interim final rule.

Subpart D—Sanctions, Enforcement Actions and Termination

In subpart D of the 1999 interim final rule, we specified the violations identified in sections 1857(g)(1) and 1903(m)(5)(A) of the Act that could result in the imposition of sanctions under sections 1894(e)(6) and 1934(e)(6) of the Act. We also specified in accordance with paragraph (e)(5) of section 1894 and 1934 of the Act, that CMS or the SAA may terminate the PACE program agreement at any time for cause and that a PO may terminate an agreement after appropriate notice to CMS, the SAA, and participants. We also specified, in accordance with paragraphs (e)(5)(C) of sections 1894 and 1934(e)(5)(C) of the Act, Part IX of the Protocol, the transition procedures that must be followed by an entity

whose PACE program agreement is in the process of being terminated. Those procedures can be found in § 460.50.

Section 460.40 Violations for Which CMS May Impose Sanctions

In § 460.40 we specified, based on paragraph (e)(6)(B) of sections 1894 and 1934 of the Act, that we can impose, in addition to any other remedies authorized by law, any of three types of sanctions if we determine that a PO has committed any of nine listed violations. The following PO violations specified in this section are based on provisions of sections 1857(g)(1) and 1903(m)(5)(A) of the Act:

- Fails substantially to furnish to a participant medically necessary items and services that are covered PACE services, if the failure has adversely affected (or has substantial likelihood of adversely affecting) the participant.
- Involuntarily disenrolls a participant in violation of § 460.164.
- Discriminates in enrollment or disenrollment among Medicare beneficiaries or Medicaid recipients, or both, who are eligible to enroll in a PACE program, on the basis of an individual's health status or need for health care services.
- Engages in any practice that would reasonably be expected to have the effect of denying or discouraging enrollment, except as permitted by § 460.150, by Medicare beneficiaries or Medicaid recipients whose medical condition or history indicates a need for substantial future medical services.
- Imposes charges on participants enrolled under Medicare or Medicaid for premiums in excess of the premiums permitted.
- Misrepresents or falsifies information that is furnished to CMS or the State under this part; or, to an individual or any other entity under this part.
- Prohibits or otherwise restricts a covered health care professional from advising a participant who is a patient of the professional about the participant's health status, medical care, or treatment for the participant's condition or disease, regardless of whether the PACE program provides benefits for that care or treatment, if the professional is acting within his or her lawful scope of practice.
- Operates a physician incentive plan that does not meet the requirements of section 1876(i)(8) of the Act.
- Employs or contracts with any individual who is excluded from participation in Medicare or Medicaid under section 1128 or 1128A of the Act (or with any entity that employs or contracts with such an individual) for the provision of health care, utilization review, medical social work, or administrative services.

We received the following comments on § 460.40.

Comment: A commenter stated that the 1999 interim final rule did not include sanctions or enforcement actions that would apply if a program fails to comply with the data collection, record maintenance and reporting requirements in subpart L. The commenter asked what is the authority to require the POs to comply with these requirements.

Response: Under the terms of the program agreement (§ 460.32(a)(2)) the PO is committed to meet all applicable requirements under Federal, State and local laws and regulations, which would include the requirements under subpart L. The reporting requirements in subpart L impact our ability to calculate Medicare capitation payments. Lacking the necessary data to compute an appropriate payment, the PO might receive an inaccurate payment or possibly no payment at all for the corresponding month(s).

Moreover, failure to submit required reports could be interpreted as a failure by the PO to comply substantially with conditions for a PO under this part (§ 460.50(b)(1)(ii)) or to comply with the terms of its PACE program agreement. Therefore, CMS and the SAA have the option of terminating the PACE program agreement due to uncorrected deficiencies.

We believe that § 460.40 as published in the 1999 interim final rule sufficiently addresses the availability of sanctions for violations of subpart L requirements.

Comment: A commenter indicated it was not clear how CMS intended to monitor performance in an identified deficient area nor how CMS and the SAA would cooperate on investigations, agree on findings, and impose sanctions, enforcement, and termination.

Response: In a cooperative effort, CMS and the SAA jointly perform onsite monitoring reviews on a regular basis to ensure quality of participant care as well as to verify clinical and administrative compliance with the PACE regulations. Both CMS and the SAAs engage in a collaborative relationship to sustain oversight of the PO. We stress communications to ensure that each party has the information necessary to take appropriate actions.

Comment: A commenter also requested we clarify the violation incorporated into § 460.40(d), which concerns practices that would have the effect of denying or discouraging enrollment.

Response: Under § 460.40(d), CMS may impose a sanction if the PO engages in any practice that would deny or discourage a participant from enrolling in PACE whose medical condition or history indicates a need for substantial medical service. The exception to this sanction is if the applicant is otherwise ineligible under § 460.150 (that is, they are under 55 years of the age, they do not live in the PO's service area, they do not meet the level of care indicated in the State's Medicaid plan, living in the community would jeopardize their health or safety under the criteria as specified in the program agreement, or any additional eligibility requirements approved by CMS and included in the PACE provider agreement).

Final rule actions:

This final rule will finalize § 460.40 as published in the 1999 interim final rule.

Section 460.42 Suspension of Enrollment or Payment by CMS

We described the two types of sanctions that we may impose in § 460.42 and § 460.46 (civil money penalties). Each of the sanctions, or remedies, that are specified in these sections for specific violations are based on provisions of sections 1857(g)(2), 1857(g)(4), and 1903(m)(5)(B) of the Act. With respect to suspension of enrollment in PACE, we may suspend enrollment of Medicare beneficiaries after the date we notify the organization of the violation. Suspending enrollment of Medicaid recipients is an action taken by the SAA rather than CMS. With respect to suspension of payment, we may suspend Medicare payment to the PO and deny payment to the State of Federal financial participation (FFP) for medical assistance services furnished under the PACE program agreement.

Comment: One commenter recommended that a decision to suspend enrollment should be a collaborative agreement by CMS and the SAA or the SAA should have the ability to do so on its own. Therefore, the commenter recommended establishing an expectation of collaboration between CMS and the SAA, at a minimum.

The commenter also recommended that we revise § 460.42(b)(2) to prospectively notify the State that FFP will be discontinued 60 days from receipt of the notice.

Response: In the event of any violation or imposition of sanctions, we work closely with the SAA of the State in which the PO is located. The interaction between CMS and the SAA is by nature a collaborative one and any action decided upon is the result of this

collaborative effort. We do not believe that adding regulatory language will enhance the inherent collaborative working relationship between CMS and the SAAs.

Moreover, should we exercise the sanction option at § 460.42(b)(2), we will use existing procedures and timeframes for the disallowance of FFP claims. These provisions can be found at 42 CFR 430.42.

Final rule actions:

This final rule will finalize § 460.42 as published in the 1999 interim final rule.

Section 460.46 Civil Money Penalties

In addition to suspension of enrollment, CMS may impose civil money penalties as specified in § 460.46. These include penalties of $100,000 plus $15,000 for each individual not enrolled as a result of the PO's discrimination in enrollment or disenrollment or practice that would deny or discourage enrollment; $25,000 plus double the excess amount above the permitted premium charged a participant by the PO; $100,000 for each misrepresentation or falsification of information; and $25,000 for any violation specified in § 460.40.

Comment: One commenter requested clarification of CMS' authority to assess financial penalties for violations to dual eligible individuals (Medicare beneficiaries that are also Medicaid eligible individuals) as well as Medicare-only beneficiaries.

Response: Authority to assess monetary penalties is provided in sections 1894(e)(6) (Medicare provisions) and 1934(e)(6)(Medicaid provisions) of the Act. If it is determined that a provider has failed to comply with the requirements of those sections of the Act and the regulations, CMS has the authority to impose monetary penalties for violations impacting either dual eligible or Medicare-only participants.

Comment: Several commenters expressed concern that the civil monetary penalties for POs are the same or greater than those of Medicaid managed care and MA organizations. The commenters pointed out that significant size and revenue differences between MA and POs warrant lower penalties for POs. In addition POs have a smaller pool of potential participants than managed care organizations, which must enroll all individuals regardless of need.

Response: We believe the current requirement as published is appropriate in that it allows for imposition of a range of penalty amount from one dollar up to and including the amounts identified in § 460.48. It is not CMS' intent to close any PACE program. We believe the imposition of the maximum financial penalty is an option that would only be used in cases of egregious violations. We believe it is appropriate to maintain the current regulatory requirements, which provide CMS the ability to impose a broad range of penalty amounts including the maximum sanction should the situation warrant.

Comment: Six commenters indicated that the level of penalties is too severe and recommend the penalties be proportionate to the size of the PACE program. One commenter recommended penalties be left to the discretion of the State, while several others indicated that an appropriate amount would be one-quarter of the amount required for Medicaid managed care and M+C plans.

Response: As noted in the previous response, the rule permits a range of amounts to be imposed and provides CMS with the necessary flexibility to impose an appropriate amount depending upon the nature of the violation. In addition, we note that statute requires CMS to make the determination (after consultation with the SAA) to impose any sanctions.

Comment: One commenter relayed the regulation did not indicate to whom the fines should be paid. They recommended the fines be shared equally between the Federal government and the SAA.

Response: Should CMS impose a fine, the PO will be informed in writing and directed where to send the penalty. The PACE statute and regulations at § 460.46(b) specify that section 1128A of the Act governs disposition of civil money penalties. It is not the purpose of this rule to further address disposition of amounts recovered.

Final rule actions:

This final rule will finalize § 460.46 as published in the 1999 interim final rule.

Section 460.48 Additional Actions by CMS or the State

In § 460.48 we specified, based on paragraph (e)(6)(A) of sections 1894 and 1934 of the Act, that if CMS, after consultation with the SAA, determines that a PO is not in substantial compliance with requirements in these regulations, CMS or the SAA can take one or more of the following actions: Condition the continuation of the PACE program agreement upon timely execution of a corrective action plan; withhold some or all payments under the PACE program agreement until the organization corrects the deficiency; or terminate the program agreement.

Comment: One commenter questioned whether CMS and the SAA could independently take action against a PO for violations providing there was prior consultation.

Response: The statute allows CMS to take an enforcement action but only after CMS has consulted with the SAA, and determines that the PACE provider has failed substantially to comply with the PACE requirements. While the SAA may take action based on its own regulations, we believe, that in light of the collaborative relationship between CMS and the SAA, the SAA would consult with CMS before taking any independent action.

Final rule actions:

This final rule will finalize § 460.48 as published in the 1999 interim final rule.

Section 460.50 Termination of PACE Program Agreement

In § 460.50 we specified, in accordance with paragraph (e)(5)(A) of sections 1894 and 1934 of the Act, that CMS or a SAA may terminate at any time a PACE program agreement for cause and that a PO may terminate an agreement after appropriate notice to CMS, the SAA, and its participants. In accordance with paragraph (e)(5)(B) of sections 1894 and 1934 of the Act, we specified that CMS or a SAA may terminate a PACE program agreement with a PO if CMS or the SAA determines that:

- Either there are significant deficiencies in the quality of care furnished to participants, or the PO has failed to comply substantially with conditions under these regulations or with the terms of its PACE program agreement; and
- The PO has failed to develop and successfully initiate, within 30 days of the date of the receipt of written notice, a plan to correct the deficiencies, or has failed to continue implementation of such a plan.

Based on the Protocol, Part IX, section A.1, we also provided for termination if CMS or the SAA determines that the PO cannot ensure the health and safety of its participants. This determination may result from the identification of deficiencies, which CMS or the SAA determines cannot be corrected. Based on the Protocol, Part IX, section A.2, we also required that if the organization terminates the agreement, a minimum of 90 days' notice must be given to CMS and the SAA regarding the organization's intent and that participants must be given a minimum of 60 days notice.

Comment: Termination of the PACE program and transitional care during transition were topics of several comments and recommendations we received. Recommendations included

adding regulatory language requiring CMS and the SAA to agree and coordinate their actions related to termination of a PACE program agreement. Another recommendation was to require that CMS and the State consider the likelihood of institutionalization of community participants in determining whether termination should be imposed.

Response: Neither CMS nor the State considers termination lightly, and our primary concern is protecting the health and safety of the participants. All possible ramifications of terminating a program agreement, including the likelihood of participants becoming institutionalized, will be considered before taking such a severe action. However, we disagree with the commenters and do not believe revisions to the regulations are warranted. As stated in response to previous commenters, we believe the cooperative nature of the relationships between CMS and the SAAs will lead to agreement on a decision to terminate a program agreement. We note however, the statute and regulations specify that CMS or the SAA may independently terminate a PACE program agreement.

Comment: A commenter suggested that the regulations include the appointment of a temporary manager to supervise the operation of the PACE program as an alternative to termination of the program agreement.

Response: To date our experience with the POs does not indicate the necessity of including this remedy in regulation. We will continue to assess the performance of POs and we may consider this sanction in the future. We note that § 460.48(a) states that CMS or the SAA may condition continuation of the PACE program agreement upon timely execution of a corrective action plan (CAP). The appointment of a ''temporary manager'' could be included within the provisions of a CAP. As such, it would be unnecessary to specify specific remedies (including a temporary manager) that CMS might include in the CAP for a particular PO.

Final rule actions:

This final rule will finalize § 460.50 as published in the 1999 interim final rule.

Section 460.52 Transitional Care During Termination

Based on the Protocol, Part IX, section B, we require that the PO develop a detailed written plan for phase-down in the event of termination which includes the following: The process for informing participants, the community, CMS and the SAA in writing about termination and transition procedures; and steps that will be taken to help assist participants to obtain reinstatement of conventional Medicare and Medicaid benefits, transition their care to other providers, and terminate marketing and enrollment activities. This information can be located at *http://www.cms.hhs.gov/pace/*, Chapter 1, section 3. Also, in accordance with paragraphs (a)(2)(C) and (e)(5)(C) of sections 1894 and 1934 of the Act, we specified in § 460.52 that an entity whose PACE program agreement is in the process of being terminated must provide assistance to each participant in obtaining necessary transitional care through appropriate referrals and making the participant's medical records available to new providers.

Comment: We were asked what constitutes ''community'' in § 460.52(a)(1).

Response: In the context of the § 460.52(a)(1) of the 1999 interim final rule, the term ''community'' refers to the general public. Notification to the community would include publishing information regarding the termination in one or more of the generally circulated newspapers in each community or county located in the PO's service area.

Comment: A commenter asked when the transition plan is due (upon notification of termination, or at an earlier point such as at the readiness review or in the context of the program agreement).

Response: A written plan for transition in the event of termination is a component of the PACE provider application and is due at the time the POs application is submitted.

Comment: A commenter was concerned that the regulation needed to provide additional participant protection against loss of services in the event of PO termination. More specifically, the commenter recommended that except where there is an immediate threat of health and safety of the participants, the PO should be required to continue services until such time as a participant is receiving alternative services under Medicare and/or Medicaid, or both, as appropriate, in accordance with the plan of care.

Response: In the event a PACE program agreement is terminated, we believe the regulation provides for sufficient participant safeguards. These safeguards are applicable regardless of who initiates the termination; the PO, CMS, or the SAA. Section 460.52(b) provides that a PO must have a written plan for phase-down in the event of termination which describes how the organization plans to provide assistance to each participant in obtaining necessary transitional care through appropriate referrals.

If the PO initiates the termination, it must provide CMS 90 days' notice, which should provide sufficient time to transition participants to alternative care. If a participant is eligible for Medicaid, the State should provide assistance in arranging for alternative care.

For Medicare beneficiaries, disenrollment from PACE permits reinstatement into original Medicare fee-for-service or enrollment into an MA plan through a special election period.

Final rule actions:

This final rule will finalize § 460.52 as published in the 1999 interim final rule.

Section 460.54 Termination Procedures

In § 460.54, we specified termination procedures based on paragraph (e)(7) of sections 1894 and 1934 of the Act, which provide that:

- The provisions of section 1857(h) of the Act apply to termination of a PACE program agreement in the same manner as they apply to a termination of a contract with a M+C organization under Part C of title XVIII of the Act.
- The provisions of section 1857 of the Act authorize termination of an agreement with an organization based on the following:
- CMS provides the organization with the reasonable opportunity to develop and implement a corrective action plan to correct the deficiencies that were the basis of the determination that cause exists for termination; and
- CMS provides the organization with reasonable notice and opportunity for hearing (including the right to appeal an initial decision) before terminating the agreement.

However, termination is authorized by section 1857(h)(2) of the Act without invoking these procedures if we determine that a delay in termination, would pose an imminent and serious risk to the health of participants enrolled with the organization.

Comment: A commenter asked what is meant by ''reasonable opportunity'' in relation to the development and implementation of a CAP and ''reasonable notice'' for a hearing before terminating the program agreement.

Response: Under normal circumstances, the PO is allowed 30 days from the time they receive the written report following a monitoring review to submit a written response with the CAP to CMS and the SAA. If the PO is unable to submit a CAP within the 30 day period, they may request an extension. The determination to permit

the extension is made based on the particular circumstances at issue.

If participant health and safety is in jeopardy, the monitoring team will inform the PO before their departure that a quicker response is required.

Implementation of the CAP is dependent on the intensity and complexity of the deficiencies identified. Initiation of the CAP should be as immediate as possible. In the event the deficiency relates to the health and safety of participants, implementation of the CAP must be immediate. On the other hand, should the deficiency be related to the physical facility itself, (for example, an electrical or plumbing issue) it may take time to retain the appropriate experts to receive a quote for required construction or repair, prepare and sign a contract to perform the services, arrange for permits, materials, staff required and then to have the construction/repair performed.

Comment: A commenter asked how CMS expects to become aware of any imminent and serious risks to participants, as described in § 460.54(b).

Response: In addition to our usual monitoring procedures, there are a number of mechanisms in place that could provide CMS and the SAA with information indicating imminent and serious risk to participants. The participant's family or caregiver is actively involved in the plan of care and the PO is required to have a robust grievance and appeals process. In this manner, we could be directly notified on any concerns about quality of care. In addition, there may be an ombudsman program in the State, which could be accessed if there were concerns about quality of care. POs are also required to report quarterly data elements for monitoring and financial reports. CMS and the SAA routinely review the reports, which would provide indications that there could be issues with patient care.

For example, there is an unexpected shortfall in revenues reported and a sudden increase in the number of falls. In this case, CMS or the SAA would follow up with the PO to inquire about the changes in their patterns, and ensure that participants are receiving adequate care.

As noted above, CMS may terminate an agreement without invoking the procedures described in § 460.54(a), if CMS determines that a delay in termination, resulting from compliance with these procedures before termination, would pose an imminent and serious risk to the health of participants enrolled with the organization.

POs are also required to inform CMS and the State by e-mail within 24 hours of the occurrence of a ''sentinel event'' (or as soon as a determination is made that the occurrence may be a sentinel event).

We have defined a sentinel event as an unexpected occurrence that caused a participant death or serious physical or psychological injury that included permanent loss of function. We included in this definition any medical equipment failures that could have caused a death and all attempted suicides.

The sentinel event policy for PACE can be found at *http://www.cms.hhs.gov/PACE/Downloads/sereporting.pdf*.

The purpose of the sentinel event reporting policy is to provide guidance to the PO regarding their responsibility should a sentinel event occur. CMS views these events as opportunities to conduct analyses of the underlying root causes, which will reduce the risk of recurrence of a similar event. We also note that generally when a concern or complaint other than a sentinel event is brought to the attention of CMS or the SAA, fact finding activities are initiated, which can include but are not limited to a desk review of documentation, conference calls, or an onsite review, depending upon the case-specific circumstances.

Lastly, POs can request to have quarterly conference calls with CMS and the SAA to discuss policy or operational issues. We believe quarterly calls between the PO, the SAA and CMS are of great benefit in facilitating more open communications. Quarterly calls foster a good working relationship that is helpful when CMS or the SAA need to investigate a concern or complaint they have received.

Final rule actions:

This final rule will finalize § 460.54 as published in the 1999 interim final rule.

Subpart E—PACE Administrative Requirements

The purpose of subpart E is to establish the administrative requirements for entities applying for participation in the PACE benefit. In this subpart, we established requirements relating to organizational structure, the governing body, and program integrity of the entity, as well as relationships between entities. In addition, we specified personnel qualifications and on-going training that must be implemented by the PO for employed and contracted staff, requirements for contracting services, and oversight of employed and contracted staff requirements. This section also established requirements related to physical environment, infection control, transportation services, dietary services, fiscal soundness, and marketing.

Section 460.60 PACE Organizational Structure

We established § 460.60 to specify the structural requirements for a PO. As we explained in the preamble to the 1999 interim final rule, we believe that the requirements specified in § 460.60 are essential to the PO's ability to ensure the health and safety of the participants. The performance of certain basic organizational functions is a minimum condition for an environment in which appropriate care can occur. We based the organizational structure requirements on Part I of the Protocol.

We require that the PO have a current organizational chart showing officials in the PO. The chart for a corporate entity must indicate the PO's relationship to the corporate board and to any parent, affiliate, or subsidiary corporate entities. In the 1999 interim final rule, we required a PO that is planning a change in organizational structure to notify CMS, the SAA, and its participants, in writing, at least 60 days before the change takes effect. Further, we required changes in organizational structure to be approved by CMS and the SAA, and after approval, to be forwarded to the PO's consumer advisory committee (described later in this preamble). Finally, in the event of a change of ownership, we would apply the general provisions described in 42 CFR 422.550.

The Protocol requires that a PO have a project director. In the 1999 interim final rule, we included this requirement, but changed the term to ''program director'' and further defined the role of this individual. The PO must have a program director who is responsible for the oversight and administration of the entity. The program director is responsible for the effective planning, organization, administration, and evaluation of the organization's operations. The program director would also ensure that decisions about medical, social, and supportive services are not unduly influenced by fiscal managers. The program director is responsible for ensuring that appropriate personnel perform their functions within the organization. The program director would inform employees and contract providers of all organization policies and procedures. If the PO is part of a larger health system, the program director would clearly define and inform PO staff (employees and contractors) of the policies applicable to the PO.

In the 1999 interim final rule, we also maintained the Protocol's requirement for a medical director, but we further delineated the responsibilities of this position. The PO must have a medical director who is responsible for the delivery of participant care, clinical outcomes, and the implementation and oversight of the QAPI program. Thus, the medical director is responsible for achieving the best possible clinical outcomes for all participants. Under this requirement, we would expect the medical director to use the organization's data to demonstrate internal improvements in outcomes over time.

The 1999 interim final rule established § 460.60 that required that the PACE program director and the medical director be employees of the PO. In order to allow for contracting of the PACE program director and medical director, in the 2002 interim final rule, we amended § 460.60(b) and (c) to require that the PO employ these staff members directly or have contracts for these staff that meet the contracting requirements specified in § 460.70.

Comment: We received several comments related to the possibility of PACE being operated as a for-profit entity. Commenters provided examples of organizations that are unable to participate in PACE due to the requirement that POs maintain non-profit status.

Response: We note that sections 1894(a)(3)(B) and 1934(a)(3)(B) of the Act allow private, for-profit entities to participate in PACE, subject to a demonstration waiver described in section 1894(h) of the Act. Should for-profit entities wish to participate in PACE, they should apply for a demonstration waiver under section 1894(h) of the Act. While participating in the PACE for-profit demonstration, they must meet all requirements set forth in PACE regulations. We explicitly stated that we would expect the PO to retain all key administrative functions including marketing and enrollment, quality assurance and program improvement, and contracting for institutional providers and other key staff.

Comment: We received conflicting opinions regarding whether to allow flexibility in contracting for various members of the IDT, the program director, the medical director, as well as PACE center services. The majority of commenters advocated for flexibility in order to be responsive to the needs of individual POs. However, some commenters expressed concern that by allowing the PO to contract for the medical director and program director, the PACE model would lose dedicated management. This concern was submitted in response to both the 1999 interim final rule and the amended 2002 interim final rule.

Response: We note that in the 1999 interim final rule, we retained the Protocol's requirement that the program director and medical director be employees of the PO.

However, in response to the large number of public comments received on § 460.60 of the 1999 interim final rule, we revised the regulatory requirements in the 2002 interim final rule to allow POs the flexibility to contract for all members of the IDT, the program director, and medical director as well as all PACE center services. We also expanded § 460.70 to include additional contract requirements.

In response to the comment about losing dedicated management because of contracting for the program director and medical director, we do not believe that a personal commitment to the PACE model is related to employment status. We continue to believe that anyone, contractor or employee, PCA, or director can believe in the PACE philosophy and wish to provide care through this model. Therefore, we are not amending this requirement in this final rule.

Comment: Several commenters stated that, as currently written, the regulatory requirement assigns responsibility for QAPI to both the governing body and the medical director. They requested confirmation that the governing body's responsibility is to affect a program-wide approach to quality, ensuring alignment of unit activities with overall objectives, whereas the responsibilities of the medical director would be more narrowly focused on clinical aspects of care.

Response: The commenters are correct. Although QAPI activities and objectives affect every staff member and contractor, the governing body has overall responsibility for the QAPI program and the medical director has overall clinical responsibility.

Comment: In response to our solicitation for comment regarding the extent to which changes in organizational structure are important to participants, we received a number of suggestions that we revise the requirement to notify CMS, or CMS and the SAA, of changes in organizational structure. Commenters were consistent in their recommendations that notification should only be required for a change in ownership, governing board, or delivery system, focusing on those changes that significantly impact service delivery.

All commenters recommended deleting the requirement to report changes in staffing. Several commenters requested that we clarify which changes in organizational structure require notifying CMS and the SAA because it appeared that any change of job title or the creation of a position or unit within the PO would warrant prior approval by CMS and the SAA. It was also noted that various staffing changes and shifts in reporting relationships can be implemented seamlessly with no disruption in service to the participants.

Approval of organizational changes was another topic that elicited comments. Some commenters suggested that the requirements regarding approval by CMS and the SAA of changes in organizational structure be deleted because micromanagement could impede a PO's ability to proactively adjust its structure to meet prevailing concerns as well as to respond to the needs of enrollees. Other commenters thought that advance approval by the SAA should be sufficient.

There were also a number of recommendations of timeframes for submitting advance notification. Suggestions ranged from not informing CMS at all to 60 days, which would include time for CMS and the SAA to review and approve the proposed organizational change. If CMS and the SAA did not respond within the 60-day period, the PO's organizational changes would be deemed approved. Some commenters suggested we follow the State Medicaid regulations of some States, which require notification at least 14 calendar days before the effective date of the change. Another commenter suggested that we require prior notification and approval of changes in ownership and only require notification of other changes in clinical or administrative structure.

One commenter recommended the regulatory language specify that the PO is responsible for forwarding information relating to changes in organizational structure to the consumer advisory committee.

Several commenters agreed that changes that impact the day-to-day experience of the participants or alter their normal patterns of interaction with the PACE program should be communicated to participants in sufficient time for them to adjust to the changes, and that this notification should be the responsibility of the PO.

Response: Comments on this section address three separate requirements, the requirement for CMS and the SAA to be notified in writing at least 60 days before a change in organizational

structure, the requirement that CMS and the SAA approve changes in organizational structure, and the requirement that changes in organizational structure approved by CMS and the SAA be forwarded to the consumer advisory committee.

We established this section in the 1999 interim final rule to require disclosure of organizational changes that affect the philosophy, mission, and operations of the PO and impact care delivery to participants. At that time, we believed that any change in ownership, relationships to another corporate board and to any parent, affiliate, or subsidiary corporate entities, the PACE governing body, its officials, program director, and medical director could result in a substantial impact on the participants and their care. However, it was not our intent to require the PO to notify CMS and the SAA in writing every time there was a change in personnel or a change in the line of reporting of direct participant care staff.

The 1999 interim final rule required that POs planning to change their organizational structure must notify CMS and the SAA, in writing, at least 60 days before the change takes place. This timeframe was to allow sufficient time for CMS and the SAA to approve or deny the proposed change. We agree with the commenters that notification of 60 days before implementing a change in organizational structure is unnecessary.

Therefore, in response to the numerous comments relating to the disclosure of changes in organizational structure, in this final rule we are amending this section to require any PO who is planning a change in organizational structure to notify CMS and the SAA, in writing, 14 days before the change takes place. We believe that 14 days advance notice provides an adequate timeframe for CMS and the SAA to review the changes, and is consistent with some States Medicaid notification requirements.

We are also deleting the requirement that changes in organizational structure must be approved in advance by CMS and the SAA. We agree with the commenters that POs have the ability to make such business decisions based on their individual circumstances. However, as CMS and the SAA are responsible for the health care provided to participants, requiring notification will allow CMS and the SAA to monitor whether the change is having a substantial impact on the participants or their care.

In the 1999 interim final rule, the PO was required to forward the CMS and SAA approval of their organizational changes to the consumer advisory committee. As changes will no longer need to be approved by CMS and the SAA we believe the requirement to forward the CMS and SAA approvals to the consumer advisory committee is now unnecessary and should also be removed.

We reiterate that in the event of a change of ownership, CMS would apply the general provisions described in § 422.550 (Effect of change of ownership or leasing of facilities during term of contract.)

Comment: Another commenter questioned whether two organizations wishing to develop PACE as a cooperative venture must establish a separate and distinct entity to comply with all requirements and provisions of the regulations. The commenter believed this approach would impede PACE development by restricting opportunities for entities to jointly approach PACE development. This commenter also requested clarification of the regulations to clearly permit flexibility within the provider community, including the ability for the PO to contract for the PACE center services.

Response: We view this comment as addressing two different issues. First, in response to whether a separate and distinct entity would need to be established if two organizations developed a cooperative venture, the organizations involved would need to establish a separate and distinct entity to be the PO that is responsible for complying with all requirements and provisions of the regulations. Because the PO signs a three-way program agreement and is the entity responsible for the management of the organization, we believe that this needs to be a single entity. The PO is the responsible entity for assuming full financial risk, administration activities, and comprehensive coordinated participant care. We do not believe these responsibilities can be split up and still maintained under a single entity. In our experience, this requirement has not unduly restricted organizations from developing a PO through a cooperative agreement.

The second issue is whether the cooperative venture arrangement would be precluded from using subcontractors. As long as the arrangements designated a PO, as noted above, the 2002 interim final rule provided flexibility to allow for contracting out all required PACE services as well as the PACE center services, providing that the PO retains all key administrative functions including marketing, enrollment, QAPI, and contracting for institutional providers and other key staff, as well as retaining ultimate responsibility for oversight of all direct participant care.

Final rule actions:

In this final rule, we are changing the requirements related to changes in organizational structure by:

- Requiring 14-days notice before making organizational changes;
- No longer requiring CMS and SAA approval; and
- No longer requiring the PO to forward the CMS approval to the consumer advisory committee.

Section 460.62 Governing Body

In the 1999 interim final rule, we established the requirements and responsibilities of the governing body that is legally and fiscally responsible for the administration of the PO. We left the specific approach to administration of the PO to the discretion of the governing body, reflecting our goal of promoting the effective management of the organization without limiting flexibility in determining how to achieve that goal.

The governing body must create and foster an environment that provides quality care that is consistent with participant needs and the program mission. To that end, the primary requirement is that an identifiable governing body, or designated person(s) so functioning, have full legal authority and responsibility for the governance and operation of the organization, the development of policies consistent with the mission, the management and provision of all services (including the management of contractors), fiscal operations, and the development of policies on participant health and safety. Also, the governing body will establish personnel policies and contract provisions with respect to employees or contractors with patient care responsibilities giving adequate notice before leaving the PO's network. These provisions would be intended to avoid disruptions in care and permit orderly transition of responsibilities.

We included a requirement that the governing body be responsible for the QAPI program. The purpose of this requirement is to link the development, implementation, and coordination of the ongoing QAPI program with all aspects of the PACE program. We believe this requirement will stimulate an aggressive effort by the organization to identify and use the best available practices for all participants. As discussed in the section on the QAPI program, the PO has the flexibility to design its own quality improvement program.

Consistent with the Protocol, we also included a requirement that the PO

must ensure community representation on issues related to participant care. This may be achieved by having a community representative on the governing body. In addition, the PO must establish a consumer advisory committee to provide advice to the governing body on matters of concern to participants. As we indicated in the 1999 interim final rule, consumer participation through advisory committees is a well-accepted community organization vehicle to maximize the involvement of participants in a program designed to serve them. With the use of such a committee, the governing body will have the benefit of participant input, including information on quality of care issues. Participants also are likely to feel a greater stake in the operation of the program. In order to ensure appropriate representation, participants and representatives of participants must constitute a majority of the membership of this committee. One specific duty of the participant advisory committee is to receive information from the governing body to be disseminated to participants.

Comment: We received several comments regarding community representation on the governing body. Commenters noted that a single consumer representative did not have a sufficient impact on health programs when the governing body is made up almost entirely of provider representatives. The commenters requested that the regulations be changed to require at least one-third of the governing body to be community representatives who are Medicare or Medicaid beneficiaries or are designated by organizations that advocate for these persons. In addition, they recommended that the governing body should include at least one PACE program participant and one family member of a participant. They also requested that we include a requirement that the PO provide information to CMS and the SAA to ensure compliance with community representation on the governing body.

One commenter stated that because POs are small programs, they may find it difficult to comply with the requirement of a consumer advisory committee in that it may be difficult to get enough consumers or their representatives to serve on an ongoing committee. They suggested instead that POs be allowed to request a waiver of this requirement, where they can demonstrate that sufficient opportunities exist for obtaining input from consumers and their representatives on matters of concern to participants.

Response: In response to these commenters, we are revising the regulation by changing the names and focus of the ''consumer advisory committee'' to the ''participant advisory committee'' and the ''community representative'' to the ''participant representative.'' We are also adding a definition of ''participant representative,'' which defines the responsibilities of this individual. We disagree with the commenters who indicated that the governing body needs to have a greater number of consumer representatives. By changing the names and objectives of the consumer committee and community representative, we anticipate participants and their representatives becoming more involved in topics that impact their care. We believe that the more participants feel they are stakeholders, the more involved they will be in their PO.

The interactive nature of the PACE model is such that participants are encouraged to be involved and voice their opinions. Therefore, we expect the governing body to be more receptive to participant input presented by the participant representative. This collaborative relationship is expected to achieve higher quality of care and higher participant satisfaction. Therefore, we would not be inclined to waive this requirement without significant justification on the part of the PO.

We do not specify how large the participant advisory committee must be, but we expect it to be representative of the size and population of the PO's participants.

We also understand that there may be topics or times when the governing body would believe that it is inappropriate for participants to attend the entire governing body meeting. When this occurs, we would expect the meeting agenda to be arranged such that the participant representative could attend a portion of the meeting to present participant issues.

We also disagree with the commenter that requested we require POs to submit information to ensure compliance with community representation on the governing body. Minutes and other official documents pertaining to governing body meetings must be available for review by CMS and the SAA during onsite visits and at the request of either agency.

Final rule action:

In this final rule we are:

- Changing the names and responsibilities of the consumer advisory committee, community representative to the participant advisory committee, and participant representative; and
- Rearranging the order of the requirements.

Section 460.64 Personnel Qualifications for Staff With Direct Participant Care Contact

We indicated in the 1999 interim final rule that although the Protocol does not specify personnel requirements for the various staff employed by or under contract with the PO, we believe that certain minimum standards must be met in order to ensure quality of care for the frail elderly population being served. To this end, we established § 460.64.

Our approach to personnel qualifications in the 1999 interim final rule followed principles described in a March 10, 1997 **Federal Register** publication proposing changes to the COPs for home health agencies (62 FR 11022). This is a flexible approach, which relies on State requirements as much as possible.

The personnel qualifications fall into three categories: (1) Personnel for whom there are statutory qualifications; (2) personnel for whom all States have licensure, certification, or registration requirements; and (3) personnel for whom we have specified requirements if the State does not have licensure, certification, or registration requirements.

Category 1: This category consists of personnel for whom the Act contains qualifications, which in § 460.64(b) pertains specifically to physicians. Section 1861(r) of the Act defines a physician as a doctor of medicine or osteopathy, legally authorized to practice medicine and surgery by the State in which that function or action is performed, or certain other practitioners for limited purposes. We adopted the definition as reflected in regulations at 42 CFR 410.20.

In addition, to reflect the key role of the PCP in the PACE model, we required the PCP to have a minimum of 1 year's experience in working with a frail or elderly population.

Category 2: For this category of personnel qualifications, we deferred to State law. We specified that all staff (employee or contractor) of the PO must meet applicable State requirements. That is, they must be legally authorized (currently licensed or, if applicable, certified or registered) to practice in the State in which they perform the function or action and must act within the scope of their authority to practice. For example, to practice nursing, every registered nurse in the State must be licensed and practice within their State's scope of practice authority.

Category 3: This category of personnel qualifications includes certain professions for which not all States had licensure, certification, or registration requirements. Our intention was that if a State has licensure, certification, or registration requirements for a professional listed in this section, then the State qualifications would apply. The following requirements would only apply to those personnel in Category 3 when the State they practice in does not have licensure, certification, or registration requirements.

After reviewing the personnel requirements of other Medicare and Medicaid providers that serve populations similar to PACE participants (for example, home health agencies, nursing facilities), in the 1999 interim final rule, we established personnel requirements for POs that were as consistent as possible with those applicable to other Medicare providers. If a State does not have licensure, certification, or registration requirements applicable to the following professions, then the qualifications specified below apply.

We required that the registered nurse be a graduate of a school of professional nursing and have a minimum of 1 year's experience working with a frail or elderly population.

We required that the social worker (1) have a Master's degree in social work from an accredited school of social work; and (2) have a minimum of 1 year's experience working with a frail or elderly population.

We required that the physical therapist (1) be a graduate of a physical therapy curriculum approved by the American Physical Therapy Association, the Committee on Allied Health Education and Accreditation of the American Medical Association, or the Council on Medical Education of the American Medical Association and the American Physical Therapy Association or other equivalent organizations approved by CMS; and (2) have a minimum of 1 year's experience working with a frail or elderly population.

We required that the occupational therapist (1) be a graduate of an occupational therapy curriculum accredited jointly by the Committee on Allied Health Education and Accreditation of the American Medical Association and the American Occupational Therapy Association; (2) be eligible for the National Registration Examination of the American Occupational Therapy Association; (3) have 2 years of appropriate experience as an occupational therapist and have achieved a satisfactory grade on a proficiency examination conducted, approved, or sponsored by the U.S. Public Health Service, except that this determination of proficiency does not apply with respect to persons initially licensed by a State or seeking initial qualification as an occupational therapist after December 31, 1977; and (4) have a minimum of 1 year's experience working with a frail or elderly population.

We required that the recreation therapist or activities coordinator have 2 years experience in a social or recreational program providing and coordinating services for a frail or elderly population within the last 5 years, one of which was full-time in a patient activities program in a health care setting.

We required that the dietitian (1) have a baccalaureate or advanced degree from an accredited college with major studies in food and nutrition or dietetics; and (2) have a minimum of 1 year's experience working with a frail or elderly population.

We required that all PACE center drivers (1) have a valid driver's license to operate a van or bus in the State of operation; and (2) be capable of and experienced in transporting individuals with special mobility needs.

We did not define personnel requirements for the PACE center manager or the home care coordinator. We gave POs the flexibility to determine who is best suited to fill these positions as each PACE center may have different needs. Because the home care coordinator is responsible for acting as the liaison between the IDT and the home care providers, she or he should possess good leadership and communication skills. In addition, the home care coordinator should be able to identify and understand participants' medical and social needs in order to evaluate the home care needs of participants. As a result, we indicated that a registered nurse or social worker would be a good candidate to fill this position. However, it was not our intention to deter the PO from considering another candidate with appropriate qualifications because they were neither a registered nurse nor a social worker.

We did not impose personnel requirements for personal care attendants (PCAs) as these individuals will primarily be providing non-skilled, personal care services (such as bathing, toileting, and transferring). In the 1999 interim final rule, we solicited comments on whether to include specific personnel requirements for PCAs. It is important that PCAs possess certain basic skills necessary to provide quality care to PACE participants. Thus, we required POs to implement a training program for each PCA to ensure that they exhibit competency in basic skills in personal care services. Although we did not define the parameters of the training program, we indicated the training program should include maintenance of a clean, safe, and healthy environment; appropriate and safe techniques in personal hygiene and grooming; safe transfer techniques and ambulation; reading and recording temperature, pulse, and respiration; and observation, reporting, and documentation of patient status and the care or service furnished. In addition, the training program developed for each PCA must include other elements consistent with their assigned duties for specific participants.

Finally, we acknowledged that PCAs in the home environment may furnish not only personal care services, but also home care services. Therefore, when the participant needs home care services, the PO must ensure that it has qualified staff (either employees or contractors) that meet the competency requirements established by the PO and approved by CMS for home care aides to furnish these services.

We received a large number of comments regarding personnel requirements.

Comment: Numerous commenters were concerned that the 1999 interim final rule did not appropriately emphasize that State licensure laws, certification, and registration requirements take precedence over the requirements specified in the 1999 interim final rule which may lead to creating unnecessary and unintended conflicts between the PACE regulation and State requirements.

Commenters believe establishment of provider qualifications is traditionally a State function. The commenters indicated it would be sufficient for the regulation to specify that individuals providing PACE services meet applicable State requirements. It was suggested that States be permitted to define a combination of education and experience qualifications and that CMS grant a waiver of these educational and experience requirements if there are staff development procedures in place for those waived individuals, and where the PO's decision to hire staff without the required qualifications will not adversely impact the quality of care. Commenters also recommended that services that do not require State licensure or certification not be subject to additional requirements in Federal regulations.

There was also concern that the requirements set forth in the 1999 interim final rule would be adopted as minimum Federal requirements, regardless of whether State licensure, certification, or other registration exists. If this adoption takes place, the PO's burden of locating adequate numbers of staff will be magnified. Recommendations ranged from removing personnel qualification requirements to allowing health professionals to be permitted to minimally meet State requirements for medical professional practice.

Response: In establishing personnel qualifications, we did not intend to usurp the State's authority. Throughout the regulation, we have indicated that POs must meet all Federal, State, and local regulations and laws. We believe that the present qualifications established for PACE set forth the necessary qualifications to ensure the health and safety of this frail elderly population. Should State regulations be more stringent than those of this regulation, then the PO must meet the State requirements as well.

We believe there was considerable confusion and misunderstanding of the personnel qualification requirements published in the 1999 interim final rule. In that rule, we based personnel qualifications on whether the State had licensure, certification, or registration requirements for a profession. In States where there was no State licensure, certification, or registration, we required minimum educational qualifications for each profession.

In response to the comments and to reduce the confusion over personnel qualifications, we are amending the title of § 460.64 and the personnel qualifications to clarify that the qualifications apply to all PACE staff with direct participant contact, to ensure the health and safety of the participants. We are accomplishing this by consolidating and clarifying requirements in § 460.64(a) that were previously located in other sections of the PACE regulations and by deleting paragraph § 460.64(c).

We are amending the title of § 460.64 and the personnel qualifications to clarify that the qualifications apply to all PACE staff with direct participant contact and decrease the burden in hiring and contracting for adequate numbers of staff members. We are removing the educational requirements and other qualifications at § 460.64(c) that we established where no States required licensure, certification or registration.

We believe that it is essential that all professionals be legally authorized (licensed, certified or registered) to practice in the State in which they practice if the State has established requirements. All States have licensed, certified or registered requirements for physicians, registered nurses, social workers, physical therapists, occupational therapists, and dietitians. All other direct care providers, must meet the State requirements that authorize them to practice in their State. We believe that all professions must act within the scope of their authorized practice guidelines. Each profession has established guidelines that define the services that may be performed within the scope of the minimum level of knowledge and training for each professional level. For example, the scope of practice is different for licensed practical nurses, registered nurses, clinical nurse specialist and nurse practitioners. Regardless, each nurse is expected to practice within his or her respective level.

In the 1999 interim final rule, each profession listed in § 460.64 (b) and (c) was required to have one year of experience working with the frail or elderly population (except for the Recreational Therapist/Activity Coordinator who was required to have two-years experience). The PACE population is comprised of the frail elderly who need to be cared for by staff that has the specific training and experience to understand the complexities and differences in geriatric patients. It is essential for staff to have the knowledge of geriatric practices and skill to work with these individuals. Experienced staff will be conscious that when dealing with the frail or elderly they need to be gentler, more patient and observant than with a healthy younger person. For example, a frail elderly person's skin is more likely to tear, a bone is more likely to break, a joint more likely to be stiff and painful, and medications are more likely to affect them differently with a potentially wider variety of adverse reactions. Therefore, we believe that all personnel having direct participant contact must have a minimum of one year of experience working with a frail or elderly population and are adding this requirement to the general requirements in paragraph (a)(3).

In the 2002 interim final rule, we established requirements for the oversight of direct participant care (§ 460.71), which included requiring the PO to ensure all employees and contracted staff furnishing direct care to participants demonstrated the skills necessary for performance of their position. We also required the PO to establish a competency evaluation program, which has to be evidenced as completed before an individual may perform participant care. We believe that demonstrating competency prior to performing direct participant care is essential to ensure the delivery of safe care. Therefore, we are adding competency as paragraph (a)(4) to the general personnel qualification requirements for staff performing direct participant care.

Section 460.71, Oversight of direct participant care required the PO to develop a program to ensure all staff furnishing direct participant care was free of communicable disease. We believe this is even more important with a frail elderly population considering their complex medical conditions and increased susceptibility. It is standard practice in the health care industry that an individual must be cleared as free of communicable disease prior to employment. We are therefore amending § 460.64 to require that all PACE staff with direct participant contact be medically cleared of communicable disease and have all immunizations up-to-date before engaging in direct contact with participants.

For those professions where not all States have licensure laws, State certification or registration requirements, specifically Recreation therapist/Activity coordinator and drivers, we believe that all States have minimum requirements to ensure that services are provided safely. For example, States require a special class of driver's license to transport people for money. In addition to the general personnel qualifications, we expect that any such State qualification requirements be met.

Comment: A large number of commenters opposed the Federally-defined qualifications for the physician which were not included in the Protocol.

Response: As stated above, section 1861(r) of the Act generally defines a physician and is reflected in 42 CFR 410.20, which defines physician, physician services and the limitations on services under the Medicare program. As all physicians participating in the Medicare program must meet § 410.20, we require that all physicians participating in the PACE program meet the qualifications of § 410.20, and also meet the general qualification requirements as stated in § 460.64(a).

To emphasize the key role of the PCP in the PACE model, we require the PACE PCPs to have one-year's experience working with a frail or elderly population to ensure their knowledge and skill with geriatric

patients. We require they demonstrate their competency prior to employment or contract. The PO must ascertain the competency of prospective physicians through the PO's established competency program. We also require the PCPs be cleared of communicable diseases to ensure that infectious diseases are not passed by the close physical proximity necessary to treat participants.

Comment: We received numerous comments related to specific staffing requirements. A large number of commenters opposed the detailed personnel requirements in the 1999 interim final rule, stating that they unnecessarily limited flexibility in the development and implementation of PACE programs.

The commenters recommended we require all POs establish an adequate staff development process to ensure that all staff members understand the unique needs of the PACE population. However, commenters wanted the States to have the option to waive these requirements. They also recommended we require that the PO also consider factors such as languages spoken and cultural sensitivity.

Response: To the extent the State has licensure, certification, or registration requirements, these apply and not the requirements in § 460.64(c)(1).

These qualification requirements, as noted in the 1999 interim final rule, were to be the regulatory foundation of PACE as a new Medicare benefit and State plan option. We believe that in clarifying the 1999 interim final rule in the 2002 interim final rule, permitting contracting of personnel and providing a waiver process to assist POs where they are unable to comply with regulations, we have addressed and resolved commenters concerns related to limited flexibility and personnel qualifications when no State licensure, certification, or registration laws exist.

We believe we addressed the recommendation regarding the establishment of an adequate staff development process to ensure all staff members understand the unique needs of the PACE population in the 2002 interim final rule, which required that all POs develop a competency evaluation program that identify those skills, knowledge and abilities that must be demonstrated by direct participant staff.

• In response to the recommendation that we require that the PO also consider factors such as languages spoken and cultural sensitivity, we believe that each PO understands the cultural diversity of their particular population. To be in compliance with the requirements of participant rights they must provide for language and cultural diversity, we expect that POs will take these important areas into consideration when hiring staff. As a result, we do not believe that it is necessary to repeat the requirement in this section of the regulation.

Final rule actions:

In this final rule we are making revisions to § 460.64, including:

• Amending the title to ''Personnel qualifications for staff with direct participant contact,'' to clarify that the qualifications apply to all PACE staff with direct participant contact.

• Amending paragraph (a) by adding (1) one year of experience working with a frail or elderly population, (2) meeting standardized competencies prior to providing participant care, and (3) being medically cleared of communicable diseases and have all immunizations up-to-date before engaging in direct participant contact.

• Deleting paragraph (c).

Section 460.66 Training

In § 460.66, we require the PO to provide ongoing training to maintain and improve the skills and knowledge of each staff member with respect to their specific duties. The training should result in the staff's continued ability to demonstrate the skills necessary for the performance of their specific positions or job duties. The ability of the PO to ensure patient safety and to achieve patient-specific performance measures necessitates competent staff. We believe there is a direct relationship between the quality of an organization's staff and patient well-being. The training requirement is intended to ensure that all staff are able to adapt to new or changing job demands. The PO is responsible for ensuring that individuals are educated and trained for their specific jobs. The individuals would continue to be responsible for their own professional education and for any continuing education needed to maintain licensure or professional certification unless the organization chooses to assume this responsibility. In addition, we included a specific training requirement for PCAs as described in § 460.66(b).

Comment: Commenters' opinions regarding the training requirements varied, with recommendations that the SAA should be authorized to establish a minimum training curriculum, and criticisms that the PO should be permitted to utilize training from other sources available in the community.

We were also asked to clarify whether PCAs, who have demonstrated competency in furnishing personal care services through certification as nursing assistants or home health aides, are required to receive redundant or additional training unless it is deemed necessary by the PO.

Response: We are retaining the requirement that POs provide ongoing training to maintain and improve the skills and knowledge of each staff member with respect to their specific duties in order to ensure that PACE participants receive the highest quality care possible. We believe POs have the ultimate responsibility for all care provided to their participants and, therefore, it is in the best interest of PACE participants and the PO that they provide training specific to their participant population. Ongoing in-service training for all staff will ensure that skills remain current and any detrimental practices are caught and rectified as early as possible.

In this final rule, we wish to clarify § 460.66(b), which requires the PO to develop a training program for each PCA in order to establish the individual's baseline competency in furnishing personal care services, including specialized skills associated with the specific care needs of individual participants. We intend that the PO evaluate the skills of each newly hired PCA and develop a training program specific to the competencies or deficiencies that they demonstrate. This training must be performed by qualified professionals. Again, the intent of this training requirement is to identify and resolve any knowledge or skill deficits of each person and educate them to a level where they can demonstrate competency in all basic skills required to provide personal care services. This clarification is intended to prevent redundant training of skills already displayed by PCAs and to reduce the burden on PO resources.

Final rule actions:

In this final rule, we are clarifying the requirement in § 460.66(b) that POs develop a training program for PCAs where there are competency deficits and that personal care attendants must exhibit competency before performing personal care services independent of supervision.

Section 460.68 Program Integrity

We established § 460.68, based on Part I, section E of the Protocol to guard against potential conflicts of interest or other program integrity problems for POs. An organization must not have any staff (employees or contractors) who have been convicted of a criminal offense related to their involvement in Medicaid, Medicare, other health insurance or health care programs, or

any social service program under Title XX of the Act. We expanded this provision from the Protocol in order to prevent an organization from employing any staff who have been excluded from participation in Medicare or Medicaid, or employing staff, in any capacity, where the employee's contact with participants would pose a potential risk because the individual had been convicted of physical, sexual, drug, or alcohol abuse. In addition, members of the PO's governing body, and their family members, are prohibited from having a direct or indirect interest in contracts with the PO. Examples of indirect interests are holdings in the name of a spouse, dependent child, or other relative who resides with the member of the governing body. These requirements are intended to protect participants by preventing fraud under Medicare and Medicaid by members of the governing body with conflicts of interest from inappropriately influencing PO decisions.

We recognize that in rural, Tribal, or urban Indian communities there may be limited availability of individuals willing to and capable of performing key functions for the PO. Therefore, the 1999 interim final rule provided for CMS and the SAA to grant a waiver of the conflict of interest requirement for POs in rural or tribal areas to allow individuals who have a direct or indirect interest in a contract or the provision of services to the PO to recuse themselves from decisions directly or indirectly affecting those interests, rather than barring them entirely from serving on the PO's governing body or serving as directors, officers, partners, employees, or consultants of the PO.

We also included a requirement that the PO must have a process to gather information on program integrity issues and respond to any request from CMS within a reasonable amount of time.

As discussed previously, in the 2002 interim final rule, we established a process for submission and approval of waiver requests and deleted § 460.68(c) that limited waivers to direct or indirect interest in contracts of rural and Tribal organizations. Although we deleted § 460.68(c), we continue to recognize the special need for flexibility in rural and Tribal areas, and remain committed to allowing waivers to promote PACE in medically underserved areas. We also remain committed to working with rural and Tribal communities to help them address the challenges of developing successful PACE programs. Organizations that seek waiver of these or any other regulatory requirements would follow the requirements specified in § 460.26.

Comment: We received several comments regarding program integrity. Commenters requested that we permit the PO the discretion to determine whether an individual's past convictions (which vary greatly in type and severity) would pose a serious threat to PACE participants and suggested modifications to § 460.68(a)(3).

Response: We believe our current policy is consistent with Medicare policy related to other provider types and do not agree that the threat posed by an individual's past convictions should be left to the discretion of the PO. PACE participants are the most frail and vulnerable members of the community, and it is their right to expect care that is free from the risk of harm by their caregivers. Therefore, it is the responsibility of Medicare, Medicaid, and the PO to ensure that every individual hired to provide care to PACE participants poses the least risk possible. We believe that facilitating contact with individuals who have a prior conviction for physical, sexual, drug or alcohol abuse increases the potential risk to the PACE participants.

Comment: One commenter recommended that conflict of interest disclosure regulations apply to the program director, medical director, and the contractor liaison. This commenter also recommended requiring disclosure of conflicts of interest to the SAA. Another commenter recommended the disclosure requirement also apply to the SAA.

Response: We discuss the SAA's role with regard to conflict of interest in this section. However, as the program director, medical director, contractor liaison, and the SAA are not on the governing body and have no voting responsibility, we do not think they are in a position to unduly influence PO decisions. Therefore, we do not believe it is necessary to amend the program integrity requirements to include them. We note that § 460.68 does not preclude a PO from developing disclosure requirements for other staff.

Comment: Two commenters requested we clarify whether the regulatory intent of § 460.68(b) is to limit contracting with related organizations or just related individuals, as many providers establish related corporations which provide services to participants and which were not prohibited in the PACE demonstration program.

Response: The intent of this requirement was to limit an unfair advantage that might be gained by any member of the governing body, or their family member, who would have a direct or indirect interest in an entity contracting with the PO for items or services.

We acknowledge that it is quite common for a PO to be part of or have a relationship with a larger entity. Consistent with § 460.60(d) and Chapter 1, Section VII of the PACE provider application, the POs' relationship to the corporate board and to any parent, affiliate, or subsidiary corporate entity must be described in the provider application under the requirements for organizational structure. In this type arrangement it would be customary to contract for services with other entities within the system. As these are entity-to-entity arrangements and no individual would personally benefit, these kinds of common business practices do not give rise to the type of conflict of interest contemplated under § 460.68(b).

Since implementation of the 2002 interim final rule, we have also received numerous requests for waiver of this section of the rule. These waivers have been approved as general organization-wide waivers contingent upon the PO developing policies and procedures for: (1) Full disclosure to the governing body of the direct or indirect conflict or potential conflict of interest of the member or an immediate family member related to the conflict; (2) recusal of voting, discussions, negotiations or any activity that would directly or indirectly affect the interest of the PO; and (3) inclusion of the disclosure and recusal actions in official records and that are readily accessible to CMS and the SAA.

In response to commenters' requests, and based on our experience with reviewing waiver requests relating to conflicts of interest procedures, we are amending § 460.68(b) to clarify our requirements for managing conflicts of interest that may involve members of the governing body or any immediate family members. We are requiring that POs establish policies and procedures for handling such conflicts of interest, that members of the governing body must disclose any such conflicts, and that members must recuse themselves from discussing, negotiating, or voting on any matter that involves an inappropriate conflict of interest.

To illustrate, we believe the following is a conflict of interest of an immediate family member: The wife of a board member owns a supply company which is the only one in the area that provides institutional laundry services, so the PO has no option but to contract with this company. The governing body member must make full disclosure of the situation to the body, and recuse themselves when the contract

negotiations are in progress as well as when voting on the contract occurs.

In response to the comments related to the SAA, we do not believe it is appropriate for CMS to impose conflict of interest restrictions on the SAA as they are not on the PO's governing body. Our concern is that decisions made by the governing body could be made specifically for the financial benefit of certain members of the governing body or their immediate family members.

All disclosure and recusal information must be recorded in the governing body's official records, which must be available for CMS and SAA review. CMS and SAA are both authorized to review this information, which can be accomplished during on-site monitoring and survey activities, or by requesting the information from the PO. Additionally, if a conflict exists at the time a provider submits their PACE provider application, we expect the PO to disclose the conflict as part of the application.

Comment: One commenter asked if the conflict of interest requirements may be waived in rural, Tribal and urban Indian communities. The commenter also asked if those areas have been designated eligible for conflict of interest waivers, and if so, they requested that the information be shared with the States.

Response: The 1999 interim final rule provided for a waiver of conflict of interest in rural, Tribal, and urban Indian communities. As a result of expanding waiver flexibility to all POs in accordance with section 903 of BIPA, that specific waiver authority, located in § 460.68(c), was deleted in the 2002 interim final rule. We established § 460.26 to implement the expanded waiver process. As previously noted, POs will now be required to have written policies and procedures in the event of a conflict of interest, and, therefore, waiver of conflict of interest will not be necessary.

Comment: Two commenters addressed conflict of interest disclosure related to the SAA. One commenter asked whether States have the responsibility to ensure the disclosure requirement is met.

Response: The SAA is not delegated the responsibility of ensuring that conflicts of interests are disclosed. The regulation does not require full disclosure to CMS or the SAA, but the PO must be able to provide documentation should CMS or the SAA request it.

Final rule actions:

In this final rule, we are providing for disclosure and recusal in the event of a conflict of interest of a member of the PO's governing body or their immediate family member(s).

Section 460.70 Contracted Services

Under the scope of benefits described in sections 1894(b)(1) and 1934(b)(1) of the Act, a PO may enter into written contracts with each outside entity to furnish services to participants. Consequently, we require in § 460.70 that all services, except for emergency services as described in § 460.100, not furnished directly by a PO must be obtained through contracts, which meet the requirements specified in regulations. In the 1999 interim final rule, we adopted the contracting provisions in Part VII, section A of the Protocol.

We specified in § 460.70(b) that a PO may only contract with entities that meet all applicable Federal and State requirements, and provided some examples of the types of requirements that contractors would be expected to meet. For example, institutional contractors (hospital and nursing home) must meet Medicare and Medicaid participation requirements. To avoid breakdowns in communication or in the provision of care, we required that POs designate an official liaison to coordinate activities between contractors and the organization. Effective coordination of services is necessary to avoid duplicative or conflicting services. Designating an individual as liaison provides a conduit for sharing information. The liaison would inform contractors of PO policies, changes in participants' plans of care, information from team meetings, and quality improvement activities and goals. Contractor staff would inform the PO, through the liaison, of updates and changes in a participant's status, personnel changes in the contractor, and any other information necessary for the continuity of participant care. All care must be evaluated by the PO, with particular attention to care provided by contracted personnel. This requirement provides a mechanism to ensure that contracted personnel are adhering to organization policies and procedures. It also affords the organization an opportunity to identify any education or training needs of contracted personnel.

We specified in paragraph (c) that the PO is required to maintain a current list of contractors at the PACE center and provide a copy to anyone upon request and in paragraph (d) that copies of signed contracts for inpatient care must be furnished to CMS and the SAA.

Under the specific contract content requirements listed in paragraph (e), we require each contract to be in writing and contain the following information:

- Name of contractor.
- Services furnished.
- Payment rate and method.
- Terms of the contract, including the beginning and ending dates, as well as methods of extension, renegotiation, and termination.
- Contractor agreement to: Furnish only those services authorized by the PACE IDT; accept payment from the PO as payment in full and not to bill participants, CMS, the State Medicaid agency or private insurers; hold harmless CMS, the State and PACE participants if the PO cannot or will not pay for services performed by the contractor under the contract; not assign or delegate duties under the contract unless prior written approval is obtained from the PO; and submit reports as required by the PO.

We did not establish a specific notice requirement for termination of contracts. We believe that POs will contract with individuals and entities that understand and embrace the organization's mission and commitment to participants. As discussed previously, we required in § 460.62 that the governing body establish personnel policies that address adequate notice of termination by contractors and employees with direct patient care responsibilities to permit an orderly transition and avoid disruptions in care.

In the 2002 interim final rule, we amended § 460.70(e) to include additional contract requirements where the PO chooses to contract for IDT members or key administrative staff. In amended paragraph (e), we required that contractors: (1) Agree to perform all the duties of their position; (2) participate in IDT meetings; (3) agree to be accountable to the PO; and (4) cooperate with the competency evaluation program and direct participant care requirements in § 460.71.

The PACE Protocol at section IV.B.13.a. provided that the IDT may be employed by the PO or the PACE center. In developing the 1999 interim final rule, we did not address this issue because we believed that in all cases the PO and the PACE center were the same organization. After publication of the 1999 interim final rule, we learned that in 1995, changes were made to the Protocol to permit contractual arrangements for all PACE center services, which reflected an operating arrangement engaged in by one of the PACE demonstration programs, On Lok Senior Health Service. Through this contractual arrangement, On Lok, Inc. had been able to expand PACE services to a different part of their service area without disrupting the care that

traditionally had been provided by the other organization.

As described above in the 2002 interim final rule, we amended the 1999 interim final rule to allow POs to provide PACE center services through contractual arrangements. As we explained in the 2002 interim final rule, we did not view this approach as a waiver authorized by BIPA. Rather, we established specific requirements for this approach consistent with the On Lok, Inc. arrangement (67 FR 61499). We added a new paragraph (f) to § 460.70 to identify the criteria that a PO must meet to contract out PACE center services. We explained in the 2002 interim final rule that we are not inclined to approve this arrangement for a PO unless it is financially stable and has demonstrated competence with the PACE model by successful CMS and State onsite reviews and monitoring efforts.

We expect the PO to retain all key administrative functions including marketing and enrollment, QAPI, and contracting for institutional providers and other key staff. We noted that, consistent with § 460.70(e)(5)(iv), any subcontracting arrangements by the PACE center would need to be approved in writing by the PO. The PACE center may employ or contract for the team and provide PACE services in accordance with the PACE regulation. However, the PO receives all payment from CMS and the State and remains responsible for all the care provided in these centers. In addition, we emphasized that contracting out PACE center services does not change the participants' relationship to the PO. All participants, whether assigned to the PO-operated PACE center or assigned to a PACE center that contracts with the PO, are enrolled with the PO and are afforded all benefits and protections offered by the PO.

On Lok, Inc. is able to monitor the care provided in the contracted PACE center through the sharing of electronic medical records. While we did not require electronic medical records as a condition of approval, we believe it is necessary for a PO wishing to pursue this type of arrangement to describe how it will monitor the care provided and perform all the administrative duties required by the PACE regulation.

In the 2002 interim final rule, we also discussed the obligation of the PO to monitor the care provided by contracted entities providing PACE center services now allowed by the amended requirements in that final rule. Given the vulnerable frail population served by the PACE program and the increased opportunity for a PO to contract out participant care services, it is important to reiterate the PO's obligation to monitor the care furnished by direct participant care staff. This obligation applies not only to employees of the PO, but extends to the care provided by contracted staff, including employees of organizations with which the organization contracts (for example, a home health agency, rehabilitation agency, nursing facility, transportation service, or staffing agency). It is especially important for the PO to monitor the care provided in all settings, including the PACE center and the participant's home, as well as in offsite locations such as physician offices and institutional providers to ensure quality care. To effectively monitor care provided outside the PACE center, the PO must be vigilant in following up on all unusual occurrences and complaints. In addition, the PO must foster an atmosphere that promotes the voicing of participant complaints about quality of care to assist the PO in monitoring the care provided by contracted staff and organizations.

In the 1999 interim final rule, § 460.66 required the PO to provide training to maintain and improve the skills and knowledge of each staff member that results in his or her continued ability to demonstrate the skills necessary for the performance of the position. In conjunction with the decision to allow POs to contract for key staff, in the 2002 interim final rule, we created a new § 460.71 to identify PO oversight requirements for PACE employees and contractors with direct patient care responsibilities. We address these requirements later in greater detail and respond to specific comments on this issue. We revised § 460.70(e) to require contractors who furnish direct participant care to cooperate with the requirements of § 460.71 as well.

We received the following questions and requests for clarification regarding contracted services.

Comment: One commenter requested we explain why a contractor must be prohibited from accepting private insurance payments directly.

Response: PACE is a capitated program at full financial risk for all services required by their participants. PACE participants sign an enrollment agreement, which states they must get all services (directly or indirectly) from the PO. To ensure coordination of care directed by the IDT, the PO needs to be aware of all services provided.

If a contractor receives payment directly from a private insurer, the contractor would have been paid twice, once by the PO and once by the private insurer. Therefore, we included § 460.70(e)(5)(ii) to require contractors to accept payment from the PO as payment in full and agree not to charge CMS, the State, the participant, or private insurers for services to PACE participants.

Comment: One commenter asked which entities are considered ''organizational contractors'' that must meet the COPs.

Response: The term ''organizational contractors'' was replaced with ''institutional contractors'' in the 2002 interim final rule. Institutional providers include but are not limited to acute care hospitals, rehabilitation hospitals and distinct part rehabilitation units of acute care hospitals, psychiatric hospitals and distinct part psychiatric units of acute care hospitals, and critical access hospitals, nursing facilities and skilled nursing facilities. The PO must contract only with institutional entities that meet all applicable Federal and State requirements. There are provider-specific COPs for institutions that participate in the Medicare program. Therefore, all institutional contractors must be in compliance with their respective COPs.

Comment: One commenter requested the rationale for singling out inpatient services contracts for submission while contracts with other entities need only be on file.

Response: We agree with the commenter and do not believe the requirement is necessary. For this reason, we are revising § 460.70 to delete paragraph (d). Our experience has indicated that having inpatient service contracts on file, provides sufficient accessibility. CMS and the SAA will review these contracts during routine monitoring surveys.

Comment: One commenter requested clarification of the role CMS expects the SAA to play in ensuring contracts are appropriate.

Response: We expect the SAA to ensure that the PO's contracts meet applicable State and local laws and requirements.

Comment: Commenters asked whether it is acceptable for an entity to submit a prepared but unsigned contract with the initial application and, following a readiness review, submit the signed contract with language specifying that the contract is not effective until the PO's program agreement is signed.

Response: We have determined that it is inappropriate for entities that are not operational to submit signed and dated contracts when they submit their PACE application. Rather, it is acceptable for entities to submit contract templates

with their initial applications. As part of the State readiness review, the SAA determines that all contracts are signed and dated. However, the contracts may not become effective until a program agreement with the entity is signed.

Comment: One commenter indicated that it is unnecessary to designate one official liaison to coordinate contracted services and urged us to leave the coordination of contracted services to the discretion of each PO. The commenter requested that we require the POs to establish a mechanism for the coordination of contracted services, but not specify the means by which to effect this objective.

Response: We do not agree with the commenter that the means of coordinating contracting services should be left up to the discretion of each PO. To ensure the health and safety of the participants, we require a contract liaison to ensure that there is a designated individual with the responsibility and authority to facilitate communication and coordinate activities, to track delivery and follow-up of services related to contractor provided care, and to act as a conduit for contractor issues whether raised by the contractor, the PO, or a participant.

Comment: In the 1999 interim final rule, we requested comments on whether to include a notification timeframe for termination of contractor or employee contracts. Three commenters supported a requirement for prior notification to terminate a subcontract, but each with a different timeframe. One commenter suggested a minimum of 60 days notice, one suggested 90 days, and the last suggested a timeframe that is consistent with M+C (now MA) and Medicaid managed care requirements.

Two commenters did not support a prior notification requirement. One commenter indicated a termination notice can be difficult and may even be contrary to the needs of the participants while the other commenter believed this was a subject best left to the POs and individual contractors. Finally, one commenter indicated that the regulations are sufficiently flexible to allow the POs to structure their employee/contractor agreements in a way that maximizes benefits to the organization and participant.

Response: We agree with the commenter who pointed out that the current regulations are flexible enough to allow the POs to take into account the needs of the organization and the participants. The 1999 interim final rule established the requirement in § 460.70 that the terms of a contract include a specified method of termination. The intent of advanced notice of termination is to provide the participants sufficient time to adjust to a change in providers. We believe the current regulation makes adequate provision for establishing any notification timeframe for termination and are retaining the language in the 1999 interim final rule.

Comment: One commenter indicated that the wording of the 2002 interim final rule may lead to unintended legal implications for contractors and POs. Specifically, the commenter believes that terms ''agree'' and ''accountable'' may be construed as evidence of an employment relationship between the PO and the contractor. The commenter recommended deletion of the accountability provision. In place of the provision, they suggested a written agreement with the contractor which sets forth the contractor's duties and responsibilities.

One commenter responded to our request for comments related to the criteria for contracting out PACE center services by recommending that we should exempt applicants in rural areas from the requirement to have demonstrated competence with the PACE model before they contract out for PACE center services. This commenter also expressed concern regarding contracting for IDT members. The commenter was concerned that contracted IDT members might be unavailable in person, participating in IDT meetings via telephone which would distance them from care planning.

Response: We require POs to have formal written contracts with all service providers, and that these contracts specifically identify the services to be provided and the responsibilities of both parties. The use of the terms questioned by the commenter does not imply an employment relationship. The PO has the ultimate responsibility for all care and services provided to participants including those provided under contract. The PO is also responsible for oversight of participant care. We are, therefore, retaining the requirement for PACE contractors to be accountable to the PO for their performance.

As we indicated in the 2002 interim final rule, we are more likely to allow POs to contract out PACE center services when they have attained experience in delivering services and managing the risk associated with the frail elderly. We continue to believe that an experienced organization will be better equipped to adequately monitor this arrangement and ensure that participants assigned to contracted PACE centers are afforded all benefits and protections offered by the PO.

We are not inclined to exempt all POs in rural areas, as we believe a PO needs experience in operating a PACE center and providing the range of services to understand exactly what they will be ultimately responsible for when they contract for services. The waiver process established in the 2002 interim final rule provides new POs the opportunity to indicate in detail the specific barriers to meeting requirements that would be resolved by contracting for services.

In response to the concern regarding the contracted IDT members being unavailable for care planning, we believe that as the PO has oversight responsibility of all care provided to participants, they will ensure that care planning is performed appropriately by all IDT members.

Comment: We received one comment suggesting that when services are contracted, funds should be allocated to permit contractual staff to participate in all clinical and administrative activities with the PACE program.

Response: Although we agree with the commenter that this could be a beneficial arrangement, we believe CMS should not dictate how POs allocate or spend their resources; thus, making this a regulatory requirement would be inappropriate. However, staff refers to both employed and contracted staff, with no distinction in job duties or responsibilities. Contracted staff are required to perform all the duties of a PACE employee related to their position including, but not limited to, being oriented to the PACE model's philosophy, mission, policies on participant right, emergency plan, ethics, and the PACE benefit, and policies related to job duties; participate in IDT meetings; meet competency requirements; and be accountable to the PO. Therefore, we expect contractual staff to participate in all clinical and administrative activities with the PACE program.

Final rule actions:

In this final rule, we are:

- Deleting § 460.70(d),
- Redesignating paragraph (e) as paragraph (d), and
- Redesignating paragraph (f) as paragraph (e).

Section 460.71 Oversight of Direct Participant Care

We intend that personnel requirements apply to both staff and contractors. In this section, we intend to clarify the requirements for the oversight of direct participant care.

As noted previously, in the 2002 interim final rule, we created a new

§ 460.71 to identify PO oversight requirements for PACE employees and contractors with direct patient care responsibilities. These requirements fall into two categories, that is, (1) competency evaluation and (2) staff and contractor requirements.

- The PO must ensure that employees and contracted staff providing care directly to participants demonstrate the skills necessary for performance of their positions.
- The PO must provide each employee and all contracted staff with an orientation. The orientation must include at a minimum the organization's mission, philosophy, policies on participant rights, emergency plan, ethics, the PACE benefit, and policies and procedures relevant to each individual's job duties.

The PO must develop a competency evaluation program that identifies those skills, knowledge, and abilities that must be demonstrated by direct participant care staff (employees and contractors). The program must be evidenced as completed before performing participant care and on an ongoing basis by qualified professionals. The PO must designate a staff person to oversee these activities for employees and work with the PACE contractor liaison to ensure compliance by contracted staff.

We note that the PO may satisfy this requirement for contract staff through receipt of competency evaluation documentation from certain independent contractors where licensure requirements include a competency evaluation component, or from organizations or agencies that employ these individuals and contract with the PO.

The PO must develop a program to ensure that all staff providing direct participant care services meet the requirements listed below. The PO will verify that direct participant care staff or contractors meet the following requirements:

- Comply with any State or Federal requirements for direct patient care staff in their respective settings;
- Comply with the requirements of § 460.68(a) regarding persons with criminal convictions;
- Have verified current certifications or licenses for their respective positions;
- Are free of communicable diseases;
- Have been oriented to the PACE program; and
- Agree to abide by the philosophy, practices, and protocols of the PO.

Comment: One commenter indicated that the requirements pertaining to contracted staff are administratively burdensome and may compromise the PO's ability to contract with high quality providers.

Response: We believe the requirements pertaining to contractual staff are essential for appropriate participation in the PACE benefit. All staff (employees and contractors) need to understand what the PACE service delivery model is and how it differs from other models. With regard to the competency evaluation requirements, we believe they are consistent with PACE, Medicare, and health care industry standards.

Comment: One commenter asked that we clarify the relationship between § 460.71(a) and (b) because they seem to cover similar points (staff and orientation).

Response: We believe § 460.71(a) is a requirement directed towards the education of staff of the PACE model; specifically, § 460.71(a) requires that all staff and contractors receive an orientation to the PACE model, what it is and how it works, and demonstrate clinical competency before performing direct participant care. Section 460.71(b) pertains more to the quality of the staff, as well as ensuring that the PO verify that staff and contractors have certification or licensure, pass a criminal background check, have been determined free from communicable diseases, and are up-to-date with immunizations. As discussed previously in § 460.64, staff furnishing direct participant care must be free of communicable diseases and are up-to-date with immunizations. Thus, we are applying this provision to both contractors and staff, amending § 460.71(b)(4) to clarify that direct participant care staff or contractors must be determined to be free from communicable diseases and are up-to-date with immunizations before performing patient care.

Comment: A commenter requested clarification regarding who is considered a contractor.

Response: A contractor is an entity with a legally binding written agreement to deliver items or services for the PO in return for payment and is not considered an employee of the PO. All contractors must meet PACE competency requirements except for staff in inpatient and nursing facilities that must meet provider-specific COPs.

Comment: One commenter asked that we clarify if references to staff include contracted staff.

Response: In § 460.71(a), we state that the PO must ensure that all employees and contracted staff furnishing care directly to participants demonstrate the skills necessary for performance of their position. In most other provisions of § 460.71, we similarly specify that oversight requirements related to direct participant care apply to all employees and contracted staff. For purposes of this regulation, references to staff are intended to include contracted staff. Their orientation to the PACE model, specifying their direct care responsibilities, the days and hours they provide services for the PO to PACE participants, and their demonstration of clinical competency must be accomplished in the same manner as employed staff. We also assume that the PO is aware of the work schedule availability of the staff, both employed and contracted.

Comment: One commenter asked if individual provider competency is required and if mechanisms such as contracting requirements established by the PO for contract providers, credentialing of staff and contractors, State licensing requirements, and Medicare certification requirements would be sufficient for ensuring compliance with § 460.71(b).

The commenter also indicated that requiring orientation of the employees of contracted provider entities (for example, hospitals, nursing homes, home care agencies, transportation providers) will not have any impact on the quality of care provided. The commenter stated that the PO's scarce resources would be better spent in focusing on the quality of communication between the PO and its contractors to ensure participant services are provided appropriately. Communication is viewed as more important than provider knowledge about the PACE program. They requested that POs be granted the discretion to orient contract providers to the program as they deem appropriate.

This commenter also views the requirement that competency evaluation must be completed before performing participant care as problematic. The commenter pointed out that emergency situations may exist where fulfilling this requirement may not be possible (for example, when temporary staff must be called upon to fill in during unanticipated absences).

Response: In response to this comment, we want to clarify that individual provider competencies are required and that contractual agreements, credentialing for physician staff and contractors, State licensure, and Medicare certification are not in themselves proof of competency. The PO must follow-up to validate individuals' competency.

We continue to believe that all direct care providers need to understand the philosophy of the PACE service delivery

model and recognize its unique features that have been proven effective in managing the health care needs of the frail elderly. We expect that during the orientation, the importance of communication will be emphasized as a pivotal aspect of the PACE model. Therefore, we are retaining the current requirement for orienting contractual providers.

Competent staff is of paramount importance when dealing with this frail population. Although we understand that emergency staffing needs may arise, we expect the PO to contract with providers that have provided information and competency evaluation documentation before assigning temporary staff.

Final rule actions:

In this final rule, we are amending § 460.71(b)(4) to clarify direct participant care staff or contractors must be determined to be free from communicable diseases and are up-to-date with immunizations before performing patient care in order to be consistent with the general requirements of § 460.64(a).

Section 460.72 Physical Environment

As we explained in the 1999 interim final rule, we established § 460.72 to ensure that the PACE center and home are free of hazards that may cause harm to the participants, staff, or visitors. Because issues of adequate space, infection control, fire prevention, dietary services, and the safety of transportation services are important to ensure quality care, we added requirements for each in the regulation.

We maintained the following requirements from the PACE Protocol, with the modifications noted below:

- The PACE center must be designed, constructed, equipped, and maintained to provide for the physical safety of participants, personnel, and visitors;
- The PACE center must ensure a safe, sanitary, functional, accessible, and comfortable environment for the delivery of services, that protects the dignity and privacy of the participant; and
- The PACE center must include sufficient suitable space and equipment to provide primary medical care and suitable space for team meetings, treatment, therapeutic recreation, restorative therapies, socialization, personal care, and dining. (We believe that a PO should furnish primary care services in the PACE center, but this provision allows flexibility to avoid duplicating an entire primary care clinic if that is not necessary.)

The PO must establish, implement, and maintain a written plan to ensure that all equipment is maintained in accordance with the manufacturer's recommendations to keep all equipment (mechanical, electrical, and patient care) free of defect. Based on the manufacturer's experience with the equipment, we believe it has the most knowledge about routine maintenance and recommended repair schedules necessary to keep the equipment in good operating condition.

With respect to protecting participants from fire and fire-related events, we incorporated by reference in our regulation at § 460.72, the Life Safety Code (LSC). The LSC was developed by the National Fire Protection Association and adopted by the Department of Health and Human Services as the standard which ensures reasonably fire-safe facilities. The LSC specifies requirements for building construction features such as walls and doors, exits and exit access, and fire protection devices such as sprinklers, smoke detectors, and fire extinguishers.

In the 1999 interim final rule, we adopted the 1997 edition of the LSC, which was divided into occupancy chapters, including Business, Education, and Health Care Occupancies. Business occupancies include clinics and offices, and educational occupancies cover schools and day care centers. Health care occupancies include facilities where the patients are rendered incapable of self-preservation and where they remain overnight. Unfortunately, the LSC does not designate a specific category for comprehensive outpatient services provided to nursing home eligible individuals, so we chose to stipulate that the PACE center must meet the occupancy provisions of the 1997 edition of the LSC for the type of setting in which it is located (for example, hospital, office building, etc.).

Each type of LSC occupancy requires a fire alarm system. A fire alarm system must provide three functions: (1) Initiation—a method of initiating the alarm, such as a pullbox; (2) Notification—a method of notifying the occupants, such as a loud bell, horn, chimes, or flashing lights for those patients who are deaf; and (3) Control—a method of controlling other fire protection functions and features, such as air conditioning shutdown, automatic release (closing) of fire doors, etc.

We require a PACE center to meet the requirements for a fire alarm system in accordance with the occupancy section of the LSC that applies to the building in which it is located. Each occupancy section also requires evacuation plans, fire exit drills, and fire procedures. The purpose of the drills is to test the efficiency, knowledge, and response of the staff and to ensure that safe care will be provided to participants during an emergency.

The statute and implementing regulations governing some Medicare providers (nursing facilities, hospitals, and hospices) authorize us to accept a State code in lieu of the LSC if it adequately protects patients. Likewise, under these regulations the LSC will not apply in a State where CMS finds that a fire and safety code imposed by State law adequately protects PACE participants and staff.

We recognize that it could be burdensome to require strict adherence to all of the requirements of the LSC. PACE centers may be established in a variety of building types (for example, hospitals or office buildings), which must be considered in requiring adherence to the LSC. We also recognize that some PACE centers may have alternative features that provide an equivalent level of protection to that required by the specific requirements of the LSC. In some buildings it may be impractical or impossible to provide a specific feature due to the construction of the building. Therefore, we specified that CMS may waive specific provisions of the LSC which, if rigidly applied, would result in unreasonable hardship on the organization. Specific provisions may be waived only if the waiver does not adversely affect the health and safety of the participants and staff.

We established four requirements that we believe are fundamental for a PO to effectively prepare for emergency situations. The PO must establish, implement, and maintain documented procedures to manage medical and nonmedical emergencies or disasters that are likely to threaten the health or safety of participants, staff, or the public including, but not limited to, fire, equipment, water or power failures, care-related emergencies, and natural disasters likely to affect their geographic location. We also stated that we do not expect organizations to develop emergency plans for natural disasters that typically do not affect their geographic area. For example, organizations in the Southeast would not typically need to develop emergency procedures for earthquakes.

POs must train each staff member (employee and contractor) on the actions necessary to address different medical and nonmedical emergencies. This requirement is designed to ensure the safety and security of both the participants and the staff. In addition, the participants must be appropriately trained on the organization's emergency procedures since they may need to take

steps to protect themselves during an emergency. PACE participants need to be informed of what to do, where to go, and whom to contact if a PACE center emergency occurs.

Appropriate medical practice dictates that the organization must have trained personnel, drugs, and emergency equipment immediately available at every PACE center at all times to adequately support participants until an Emergency Medical System (EMS) responds to the PACE center. We defined the minimum emergency equipment that must be on the premises and immediately available as easily portable oxygen, airways, suction, and emergency drugs. In addition, the PACE center must have a documented plan to obtain EMS services from sources outside the PACE center when needed.

At least annually, a PO must test, evaluate, and document the effectiveness of its emergency and disaster plans to ensure and maintain appropriate responses to the situations and needs that may arise from both medical and nonmedical emergencies. Drills and emergency episodes often reveal a weakness or flaw in the design of the emergency plan. An annual review will allow flaws or potential problems to be identified and corrected.

In the January 10, 2003 **Federal Register**, we published a final rule, ''Fire Safety Requirements for Certain Health Care Facilities'' (68 FR 1374), which among other changes, amended § 460.72(b) to adopt the 2000 edition of the LSC for Medicare and Medicaid health care facilities. It is important to note that the 2000 LSC prohibits the use of roll latches on corridor doors in buildings not fully protected by an approved sprinkler system and requires replacement with positive latching devices in both existing sprinklered and unsprinklered buildings. It also requires that, effective March 13, 2006, emergency lighting must provide illumination for at least a 90-minute duration.

Section 460.72(b) was further amended by the March 25, 2005 (70 FR 15229) publication of the interim final rule, ''Fire Safety Requirements for Certain Heath Care Facilities; Amendment,'' which allows certain health care facilities, including PACE facilities, to place alcohol-based hand rub dispensers in egress corridors under specified conditions.

Comment: One commenter stated they believe that identification and enforcement of physical plant standards for PACE centers are responsibilities of the State. The commenter indicated that the provisions allowing CMS to waive the LSC effectively permits an organization to disregard State requirements.

Response: Current regulations require that PACE centers meet the LSC with the following limited exceptions: (1) The LSC provisions do not apply in a State in which CMS determines that a life and safety code imposed by State law adequately protects participants; and (2) CMS may waive specific provisions of the LSC that, if rigidly applied, would result in unreasonable hardship on the PACE center, but only if the waiver does not adversely affect the health and safety of participants and staff.

Although there is specific waiver authority under § 460.26 and § 460.28, it does not apply to the approval of LSC waivers. CMS staff responsible for LSC compliance would approve LSC waivers. However, we note that PACE centers are often licensed as adult day health centers or clinics, which are not among the types of Medicare providers that we typically survey for compliance with the LSC. As a result, in these cases, we will accept State licensure requirements for fire and safety as meeting the LSC.

Comment: Three commenters indicated that a PO's responsibility related to safety in the home should be limited.

One commenter indicated the regulation only mentions POs being responsible for safety of the physical environment of the PACE center and the primary care clinic, while the background description states that this section's purpose is ''to ensure that the PACE center and home are free of hazards.'' The commenter continued by stating the regulation does not address the PO's responsibility for ensuring that an enrollee's home is free of hazards. The enrollee is living at home and not in a licensed health care facility subject to Federal and State oversight. However, the local fire marshal, health department, Adult Protective Service, and building inspectors have specific responsibilities to ensure a safe living environment. Therefore, the commenter recommended that we limit PO responsibilities by requiring that the initial comprehensive assessment includes an assessment of the home environment and that the participants must be determined as able to live in a community setting without jeopardizing their health or safety.

Response: We disagree with the commenters. POs are at risk for all health care services the participant receives, and, therefore, we expect that POs will be involved in assuring the health and safety of participants at all times, including when they are at home.

However, PACE staff will not have the ultimate authority regarding potential hazards. PACE staff performing the initial assessment should identify all potential hazards and make all reasonable attempts to explain them to the participant and caregiver. Should staff be unable to rectify the potential hazard before enrollment, they should document the hazard, their attempts to have the hazard rectified, and all other pertinent information. Should the participant and caregiver agree to a resolution of the hazard, that information should be included in the participant's care plan. If the participant and caregiver do not agree to rectify the hazard potential, the PO staff are expected to document the hazard, their suggestions to resolve the hazardous issue, and all other pertinent information.

Comment: One commenter recommended that the regulations require that accessibility requirements be met in accordance with the Americans with Disabilities Act and section 504 of the Rehabilitation Act.

Response: Both the 1999 and 2002 interim final rules state repeatedly that POs must meet all applicable Federal, State, and local laws and regulations, which include the Americans with Disabilities Act and section 504 of the Rehabilitation Act. We note the Americans with Disabilities Act is specifically addressed in § 460.32.

Comment: Another commenter recommended that this section of the regulation include suggestions for addressing the common visual deficits of the PACE population and provided the following as examples of potential safety concerns: High gloss floors and surfaces which provide high contrast in floors, steps, and walls and installing low glare but sufficient lighting.

Response: We expect each PO to assess their participants and to implement all appropriate safety precautions. We do not believe it is necessary to establish regulatory requirements specific to individual health issues. We believe the addition of specific common deficits to the regulation would be unreasonably burdensome. Therefore, we are not including specific requirements regarding visual deficits or other individual health deficits. We will continue to assess LSC and State licensure developments to ensure participants receive services in a safe manner.

Comment: Two commenters requested clarification of the emergency equipment requirement, which states that staff be on the premises of the PACE center at all times. The

commenter indicated that it would be helpful to clarify what emergency drugs are required to be available at the PACE center.

One of the commenters requested that we clarify that the requirement that the POs are required to establish, implement, and maintain a written plan to ensure maintenance in accordance with manufacturer's recommendations refers only to equipment deemed to be life-sustaining and biomedical equipment.

Response: The intent of the staffing requirement is that we believe POs should have staff qualified to operate emergency equipment on the premises whenever the PACE center is open.

For purposes of this regulation, emergency drugs are those pharmaceuticals that would be used in an emergency that follow current emergency practice guidelines/protocol.

We agree with the commenter asking for clarification on the equipment maintenance requirement, and we are clarifying that in addition to written policies, the PO is responsible for implementing the manufacturer's recommendations for emergency and biomedical equipment maintenance.

Final rule actions:

In this final rule, we are clarifying that POs must perform the manufacturer's recommended maintenance on all equipment as indicated in their written plan.

Section 460.74 Infection Control

Infection control is vital to the health and safety of participants, so we require in § 460.74 that the PO adhere to accepted policies and standard procedures, including the standard precautions developed by and available from the Centers for Disease Control and Prevention (CDC). These guidelines have been developed by the CDC in collaboration with industry representatives and have proven effective as a means of diminishing the spread of blood-borne pathogens and other infectious agents. The PO must establish, implement, and maintain a documented infection control plan that will ensure a safe and sanitary environment and prevent and control the transmission of disease and infection. At a minimum, the infection control plan must include the following:

(1) Procedures to identify, investigate, control, and prevent infections in every PACE center and in a participant's place of residence;

(2) Procedures to record any incidents of infection; and

(3) Procedures to analyze the incidents of infection, to identify trends, and develop corrective actions related to the reduction of future incidents.

Comment: We received several comments regarding infection control. One commenter did not find the requirements overly onerous, while another commenter was concerned this provision preempts State's regulatory authority regarding infection control practices.

Another commenter requested we clarify that the intent of this section is to hold POs responsible for universal precautions. Five commenters requested we distinguish between what can be required in a PACE center and what can be expected in a participant's home.

Response: It is not our intent to usurp the State's authority in this area. Should State requirements be more stringent than those of CMS, we would expect States to enforce their more strict requirements. We believe these regulations to be the minimum acceptable requirements for infection control.

In response to the question on universal precautions, the intent of these regulations is to require the POs to practice universal precautions. Universal precautions are CDC guidelines accepted as routine practice by the health care industries at large.

Moreover, POs are expected to observe infection control practices in all settings including the participant's residence and teach and reinforce infection control practices to participants and their caregivers. This would include reinforcing the simple practices such as handwashing after using the restroom or blowing one's nose, and refrigerating foods appropriately. It is in the PO's interest to work with participants and caregivers to minimize the risk of infections.

Final rule actions:

This final rule will finalize § 460.74 as published in the 1999 interim final rule.

Section 460.76 Transportation Services

Transportation services are a critical component of PACE service delivery, so it is crucial that the PO take appropriate steps to ensure that participants can be safely transported from their homes to the PACE center and to appointments. We established § 460.76 to require that the PO's transportation services must be safe, accessible, and equipped to meet the needs of each participant. In addition, we require that the organization's transportation program include procedures on at least the following: (1) Maintaining of transportation vehicles according to the manufacturer's recommendations; (2) equipping transportation vehicles to communicate with the PACE center; (3) training transportation personnel on the special needs of participants and appropriate emergency response; and (4) as part of the IDT process, communicating relevant information about the participants' to transportation personnel or other PACE staff in accordance with the PO's policies and procedures.

Comment: We received two comments that addressed concerns regarding transportation. The first commenter emphasized that transportation must meet the special needs of persons with disabilities while the second commenter indicated that there are situations in which routine transportation services can not be safely provided to participants. The commenter believes this point needs to be a consideration when determining if a participant can be cared for appropriately in PACE.

Response: We agree with the commenter, that transportation services that meet the special needs of disabled participants are crucial especially for frail elderly PACE participants. The requirements established in the 1999 interim final rule were intended to ensure that safe and appropriate transportation practices are used with this frail participant population.

We also agree that when the PACE staff performs their initial assessment, it is the PO's responsibility to determine if they can adequately address the transportation needs of the individual, and that this should be a consideration in determining whether or not a prospective enrollee can be cared for safely in their community. However, we believe that transportation considerations alone would rarely, if ever, be the reason to deny enrollment.

Final rule actions:

This final rule will finalize § 460.76 as published in the 1999 interim final rule.

Section 460.78 Dietary Services

In the 1999 interim final rule, we established that it is important that each PACE center provide participants with nourishing, palatable, well-balanced meals that meet the daily nutritional and special dietary needs of each participant. We required that each meal must meet specific requirements, including preparation by methods that conserve nutritive value, flavor, and appearance; preparation in a form designed to meet individual needs; and preparation and service at the proper temperature. The PACE center must provide substitute foods or nutritional supplements that meet the daily nutritional and special dietary needs of any participant who refuses the food served, cannot tolerate the food served,

or who does not eat adequate amounts. In addition, the PO must provide nutritional support (that is, tube feedings, total parenteral nutrition, or peripheral parenteral nutrition) to meet the daily nutritional needs of a participant if indicated by his or her medical condition or diagnosis.

It is vital to the health and safety of participants that the food provided meets acceptable safety standards. Therefore, we require the PO to:

(1) Procure foods (including nutritional supplements and items to meet special nutrition needs) from sources approved or considered satisfactory by Federal, State, Tribal, or local authorities that have jurisdiction over the service area of the organization;

(2) Store, prepare, distribute, and serve foods (including nutritional supplements and items to meet special nutrition needs) under sanitary conditions; and

(3) Dispose of garbage and refuse properly.

Comment: We received several comments regarding dietary services, with several proposed language changes. One commenter reiterated these are areas under State responsibility. Dietary and food service sanitation practices in a variety of establishments, including those under which PACE would operate, are regulated by the State. This commenter recommended that the regulation simply state that the PACE center will provide the enrollee a meal when necessary.

Response: In response to the comment regarding State requirements, we want to clarify that we believe the requirements in our regulation to be the minimum acceptable requirements for dietary services. If State requirements are more stringent than those under this regulation, we expect the State to enforce its more stringent requirements.

In response to the suggestion that we amend the requirement as recommended, we believe that as a participant protection, the PACE dietary services requirement must be more specific. Again, due to the frailty of the targeted population, a greater effort must be made to ensure that the appropriate nutrition is received by the most appropriate method in a safe and sanitary manner.

Comment: One commenter provided two technical suggestions. First, to ensure that dietary needs are provided in accordance with the participant's treatment plan, the commenter recommended inserting the phrase ''In accordance with each participant's plan of care'' at the beginning of § 460.78(a)(1), § 460.78(a)(2), and § 460.78(a)(3).

The second suggestion was to replace the phrase ''provide each participant'' with ''offer each participant'' ensuring participant choice with respect to meals.

Another commenter disagreed with the requested language change of ''offer each participant'' stating there is a high proportion of PACE participants with some form of dementia who may require supervision or assistance with eating. The commenter requested the language be modified to read ''Except as specified in paragraphs (a)(2) or (a)(3) of this section, the PO shall ensure, through the assessment and care planning process, that each participant receives nourishing, well-balanced meals that meet the participant's daily nutritional and special dietary needs.''

Another commenter requested that we clarify that the requirement is meant to apply when PACE participants are institutionalized or to limit the requirement to individuals when the provision of meals is specified in the plan of care. Alternatively, they recommended that the regulations could specify that the PO must ''assure that each participant has access to meals to meet the daily nutritional requirement,'' which would enable the PACE provider to document the provision of meals by family or others, as appropriate.

Response: In response to comments on provision of meals, we want to clarify that meals are a required service in the PACE program. Dietary services are to be provided when a participant is attending the PACE center, when he or she is institutionalized, and when he or she is in the home as indicated in the participant's plan of care. The PO must assess each participant's individual situation when determining the most appropriate method of assuring that each participant's daily nutritional needs are met in the most appropriate manner. The POs must ensure that each participant is receiving adequate nutrition by the required modality, as prescribed in the participant's plan of care. We agree with this commenter and recognize that in the geriatric population, for a number of medical and psychosocial reasons, eating is not a high priority for many individuals. Thus, we do not believe that language such as ''offering'' or ''has access to'' is sufficient to ensure participants receive adequate and appropriate nutrition. Therefore, in this final rule we are revising the first sentence of § 460.78(a)(1) by adding the requirement that the ''PO must ensure, through the assessment and care planning process,'' that each participant receives nourishing, palatable, well-balanced meals that meet the participant's daily nutritional and special dietary needs.

Comment: One commenter indicated that the regulation fails to mention the special needs of those with swallowing problems.

Response: In response to this comment, we believe that although choking is a serious issue, particularly in this population, and has been known to lead to death, this problem should be assessed by the appropriate professional, as part of the participant assessment. This comment provides a good example of where it would be appropriate for an additional discipline (for example, a speech therapist) to be included in the initial comprehensive assessment and periodic reassessments.

Final rule actions:

In this final rule, we are amending the regulatory language of § 460.78(a) by revising the first sentence to read as follows: ''Except as specified in paragraphs (a)(2) or (a)(3) of this section, the PO must ensure, through the assessment and care planning process, that each participant receives nourishing, palatable, well-balanced meals that meet the participant's daily nutritional and special dietary needs.''

Section 460.80 Fiscal Soundness

Part I, section F of the Protocol addresses fiscal soundness and paragraph (e)(4)(A)(ii) of section 1894 and section 1934 of the Act requires that, during the trial period, we conduct a comprehensive assessment of a PO's fiscal soundness. We established § 460.80 to address requirements for fiscal soundness.

As we indicated in the 1999 interim final rule, each PO must have a fiscally sound operation as demonstrated by total assets being greater than total unsubordinated liabilities, sufficient cash flow and adequate liquidity to meet obligations as they become due, and a net operating surplus or a plan for maintaining solvency.

Each organization must have a documented insolvency plan approved by CMS and the SAA which, in the event of insolvency, provides for the continuation of benefits for the duration of the period for which capitation payment has been made; the continuation of benefits to participants who are confined in a hospital on the date of insolvency until their discharge; and protection of participants from liability for payment of any fees which are the legal obligation of the PO.

Each organization must have adequate arrangements to cover expenses if it becomes insolvent. To this end, we specified requirements in this section that are consistent with the Protocol.

We received comments from five commenters regarding fiscal soundness.

Comment: Two commenters indicated that this section of the regulation made no reference to meeting applicable State requirements, which in some situations may be inconsistent with these requirements.

Response: As with any type of regulatory requirement, States may establish or impose more restrictive requirements applicable to the PO regarding fiscal soundness as long as they do not conflict with the Federal PACE regulations. We recognize that some States have specific fiscal requirements applicable to the POs, particularly based on State licensure programs for POs. We also acknowledge the State's role in relation to fiscal soundness; however, we do not believe the regulations would need to reflect the States' role in this case.

Comment: Two commenters recommended that CMS specify that POs must have requirements to cover expenses of $250,000.

Response: We appreciate that a minimum amount of capital is critical to ensure that the organization can adequately cover the costs of meeting the needs of a frail elderly population. However, we are not inclined to impose specific dollar amounts because we assess each organization's financial situation individually. In addition, an amount set at a particular point in time may not be adequate over an extended period due to inflationary and economic factors.

Comment: Two commenters agreed with the fiscal soundness requirements, but pointed out that the measure of fiscal soundness is different for a new PACE program than for an established program. One commenter questioned whether fiscal soundness should apply during the trial period because it could inhibit the start-up of new programs. The commenters recommended that POs be permitted to utilize a variety of arrangements to cover expenses in case of insolvency.

The other commenter indicated that the requirements are based on a shared-risk model of an established PACE program that enrolls the certain number of participants and spreads its risk among all its enrollees. The commenter believes that the measures are too stringent for a program just starting operations. The commenter recommended that CMS consider the measure for fiscal soundness and differentiate the measure for new PACE programs and established programs. The commenter suggested that for an established program, the minimum of 1 month of cash available be liquid financial assets and not merely line-of-credit. However, for new POs, cash in the form of line-of-credit would be appropriate.

Response: We assess each PO's fiscal soundness individually taking into account whether it is an established or newly operational organization. However, we believe that it is critical for the organization to meet the established requirements upon start-up to ensure that the organization can adequately cover the costs to meet the needs of a frail elderly population. As each situation is different, we do not dictate the means for providing arrangements to cover expenses. Organizations have flexibility to meet the requirements, and the regulation offers potential options such as letters of credit or other guarantees.

Final rule actions:

This final rule will finalize § 460.80 as published in the 1999 interim final rule.

Section 460.82 Marketing

Based on Part III, section B of the Protocol, we established § 460.82 to address marketing activities of PACE programs. POs must conduct marketing activities that inform the general public about their programs.

As we indicated in the 1999 interim final rule, all marketing material must be approved by CMS and the SAA. Initial marketing material is reviewed as part of the application process. After an organization is under a PACE program agreement, any new or revised marketing materials must be submitted for review by CMS and the SAA. We will complete our review within 45 days after we receive the information from the organization or the material will be deemed approved. We included the requirement for review and approval of revised marketing materials as revisions could potentially introduce false or misleading information. Although the Protocol includes a 30-day review and approval timeframe, we adopted a 45-day period to be consistent with the process used by CMS for review of changes to M+C organization (now MA) marketing materials.

Printed marketing materials must meet participants' special language requirements. Marketing materials must also provide complete and clear information regarding the requirement that all services (other than emergency services), including primary care and specialist physician services, be furnished by or authorized by the PO and that participants may be fully and personally liable for the costs of unauthorized or out-of-PACE program agreement services.

POs must ensure that their employees or agents do not conduct prohibited marketing activities such as discrimination of any kind among individuals who meet PACE eligibility standards; activities that could mislead or confuse potential participants or misrepresent the PO, CMS, or the SAA; activities that involve gifts or payments to induce enrollment; contracting outreach efforts to individuals or organizations whose sole responsibility involves direct contact with the elderly to solicit enrollment; or unsolicited door-to-door marketing.

Each PO must establish, implement, and maintain a documented marketing plan with measurable enrollment objectives and a system for tracking its effectiveness.

We received numerous comments regarding the marketing section.

Comment: Three commenters believed that to ensure that all PACE participants are fully informed of the services they will receive, the PO's marketing materials should specify not only the covered benefits and services, but also the benefits and services excluded from the program both before and at enrollment, with one commenter providing proposed regulatory language.

Response: We disagree with the commenter because of the dynamic nature of PACE, its reliance on the IDT's determination of a specific participant's need to determine the covered and excluded services and its interaction with the participant. We do not believe identifying excluded services appropriately expresses the flexibility of services provided by the PACE model.

Comment: Several commenters requested clarification of the process for review of marketing materials, with some commenters addressing the State's role in the review of marketing materials. One commenter questioned the intent regarding SAA approval of marketing materials noting that as the initial program application must be submitted with SAA approval, marketing materials would have been approved by the SAA before CMS review.

Another commenter suggested that CMS delegate the approval of any revised or updated educational and marketing materials to the SAAs in order to prevent unnecessary delay in approvals and to avoid discouraging POs from revising their materials.

Response: We believe the process for review is fairly noted in the regulations but remind the public that as a partner in the three-way program agreement, the SAA has the right to review and approve all educational and marketing materials the PO intends to distribute.

Accordingly, all materials must go through the SAA for approval before the SAA forwarding the materials to CMS. This review of marketing and educational materials by CMS is to ensure that marketing materials meet CMS requirements.

Although a PO's initial educational and marketing materials are approved by CMS and the SAA during the application process, revised and updated materials must be approved to ensure that no erroneous information is disseminated. The requirement to have educational and marketing materials reviewed is consistent with MA requirements.

Comment: This commenter suggested the regulations differentiate between educational and marketing components of the PACE program, as the desired outcomes of marketing activities are fundamentally different from those of educational activities and materials.

Response: We view marketing materials as those materials used to promote the PACE program before an individual enrolls in PACE. Educational materials, on the other hand, are those materials provided to PACE participants and family or their authorized representatives, that provide information about the PACE program. The regulation addresses review of the marketing materials as it is essential that accurate and complete information be disseminated to potential PACE participants. We believe that the educational component of PACE is covered by annual notices, newsletters, and other materials presented to participants, and their families or authorized representatives, after they have enrolled in PACE. We believe the differentiation between marketing and educational materials is an operational issue and not appropriate for regulation.

Comment: A commenter indicated that marketing plans should be a submission requirement in support of program oversight and monitoring.

Response: We agree with the commenter, and the regulation reflects this requirement. The PO is required to establish, implement, and maintain a documented marketing plan with measurable enrollment objectives and a system for tracking effectiveness. Marketing plans are submitted by the PO and reviewed by the SAA and CMS as part of the provider application and when there is a significant revision to the marketing plan. These materials are also reviewed during onsite monitoring visits.

Comment: A commenter indicated that PACE marketing requirements should be the same as the Medicare and Medicaid managed care requirements, particularly the prohibited practices. The regulation prohibits door-to-door solicitation but does not mention other forms of unsolicited marketing such as telephone calls, e-mails, or targeted mailings.

Response: The commenter is correct. The only prohibited marketing practice included in the 1999 interim final rule was unsolicited door-to-door marketing. We are not aware of marketing abuses by POs. We believe that any change in marketing policy should be presented in a proposed rule and allow for public comment. We will continue to monitor marketing practices by POs and will propose additional safeguards as appropriate.

Comment: A commenter recommended that the information supplied to prospective participants should include a review of the responsibility to share in the cost of services by way of post-eligibility treatment of income, which is not expressly included in the rule.

Response: We agree that participants should be made aware that the share of cost requirements continues to apply after PACE enrollment; however, this requirement is not a PACE eligibility requirement. We would expect that the participant be informed at the time of his or her enrollment that their Medicaid eligibility requirements continue to apply as required in § 460.152(a)(1).

Comment: Since the regulations state that approval of an entity's provider application includes approval of marketing materials, one commenter asked whether the application process would permit use of the marketing materials in attracting enrollees.

Response: A prospective PO is not permitted to market PACE services until they have an approved application. Prospective applicants are informed in writing when their application has been approved. In this way, marketing activities may begin before the effective date of the program agreement.

Comment: One commenter indicated that the marketing materials must state that enrollees may be fully liable for unauthorized or out-of-plan services, and asked what would be the financial responsibility of a Medicaid recipient in this situation.

Response: The 1999 interim final rule established in § 460.82(d)(2) that all marketing materials must clearly state that PACE participants may be fully and personally liable for unauthorized or out-of-network services. Thus, a Medicaid recipient would be financially responsible for any unauthorized out-of-network services.

Comment: One commenter asked what constitutes a principal language of the community, whether there is a percentage threshold, and whether we intended that the reference to principal languages of the community applies to the community as a whole or the target population PACE intends to enroll.

Another commenter urged CMS to consider providing programs serving multilingual populations with some financial assistance to cover translation expenses.

Response: The determination of the principal languages of a PO's service area is a State determination. Therefore, we recommend that interested parties contact their State for specific information.

In response to the request that we consider providing financial assistance for translation services, we have no mechanism to provide financial assistance for entities serving multilingual populations.

Comment: One commenter asked whether, like M+C organizations, the prohibition against gifts and payments to induce enrollment does not include items of nominal value.

Response: We have adopted the MA policy regarding nominal gifts. In response to inquiries regarding nominal gifts, we consulted § 422.80(e) of the MA rule. For further guidance related to promotional activities, we reviewed § 50.1 of the Medicare Managed Care Manual, which was originally developed for M+C plans and is currently being revised for MA plans.

Offering gifts to potential enrollees that attend a marketing presentation is permitted as long as these gifts are of a nominal amount and are provided whether or not the individual enrolls in the PACE program. The gift cannot be a cash gift or be readily converted into cash regardless of the amount.

Final rule actions:

The final rule will finalize § 460.82 as published in the 1999 interim final rule.

Subpart F—PACE Services

The purpose of subpart F is to establish the service requirements for POs. In this subpart we specify the limitations and conditions relating to Medicare and Medicaid benefits. We stipulate that participants must receive all services from the PO, the required services that must be provided by the PO and those that may be excluded, emergency services, and the requirements for delivery of required services at the PACE center and other settings. In addition, we establish the requirements for composition of the IDT and its responsibilities, and

requirements for participant assessments and the plan of care.

The scope of this subpart led to a large number of comments related to the IDT, required services and their delivery. Included among the comments were requests for clarification, re-evaluation of various service related policies, and proposed changes to regulatory language.

Section 460.90 PACE Benefits Under Medicare and Medicaid

Under sections 1894(a)(2)(B) and (b)(1) and 1934(a)(2)(B) and (b)(1) of the Act, we established § 460.90 to specify that Medicare and Medicaid benefit limitations and conditions relating to amount, duration, scope of services, deductibles, copayments, coinsurance, or other cost sharing that are generally applicable under the Medicare and Medicaid programs do not apply to PACE benefits. In addition, we specified that, in accordance with sections 1894(a)(1)(B)(i) and 1934(a)(1)(A) of the Act, the PACE participant shall receive Medicare and Medicaid benefits solely through the PO.

Comment: We received one comment requesting clarification that the amount, duration, and scope of services are not subject to the limits of traditional Medicare and Medicaid services but also are not required to exceed those amounts unless the IDT determines it to be necessary and appropriate.

Response: The limits on amount, duration, and scope of services that apply to either the traditional Medicare or Medicaid benefit packages do not apply to PACE. The amount, duration or scope of services provided to PACE participants are participant-specific; therefore the amount, duration, or scope of services for each participant are indicated in his or her plan of care based on the IDT assessment. If an assessment indicates need for a particular service, the PO must provide the service without regard to whether the service would otherwise be covered for a Medicare beneficiary or a Medicaid recipient not enrolled in a PO.

Final rule actions:

This final rule will finalize § 460.90 as published in the 1999 interim final rule.

Section 460.92 Required Services

Based on the provisions of sections 1894(b)(1)(A) and 1934(b)(1)(A) of the Act, we require in § 460.92 that each PACE benefit package include for all participants, regardless of payment source, all Medicare services and all Medicaid covered services as specified in the State plan, a variety of services specified in the Protocol, and other services determined necessary by the IDT to meet the participant's needs (for example, respite care). Based on the Protocol, we included the following required services in § 460.92 of the 1999 interim final rule:

(a) All Medicaid-covered services, as specified in the State's approved Medicaid plan.

(b) Multidisciplinary assessment and treatment planning.

(c) Primary care, including physician and nursing services.

(d) Social work services.

(e) Restorative therapies, including physical therapy, occupational therapy, and speech-language pathology services.

(f) Personal care and supportive services.

(g) Nutritional counseling.

(h) Recreational therapy.

(i) Transportation.

(j) Meals.

(k) Medical specialty services including, but not limited to the following:

(1) Anesthesiology.
(2) Audiology.
(3) Cardiology.
(4) Dentistry.
(5) Dermatology.
(6) Gastroenterology.
(7) Gynecology.
(8) Internal medicine.
(9) Nephrology.
(10) Neurosurgery.
(11) Oncology.
(12) Ophthalmology.
(13) Oral surgery.
(14) Orthopedic surgery.
(15) Otorhinolaryngology.
(16) Plastic surgery.
(17) Pharmacy consulting services.
(18) Podiatry.
(19) Psychiatry.
(20) Pulmonary disease.
(21) Radiology.
(22) Rheumatology.
(23) General surgery.
(24) Thoracic and vascular surgery.
(25) Urology.

(l) Laboratory tests, x-rays and other diagnostic procedures

(m) Drugs and biologicals.

(n) Prosthetics, orthotics, durable medical equipment, corrective vision devices, such as eyeglasses and lenses, hearing aids, dentures, and repair and maintenance of these items.

(o) Acute inpatient care, including the following:

(1) Ambulance.
(2) Emergency room care and treatment room services.
(3) Semi-private room and board.
(4) General medical and nursing services.
(5) Medical surgical/intensive care/coronary care unit.
(6) Laboratory tests, x-rays, and other diagnostic procedures.
(7) Drugs and biologicals.
(8) Blood and blood derivatives.
(9) Surgical care, including the use of anesthesia.
(10) Use of oxygen.
(11) Physical, occupational, respiratory therapies, and speech-language pathology services.
(12) Social services.

(p) Nursing facility care.

(1) Semi-private room and board.
(2) Physician and skilled nursing services.
(3) Custodial care.
(4) Personal care and assistance.
(5) Drugs and biologicals.
(6) Physical, occupational, recreational therapies, and speech-language pathology, if necessary.
(7) Social services.
(8) Medical supplies and appliances.

(q) Other services determined necessary by the IDT to improve and maintain the participant's overall health status.

Comment: We received several comments related to the list of required services. One commenter stated that the list of services is extensive and considerably longer than the list for nursing facilities, presenting a dilemma to States to establish the cost effectiveness of PACE compared to nursing facility cost.

Another commenter requested we re-evaluate the required services and ensure they are in fact the minimum requirements necessary to protect the health, safety, welfare, and rights of consumers in the PACE program.

Response: In accordance with sections 1894(b)(1)(A) and 1934(b)(1)(A) of the Act, the scope of benefits for PACE is all items and services covered under title XVIII and all items and services covered under title XIX without regard to an individual participant's source of payment and without any limitation or condition as to amount, duration, or scope and without application of deductibles, copayments, coinsurance, or other cost sharing that would otherwise apply. In addition, the PACE scope of benefits includes all additional items and services specified in regulations, based upon those required under the Protocol. Based on this authority, we established § 460.92 in an attempt to list the items and services covered under titles XVIII and XIX of the Act and the Protocol, to clarify that the scope of benefits under title XIX is the services specified in the State's approved Medicaid plan, and to clarify that the scope of benefits under PACE includes any other item or service determined necessary by the IDT to improve and maintain the participant's overall health status.

We have examined our approach to setting forth required PACE services and have determined that it is not possible to provide a complete list of all inpatient, outpatient, physician specialty, care planning, and social support services that must be furnished to participants if ordered by the IDT. As the scope of benefits under PACE is so broad, we are revising this section to summarize Medicare and Medicaid covered items and services and to highlight the services that are unique to the PACE model, instead of the current listing of services required. Under this final rule, the required services under PACE are all Medicare-covered items and services (including outpatient prescription drug coverage), all Medicaid-covered items and services identified in the State Medicaid plan, and other services determined necessary by the IDT to improve and maintain the participants' overall health status.

In response to the commenter's concern that the PACE benefit package is broader than the services furnished in nursing facilities, which complicates cost comparison, we note that currently most States establish capitation rates based on a blend of the cost of nursing home and community-based care for the frail elderly.

Comment: We received several comments related to the respiratory therapy and the respiratory therapist (RT). Several commenters recommended that the IDT be expanded to include RTs and that respiratory therapy be added to the list of required services provided not just in an acute care setting but also in nursing facilities and in community settings. We were also asked to clarify our expectations for coverage of respiratory therapy in these additional settings.

Response: The IDT is responsible for determining whether additional disciplines are required to assess specific health concerns. If a participant requires the services of specialists, whether or not the specialist is on the IDT, then the services become required for that participant. Unlike traditional Medicare and Medicaid, the site of service is not an issue in PACE. The participant may receive services wherever the IDT determines appropriate. Therefore, respiratory therapy services may or may not be furnished in an inpatient setting, based on the particular participant's needs. We believe the regulation as revised will provide the flexibility needed for providing Recreational Therapy (RT) in a PO if needed. Upon review, we believe the RT is a valuable adjunct position but not an essential position for every IDT. Therefore, we are not requiring the addition of this discipline to the IDT at this time.

Comment: One commenter asked that we clarify the description of the benefit package as ''all State plan services'' because this characterization includes services not applicable to and not expected to be accessed by the PACE population, as well as being mutually exclusive services.

Response: In accordance with section 1934(b) of the Act, PACE is required to provide all items and services covered under title XIX. The services that are actually provided are those determined by the IDT to be required for a particular PACE participant. For example, neonatal intensive care unit services will probably not be needed by a PACE participant; however, these services are required services under Medicaid and must be furnished by the PO if the IDT were to determine they are necessary for a particular PACE participant.

Comment: We were also asked to clarify our expectations regarding mental health services, other than psychiatric services, for alcohol and substance abuse.

Response: We expect participants to be assessed, diagnosed, and treated for all types of health issues or conditions, including mental health issues or substance abuse.

Comment: Two commenters objected to POs being responsible for providing three meals per day, recommending we either omit meals from the benefit package or, alternatively, clarify that POs are required to provide meals on a limited basis.

Response: The intent of this rule is to ensure all PACE participants' nutritional needs are met. PACE is responsible for a participant's health and safety including his or her nutritional needs 24 hours a day/7 days a week. That responsibility includes providing nourishing, palatable, well-balanced meals that meet the daily nutritional requirements and the special dietary needs of each participant. The IDT must assess the participant's needs as well as his or her access to adequate nutrition. The participant's nutritional requirements and dietary needs should be included in the participant's plan of care, whether it is providing tube feedings, arranging for Meals on Wheels, sending meals home with the participant after his or her visit to the PACE center or documenting that appropriate meals are provided by the family/caregiver.

Comment: One commenter recommended that durable medical equipment (DME) requirements should not be unnecessarily restrictive as technology is continually changing and as more options become available, these options should not be excluded for PACE participants. Therefore, we should relax the regulatory requirement by adding ''other assistive devices'' and ''magnification devices'' to § 460.92(n).

Response: We do not believe there needs to be a change in the regulatory language as the PO is required to provide anything the IDT determines necessary to assist the participant to remain living safely in the community. When determined necessary by the IDT, POs must provide participants with assistive devices that may not be provided under traditional Medicare.

In order to clarify the services provided by the PACE program and to emphasize what makes a program uniquely PACE, in this final rule we are revising § 460.92 by removing the enumerated list of required services and replacing the list with a requirement that the PACE program must provide all Medicare services, all Medicaid-covered services specified in the State's approved Medicaid plan, and other services determined necessary by the IDT to improve and maintain the participant's overall health status.

Final rule actions:

In this final rule, we are revising § 460.92 by replacing the current list of required services with the following:

(a) All Medicare-covered items and services;

(b) All Medicaid-covered items and services, specified in the State's approved Medicaid plan;

(c) Other services determined necessary by the IDT to improve and maintain the participant's overall health status.

Section 460.94 Required Services for Medicare Participants

In accordance with paragraph (b)(1)(A)(i) of sections 1894 and 1934 of the Act, we specified in the 1999 interim final rule that the PACE benefit package for Medicare participants must include, in addition to the services required by § 460.92, the scope of hospital insurance benefits described in 42 CFR part 409 and the scope of supplemental medical insurance benefits described in 42 CFR part 410.

We also specified the following requirements of title XVIII of the Act (and regulations relating to such requirements) that are waived and do not apply to services under the PACE program:

- The provisions of subpart F of part 409 of 42 CFR that limit coverage of institutional services;
- The provisions of subparts G and H of 42 CFR part 409 and parts 412

through 414 that relate to rules for payment for benefits;

• The provisions of subparts D and E of 42 CFR part 409 that limit coverage of extended care services or home health services;

• The provisions of subpart D of 42 CFR part 409 that impose a 3-day prior hospitalization requirement for coverage of extended care services; and

• The provisions of 42 CFR 411.15(g) and (k) that may prevent payment for PACE program services to individuals enrolled in the PACE program.

Comment: We were asked to clarify whether the reference in § 460.94(b)(5) to ''payment for PACE program services to PACE participants'' means payment ''on behalf of'' participants. If not, commenters asked whether the regulatory language was meant to permit PACE centers to implement direct payment/cash benefits to enable consumers to hire personal care attendants directly. The commenters stated that this would be a positive innovation in the PACE model.

Response: Section 411.15 specifies items and services excluded from traditional Medicare. Section 411.15(g) pertains to requirements related to custodial care, and § 411.15(k) pertains to requirements related to services that are not reasonable and necessary. Section 460.94 waives Medicare exclusion of these services for POs. Therefore, it allows payment for PACE services that are provided to PACE participants, including custodial services and services that would be considered not reasonable and necessary under traditional Medicare when furnished by a PO to a participant. This section in no way implies that the PO can implement direct payment or cash benefits to be paid to PACE participants. We are amending § 460.94(b)(5) to waive those specified sections that may prevent payments for PACE program services ''that are provided to'' PACE participants to clarify this issue.

Final rule actions:

In this final rule, we are amending § 460.94(b)(5) to clarify that payment is for PACE program services ''that are provided to'' PACE participants.

Section 460.96 Excluded Services

In this section, we provide a list of excluded services based on Part IV, section A.6 of the Protocol. The services that are excluded from coverage under the PACE program are as follows:

• Any service that is not authorized by the IDT, even if it is listed as a required service, unless it is an emergency service.

• For services in inpatient facilities, private room and private duty nursing services, unless medically necessary and non-medical items for personal convenience such as telephone, radio or television rental, unless specifically authorized by the IDT as part of a participant's plan of care.

• Cosmetic surgery does not include surgery required for improved functioning of a malformed part of the body resulting from an accidental injury or for reconstruction following mastectomy.

• Experimental medical, surgical, or other health procedures.

• Services furnished outside the United States, except as may be permitted in accordance with 42 CFR 424.122 and 424.124 or as may be permitted under the State's approved Medicaid Plan. While the Protocol did not recognize any exceptions, the required inclusion of Medicare and Medicaid covered services results in certain limited exceptions being possible. For example, a State that borders another country might include some Medicaid coverage across the border, and Medicare covers some emergency hospital, ambulance, and physician services outside the United States. (As defined in 42 CFR 400.200, the United States includes the Commonwealth of Puerto Rico, the Virgin Islands, Guam, American Samoa, and the Northern Mariana Islands.)

In the 1999 interim final rule, there was a technical inconsistency between the § 460.96(e) preamble language and regulatory language regarding services furnished outside the United States. In the preamble, we referenced § 424.122 and § 424.124; in the regulatory language, we referenced § 424.122 through § 424.124. To rectify this technical inconsistency, we are revising the regulatory language in § 460.96(e)(1) to conform the regulatory language to the preamble language. The regulatory language in § 460.96 will now read: (e) Services furnished outside of the United States, except as follows: (1) In accordance with § 424.122 and § 424.124 of this chapter.

Comment: Two commenters requested clarification regarding excluded services. One commenter questioned whether the PACE center is prohibited from covering services such as a private room, experimental medical, surgical, or other health procedures. The commenter questioned why under a capitated payment, a PO would be prohibited from covering procedures they deemed beneficial if they have the resources to do so.

The second commenter stated that he believed that some Medicaid programs cover a procedure deemed experimental and CMS may choose to cover such a procedure under Medicare. Thus, the regulation should clarify that such a procedure is not prohibited but at the discretion of the PACE program.

Response: In response to the comments relating to services that are generally excluded services under the PACE program, the list of services excluded from coverage under PACE is based on the Protocol. Therefore, the Medicare and Medicaid capitation rates are not based on these excluded services. As with all items and services provided by PACE, it is the IDT and each participant's plan of care that establish whether or not a service is covered as a required PACE service.

To further clarify, should the IDT determine that an experimental surgery or procedures would be appropriate for a participant and complications arise, the PO would remain at full risk and would not be able to disenroll the participant for changes in health status resulting from the experimental surgery or procedure.

Final rule actions:

In this final rule, we are making a technical correction by revising § 460.96(e)(1) by replacing the word ''through'' with the word ''and'' so that paragraph (e) reads ''Services furnished outside of the United States, except as follows: (1) In accordance with § 424.122 and § 424.124 of this chapter.''

Section 460.98 Service Delivery

We require in § 460.98 that the PO must establish and implement a written plan for providing care to each individual participant that meets that individual's needs across all care settings on a 24-hour basis, each day of the year. The PO must furnish comprehensive medical, health, and social services that integrate acute and long-term care. At a minimum, these services must be furnished in the PACE center, the participant's home, and inpatient facilities. The PO must not discriminate against any participant based on race, ethnicity, national origin, religion, sex, age, mental or physical disability, or source of payment.

The requirements in this section implement provisions in Part IV, section B of the Protocol and ensure the availability of and access to services as a PO grows. The following requirements are based on the Protocol:

• At least the following services must be furnished at every PACE center: primary care (including physician and nursing services); social services; restorative therapies (including physical and occupational therapy); personal care and supportive services; nutritional

counseling; recreational therapy; and meals.

- The PO must operate at least one PACE center either in or contiguous to its designated service area, with sufficient capacity for routine attendance by its participants.
- The PO must ensure accessible and adequate services to meet the needs of all its participants. When necessary, the organization must increase the number of PACE centers, staff, and other PACE services.
- The frequency of a participant's attendance at the PACE center is determined by the IDT based on the needs and desires of each participant.

Finally, if the PO operates more than one PACE center, each PACE center must offer the full range of services and have sufficient staff to meet the needs of participants.

Comment: We received numerous comments relating to the minimum range of services required to be furnished at the PACE center. One commenter recommended we delete the requirement that each PACE center offer the full range of services, if the organization operates more than one PACE center in a defined service area, as long as all required services are readily available to all participants.

Two commenters believe the focal point of PACE service delivery is the IDT rather than the PACE center and requested that we explicitly recognize the provision of services at alternative sites. One commenter indicated that this approach would avoid potentially adverse situations in which all alternative delivery sites are subject to PACE center regulatory requirements and survey criteria, in addition to any State certification or licensure requirements applicable to such facilities. One of the commenters proposed that services be allowed in alternative locations provided they meet applicable State licensure and certification requirements.

One commenter emphasized that there is a critical distinction that should be made between a participant being assigned to a team ''operating from'' a PACE center and PACE center attendance. As published in the rule, § 460.98(e) states that ''the frequency of a participant's attendance at a PACE center is determined by the IDT, based on the needs and preferences of each participant.''

Commenters indicated the regulation should afford flexibility to enable programs to offer services either on or off site in order to best meet the needs and preferences of participants and maximize efficient use of organizational resources.

Another commenter suggested that satellite PACE centers that furnish a core set of services (but not full range of services) and are within a reasonable distance of a full-service PACE center should be allowed.

Response: We disagree with these commenters. We believe that omitting the requirement that each PACE center provide the full range of services would fragment the care the PACE program was established to coordinate.

In addition, we believe that the PO has the flexibility to provide services in settings other than the PACE center. However, every participant must have a PACE center home that is capable of furnishing all PACE required services. For POs that are sufficiently large to require multiple PACE centers, each center would need to have a sufficient number of IDTs to provide the full range of services to meet the needs of all participants assigned to that PACE center.

We believe the success of the PACE delivery model is due to the combination of the IDT assessment and care planning and the PACE center. Independent of each other, neither would produce the remarkable participant care successes they do together. The PACE center provides a point of service where the primary care clinic is located, where services are provided, and socialization occurs with staff that is consistent and familiar. The IDT not only works from the PACE center, they provide the majority of services to participants at the PACE center, where most participants come on a regular basis to receive the majority of their care. We also believe the attendance at the center is an important aspect of the PACE model, which helps to differentiate it from home health care or institutional care. Therefore, we will continue to require that the full range of PACE services be offered at the PACE center and will encourage development of PACE centers in rural and Tribal areas, wherever possible.

We allow alternative care settings (ACS) where a limited number of services may be provided. Should participants choose to attend an ACS to receive certain services, they would attend the PACE center for the services not offered at the ACS. We do not believe that an ACS should replace the PACE center. We believe that every participant must be assigned to and have the option to receive PACE services at a PACE center.

Comment: Another commenter endorsed flexibility in staffing for POs that operate more than one PACE center.

Response: Each PACE center must have at least one complete IDT and enough support staff to ensure all participants receive the services and attention they require. We believe the flexibility the commenter requested was provided in the 2002 interim final rule, which permits POs to contract for IDT staff and as well as for PACE center services.

Comment: Another commenter added that flexibility would increase access to PACE services in rural areas and in the development of specialized POs, that is, programs designed and staffed for treatment of the mentally ill or Alzheimer's patients.

Response: We believe that every PACE center must provide for every participant that meets the eligibility requirements and wishes to enroll in PACE. We are aware that some POs have specialized staff and accommodations specifically for Alzheimer's/Dementia patients. As the regulation reads currently, a PO choosing to limit enrollment to a targeted population would be viewed as discriminatory. We are not inclined to permit POs to limit enrollment to certain target populations at this time. Should we consider such a change, we would include it in future rulemaking and permit the public to comment.

Comment: Two commenters requested we broaden the list of categories under which the PO cannot discriminate to include sexual orientation.

Response: In response to this request, we are amending the language of § 460.98(b)(3) to include sexual orientation.

Comment: We also received a request for an explanation of the procedures a PO needs to follow in order to establish additional PACE centers.

Response: We have provided a number of scenarios to explain our policy regarding expansions on our CMS PACE home page at *http://www.cms.hhs.gov/pace/*. A separate application for the sole purpose of expansion is also provided on the CMS PACE homepage. This expansion application is abbreviated to take into account only processes or practices that would be different due to the expansion.

Final rule actions:

In this final rule, we are amending § 460.98, paragraph (b)(3), to add sexual orientation.

Section 460.100 Emergency Care

We note that as sections 1894 and 1934 of the Act do not contain specific requirements regarding emergency care, in the 1999 interim final rule we relied on the Protocol and regulations governing emergency care under Medicare and Medicaid managed care to develop the requirements for emergency

care under PACE. We expanded on and clarified the provisions in Part IV, section A of the Protocol to ensure access to necessary services and to adopt a beneficiary-centered approach.

Section 460.100 requires a PO to establish and maintain a written plan for handling emergency health care needs. The organization must ensure that the participants and their caregiver know when and how to access emergency services and ensure that CMS, the State, and PACE participants are held harmless for emergency services.

As we explained in the 1999 interim final rule, emergency care is appropriate when services are needed immediately because of an injury or sudden illness and the time required to reach the PO or a network provider would cause the risk of permanent damage to the participant's health. Thus, emergency care services include inpatient and outpatient services, furnished by a qualified emergency services provider (other than the PO or one of its contract providers) either in or out of the PO's service area, that are needed to evaluate or stabilize an emergency medical condition.

An emergency medical condition means a condition manifesting itself by acute symptoms of sufficient severity (including severe pain) such that a prudent layperson, with an average knowledge of health and medicine, could reasonably expect the absence of immediate medical attention to result in: Serious jeopardy to the health of the participant; serious impairment to bodily functions; or serious dysfunction of any bodily organ or part.

Emergency services that fall within this description do not require prior authorization by the PO. We believe that relying on the prudent layperson standard in establishing a participant's need for emergency services is more clear than the definition of emergency care in the Protocol. We adopted the prudent layperson standard from the Consumer's Bill of Rights and Responsibilities (CBRR) (discussed in the section on participant rights). The same standard is used in the M+C (now MA) definition of emergency medical condition. This standard encompasses a slightly broader range of circumstances than does the Protocol language, by including some situations that could fit under the Protocol description of urgent care or urgently needed services. We think this clarification is helpful because the Protocol wording does not clearly distinguish between emergency and urgent care.

Services a participant may need while temporarily absent from the PO's service area that are not emergency services but cannot be delayed until the participant returns would need prior authorization. The fact that these services may be urgently needed means that the PO would be expected to authorize a participant to obtain them from a non-contract provider outside of the service area, but it does not exempt them from the requirement for prior authorization. This approach differs from that applied to MA organizations, where prior authorization for urgently needed services is not required. We believe that the differences in the population served by POs warrant the different treatment of urgent, though not emergency, care needs. Due to the relative frailty, more limited mobility, and more complex health status of PACE participants, we believe the need to maintain the coordination of care by the IDT justifies contact with and authorization by the PO before receipt of non-emergency care outside the PACE network.

The emergency services plan must also provide for the availability of appropriate on-call providers. We expanded this requirement from the Protocol to provide a safety net for unanticipated health incidents, so participants do not encounter difficulty in obtaining care when they are away from the PACE center, when they are away from the PO's service area and require services that cannot be delayed until they return, or when they require post-stabilization care services following emergency services. An on-call provider must be available 24 hours per day to address any participant questions about accessing emergency services and respond to requests for authorization of urgently needed out-of-network services or post-stabilization care services following emergency services.

We believe that POs must be responsive to all participant care needs, including the need for urgently needed or post-stabilization services. In order to ensure that unforeseen circumstances do not result in delays in needed care, we clarified that the PO must cover urgently needed out-of-network or post-stabilization care services if it does not respond to a request for approval within 1 hour after being contacted or cannot be contacted for approval.

Comment: We received several comments regarding emergency care. One commenter requested clarification about when the PO would not be responsible for the cost of emergency services, and asked whether the PO would always be obliged to provide for emergency care if the prudent layperson test is met.

Response: The PO is obligated to pay for all emergency care if the prudent layperson standard as specified in § 460.100(c) is met and the participant believes he or she is in a critical health emergency or, in other words, if the participant fears for his or her life or well-being.

Comment: One commenter recommended that the requirement that POs explain policies regarding emergency care be modified to include a clarification that no prior approval is required for emergency services.

Response: We agree with this commenter and are modifying paragraph (d) in this final rule to require the PO to explain that no prior authorization is required for emergency care.

Comment: One commenter requested a definition of the term ''caregiver'' in our requirement at § 460.100(d) that the PO must explain policies regarding emergency care.

Response: We believe that the nature of PACE and the living arrangements experienced by PACE participants covers a wide range of diverse circumstances making a definition of ''caregiver'' inappropriate. A PACE participant could be living alone, with family members, in a residential facility or be in another type of living arrangement. They could have a caregiver or many different caregivers. The caregiver could be a family member, attendant, friend, neighbor, member of a church or other organization, or anyone who attending to participant's needs and which constitutes a caregiving relationship. Therefore, for purposes of PACE, we consider a caregiver anyone who attends to the participant's needs and we use the terms ''family member'' and ''caregiver'' interchangeably.

Comment: One commenter asked that we clarify if on-call providers can be accessed via an answering service, beeper, or other device and if the on-call provider must be a member of the IDT.

Response: There is no prohibition on providers using an answering service, beeper or other device, but we expect that on-call providers respond to all participant calls as soon as possible and at a minimum within the 1 hour allotted for response to calls for prior authorization. There is no requirement that the on-call provider must be an IDT member.

Comment: Three commenters requested we define urgently needed care, and distinguish between emergency, urgently needed care, and post-stabilization services.

Response: In response to these requests, we are establishing the following definitions in this final rule:

As defined in the 1999 interim final rule, an *Emergency Medical Condition* is a condition manifesting itself by acute symptoms of sufficient severity (including severe pain) such that a prudent layperson, who possess an average knowledge of health and medicine, could reasonably expect the absence of immediate medical attention to result in placing the health of the individual in serious jeopardy, serious impairment to bodily functions, or serious dysfunction of any bodily organ or part.

As also defined in the 1999 interim final rule, *Emergency care* is appropriate when services are needed immediately because of injury or sudden illness and the time required to reach the PO or one of its contact providers, would cause risk of permanent damage to the participants health. Emergency services include inpatient and outpatient services that are furnished by a qualified emergency services provider, other than the PO or one of its contract providers, either in or out of the PO's service area and are needed to evaluate or stabilize an emergency medical condition. In addition, in accordance with § 460.112(d), we are clarifying in this final rule that we are amending paragraph (d) of this section to require POs to explain to PACE participants that emergency care services that are provided for medical conditions that fall within this description must be covered by the PO and do not require prior approval.

Urgent care means the care provided to a PACE participant who is out of the PACE services area, and who believes their illness or injury is too severe to postpone treatment until they return to the service area, but their life or functioning is not in severe jeopardy.

We note that participants are expected to seek prior approval from the PO in order to be covered for urgent care.

Post-stabilization care means services provided subsequent to an emergency that a treating physician views as medically necessary after an emergency medical condition has been stabilized. They are not emergency services, which POs are obligated to cover. Rather, they are non-emergency services that the PO should approve before they are provided outside of the service area.

Prior approval of these services is intended to ensure efficient and timely coordination of appropriate post emergency care by the IDT.

To further clarify, an example of urgent care might be a severe cough without other symptoms. The participant does not believe his or her life is in jeopardy, so he or she must call the PO. The PO physician advises the participant not to go to the ER, take a certain over-the-counter medication, and see the physician when the participant returns tomorrow.

While post-stabilization care services are the follow-up care required after an emergency condition that has stabilized, also while the participant is outside the PO service area. For example, the participant is hospitalized due to bacterial pneumonia. It was treated and resolved enough for discharge but some residual symptoms remain. The treating physician knows the participant will not be returning home for 2 weeks, which he believes is too long a period of time before having a follow-up x-ray ordered by her physician. Therefore, the treating physician must contact the PO for approval to order a follow-up x-ray. The x-ray is not emergency care but is necessary and customary to ensure the improving condition of the lungs.

Comment: One commenter requested that we lengthen the time the PO may take to respond to a request for approval of non-emergent care services from 1 hour to 24 hours.

Response: We believe that the PO's responses to urgent and post-stabilization care services requests need to be completed as expeditiously as possible in order to prevent any misunderstanding between the PO, the participant, and the non-network physician. We seek to avoid a situation that might result in failure to provide essential care or result in providing non-covered services because of the length of the PO's response time. Therefore, we are retaining the 1-hour response time for urgent care and post-stabilization care requests.

Final rule actions:

In this final rule, we are:

- Adding language to paragraph (d) to require the PO to explain to the participant that no prior authorization is required for emergency care; and
- Revising § 460.100 to include definitions for urgent and post-stabilization care.

Section 460.102 Interdisciplinary Team

This section is based on provisions in Part IV, section B of the Protocol. In the 1999 interim final rule, we included a requirement that the PO must establish an IDT at each PACE center to comprehensively assess and meet the individual needs of each participant. In § 460.102(a)(1), we require that the PO assign each participant to an IDT based at the PACE center the participant attends.

As we explained in the 1999 interim final rule, we believe that a well-functioning IDT is critical to the success of the PACE program, as the team is instrumental in controlling the delivery, quality, and continuity of care. Members of the IDT should be knowledgeable about the overall needs of the participants, not just the needs that relate to their individual disciplines. In order to meet all of the health, psychosocial, and functional needs of the participant, team members must view the participant in a holistic manner and focus on a comprehensive care approach.

Based on the Protocol, in paragraph (b) we require that the IDT be composed of at least the following members:

a. Primary care physician (PCP)—We considered expanding this to include nurse practitioners but decided to retain the requirement in the Protocol. While it would be acceptable for a PO to include a nurse practitioner on the IDT, we believe that this should be in addition to rather than instead of the PCP, at this time. This approach is consistent with other Medicare regulations. We believe such a change should be included in a proposed rule in order to allow for public comment on this issue. In the meantime, we are continuing to assess the appropriateness of allowing nurse practitioners to assume the role of the PCP consistent with State licensure for nurse practitioners.

b. Registered nurse (RN)—The Protocol requires the inclusion of a ''nurse.'' In paragraph (b)(2), we specified that this team member be an RN. The nurse represented on the IDT must exhibit leadership and management skills that are more consistent with the training received by RNs, as opposed to licensed practical nurses. In addition, we believe that an RN would be better able to determine and respond to the health care needs of the frail population, particularly for home care services.

c. Social worker;

d. Physical therapist (PT);

e. Occupational therapist (OT);

f. Recreational therapist or Activity Coordinator;

g. Dietitian;

h. PACE center manager—We changed the Protocol terminology from ''PACE Center Supervisor'' to ''PACE Center Manager.'' The PACE center manager is responsible for overall operation of the PACE center and ensuring service delivery. The individual who holds this position should be a good facilitator and should possess good communication skills. In many POs, the PACE center manager

leads IDT meetings. We are permitting the PO and the IDT the flexibility to decide who should lead the team and facilitate the discussions.

i. Home care coordinator—Since PACE services may be furnished in the home, the coordination of in-home services with PACE center and primary care services is critical to effective service delivery. This coordination is especially important if the PO has contractors providing the home care services. The PO must designate a home care coordinator to supervise and coordinate home care services, whether these services are furnished by a PACE employee or through a contractor. We changed the Protocol's term ''home care liaison'' to ''home care coordinator,'' because ''home care liaison'' has another meaning in Medicare, and we wanted to avoid confusion.

j. Personal care attendants (PCAs) or their representatives—We changed the Protocol term ''health care worker/aide'' to ''personal care attendant,'' as we believe this term more accurately describes this position. We believe that ''health care worker'' is too general and could apply to other members of the team.

k. Drivers or their representatives—This requirement remains unchanged from the Protocol.

Due to the age of most PACE participants, a geriatrician could be a valuable member of the IDT. As one option, the PCP could be a geriatrician. However, physicians who specialize in geriatrics are relatively rare, and availability might be a serious problem. We have not required the involvement of a geriatrician but in the 1999 interim final rule, we invited comments about whether such a requirement would be desirable and, if so, whether the geriatrician should be employed by the PO and should primarily serve PACE participants.

Consistent with the Protocol, we require in paragraph (c) that primary medical care for all participants be furnished by the PCP(s). The PCP must serve as the gatekeeper to the participant's use of medical specialists and inpatient care, and he or she must be an integral member of the IDT. Ultimate responsibility for management of medical situations must rest with the PCP.

The IDT is responsible for the initial assessment, periodic reassessments, the plan of care, and coordinating 24-hour care delivery. A critical element of the success of the IDT is the degree to which team members share information and communicate with one another. The Protocol requires the physician to keep the IDT informed of the medical condition of each participant and to remain alert to pertinent input from other team members. We believe this should be the responsibility of each member of the team rather than just the physician, as it is critical to timely intervention to address potential problems. To reflect this position, we require in paragraph (d) that each member of the team must regularly inform the IDT of the medical, functional, and psychosocial condition of each participant and remain alert to pertinent input from other team members, participants, and caregivers. This communication can take place through formal measures such as team meetings and written documentation in participants' medical records, but should not be limited to formal mechanisms. Informal communication between team members (for example, CARDEX systems, informal updates during shift changes) should be encouraged as well. It is critical that personal care attendants be involved in the communication process. As they often have the first contact with the participant, it is important that they regularly share information, for example, on the participant's mood, activities, and daily habits. In the 1999 interim final rule, we required that each team member must document all changes in the participant's condition in the participant's medical record.

In paragraph (d)(3), we require that members of the IDT must serve primarily PACE participants, unless a waiver is granted. After considering this issue, we concluded that in order to effectively serve a frail elderly population, such as is served by the PACE program, it is important to support and retain measures that promote quality and continuity of care. If team members serve primarily PACE participants, they are able to develop a rapport with participants and are better able to plan for and provide their care. We recognize that team members may have other clients, but this must not interfere with the provision of services for PACE participants.

In paragraph (g), we included conditions for waiver of the employment requirement for IDT members. CMS and the SAA were authorized to grant a waiver of this requirement if they determined that—

- There are not enough individuals available in the PO's service area who meet the PACE requirement or State licensing laws make it inappropriate for organizations to employ physicians; and
- The proposed alternative does not adversely affect the availability of care or the quality of care that is provided to participants.

In response to public comment on the 1999 interim final rule, and to implement section 903 of BIPA, we made the following changes in § 460.102 in the 2002 interim final rule.

We amended paragraph (d)(2)(iii) to clarify that IDT members must document changes in a participant's condition in the participant's medical record consistent with the documentation policies established by the medical director of the PO. This ensures that only designated team members have access to patient records.

Also, in consideration of the expanded contracting opportunities in the 2002 interim final rule, we removed paragraph (f) that required members of the PACE IDT to be employed by the PO. Finally, we removed paragraph (g) that allowed CMS and the SAA to waive the employment requirement for the PCP and the requirement that the IDT serve primarily PACE participants. Since the PO may contract for PCPs in accordance with the requirements specified in § 460.70 (described in the section I.B.3.b. of this preamble) and other waivers are governed by § 460.26 (described in section I.B.f. of this preamble), these specific waiver provisions are no longer necessary. We amended paragraph (d)(3) by removing the cross reference to paragraph (g).

Comment: There were numerous recommendations on variations of IDT composition, the roles of the IDT members, services the IDT members provide and the locations where the IDT members may provide services. One commenter recommended we grant greater flexibility by specifying in the regulation the teams ''operate from'' the PACE center, regardless of where the services are furnished. This commenter also recommended we omit the requirement relating to physical location of the IDT. Commenters also recommended that we provide greater flexibility in composition of the IDT including when POs operate multiple PACE centers.

One commenter recommended we omit the positions of dietitian, PACE center manager, home care coordinator, PCA, and driver from mandatory membership on the IDT and add a requirement that the core team coordinate and supervise services provided by other staff.

Response: There are other delivery models with an interdisciplinary team approach but none revolve around a PACE center. We believe the cohesive interaction between the IDT and the PACE center is one of the elements that makes PACE not only different but also successful.

The 2002 interim final rule expanded the flexibility available to POs by permitting contracting of individual IDT members or contracting for the entire PACE center and services. One of the essential elements of the IDT is the consistency with which services are provided to participants. Each PACE center is required to have at least one IDT or more if necessary to ensure that each participant is assigned to an IDT at the PACE center the participant attends. As a result, we are not inclined to delink the physical location of the IDT service to the PACE center.

After reviewing the recommendations made by commenters for members of the IDT, we continue to believe that the required membership of the IDT specified in paragraph (b) has been an essential element in the PACE program's proven success in managing the complex health conditions of the frail elderly. Nutritional status has an immense impact on health especially on the frail and the elderly; thus, we believe a dietitian is an essential member of the IDT. The home care coordinator is another position that has a vital impact on the health and safety of participants while they are living at home in the community. The PCAs often have the first and closest interaction of the day with the participants and the driver has contact with the participants both in the early morning and in their home environment. Input from these IDT members or their representatives can be instrumental in the detection of the first signs of impending illness or environmental issues. Therefore, we are retaining the required membership composition of the IDT as published in the 1999 interim final rule in § 460.102(b).

Comment: We received one comment regarding the 2002 interim final rule modifications to the IDT. This commenter requested we retain paragraph (f), which was deleted from the 2002 interim final rule. The commenter also suggested that paragraph (g) be replaced with language the commenter proposed related to contracted PCPs.

Response: The changes to the 2002 interim final rule were made in response to numerous comments requesting flexibility to contract for all members of the IDT. As we stated in the preamble to the 2002 interim final rule, we removed paragraph (f)(requiring members of the IDT to be employed by the PO) and paragraph (g)(allowing waiver of specified requirements) in consideration of the expanded contracting opportunities that were added in the 2002 interim final rule. As the PO may contract for PCPs in accordance with the requirements specified in § 460.70 and other waivers are governed by § 460.26, we determined that this provision was no longer needed.

The commenter's proposed language would have permitted contracting of services for most IDT positions, but dictated when and where services could be provided. We continue to believe that the amendments made in the 2002 rule provide the flexibility requested in comments we received on the 1999 interim final rule. Therefore, we are retaining the changes implemented in the 2002 interim final rule.

Comment: One commenter recommended the IDT include the participant's personal representative.

Response: The intent of § 460.102 was to establish the staff responsibilities for the disciplines that constitute the IDT team of care providers. Although the participant (or his or her representative) is not specifically identified as a member of the IDT under § 460.102, § 460.106(e) requires the team to develop, review, and reevaluate the plan of care in collaboration with the participant or caregiver, or both to ensure there is agreement with the plan of care and the participant's concerns are addressed. Although the participant or his or her representative contributes to the decision-making process, we do not believe that it is appropriate to include the participant or their representative as an IDT member.

The following are comments and recommendations related to specific IDT members.

Comment: In response to our request for comments related to requiring that the PO employ a geriatrician on the IDT, a number of commenters indicated that it is desirable but not feasible to require POs to employ a geriatrician at each PACE center.

Response: We agree with these commenters and are not requiring a geriatrician on each IDT.

Comment: One commenter requested we delete the requirement that PCPs must serve primarily PACE participants.

Response: We are retaining the ''primarily serve'' requirement for all IDT members because this requirement was established to ensure the participants receive the unique benefits offered by the PACE program model.

Comment: A very large number of comments were related to physician adjunct positions, specifically nurse practitioners (NPs) and physician assistants (PAs). One commenter recommended that we include NPs and PAs in IDT requirements because the role of the NP to include primary care and team leadership under a collaborative agreement with an actively involved and fully accessible physician.

Another commenter requested we permit more flexibility in the delivery of primary care through the acknowledgement of the role of NPs and PAs and modify both regulatory sections by adding the phrase ''or a nurse practitioner/physician assistant working in collaboration with a PCP, as reasonable, appropriate, and allowable under State law and regulation.''

Response: In accordance with the PACE Protocol, the regulation requires participation of a physician. Physician is defined in the Medicare program to mean a doctor of medicine or osteopathy as recognized in section 1101(a)(7) of the Act. As a result, there must a PCP on the IDT. The regulation does not prevent the participation on the IDT of NPs or PAs acting in collaboration with the physician and within their scope of practice. However, NPs and PAs may participate on the IDT in addition to the PCP, but may not replace the PCP.

We acknowledge the dedicated service and quality care provided by NPs and PAs to PACE participants, but we do not believe that addition of a specific role description for NPs or PAs in the regulatory language in § 460.102 would provide any additional flexibility to the POs in establishing their IDTs.

Comment: We received three comments related to the requirement for an RN on the IDT. One commenter supported the regulation requiring an RN as opposed to a nurse on the IDT. Another commenter supported flexibility depending on the composition of the team. Another commenter requested the roles of the NP and the clinical nurse specialist (CNS) be consistent with established CMS rules and regulations.

Response: We believe the term ''registered nurse'' is a more clear and definitive title than ''nurse'' and have therefore specified that the IDT must include a registered nurse. We believe that the IDT membership should include an RN, but that does not imply that the PO cannot utilize licensed practical nurses, NPs, or CNSs in other direct care positions acting in collaboration with the physician and within their scope of practice. This approach is consistent with established CMS rules and regulations.

Comment: Several commenters requested that the requirements for the social worker be consistent with those contained in the nursing home regulations with the additional requirement that each PO employ or

contract with at least one Master's level social worker (MSW).

One commenter recommended an alternative to a Master's degree in social work. They recommended that social workers hold a Baccalaureate degree in social work or in a human services field and 1 year of supervised social work experience in a health setting working directly with individuals.

Response: We agree with the commenter and note that a Baccalaureate degree in social work does not include the training in social counseling that is required for a Master's in social worker. Therefore, to clarify the position and responsibilities of the social worker on the IDT, we are amending § 460.102(b)(3) to require a MSW be part of the IDT, rather than a ''social worker.'' In the 1999 interim final rule, § 460.64(c)(2) listed the personnel qualification for a social worker, which included having a Master's degree in social work from an accredited school of social work. In this final rule, we have removed § 460.64(c)(2). We are requiring a MSW on each IDT to establish the social work plan of care and to provide counseling services. The MSW may participate on several teams, perform assessments, reassessments, care planning, and counseling consistent with their education and training. For consistency we are also reviewing § 460.104(a)(2)(iii) and § 460.104(c)(1)(iii), to refer to a Master's-level social worker to perform assessments and reassessments.

Therefore, in § 460.64, we are deleting the specific educational and experience qualifications for social workers as all States require licensure, certification, or registration of social workers as well as qualifications for MSWs. The PO may contract with other MSWs to augment their staffing levels to ensure all participants receive the counseling services provided by MSWs. The PO may employ or contract with Baccalaureate social workers to provide services within their scope of practice.

Comment: A commenter requested that we clarify the terms ''Personal care attendant or his or her representative'' and ''Driver or his or her representative'' in relation to composition of the IDT.

Response: We expect the driver and PCA to be members of the team but understand that a representative may attend morning meetings. Most POs conduct morning IDT meetings during the time when PCAs are actively engaged in morning caring at the PACE center or participants' residences and drivers are engaged in the transporting participants to the PACE center. Therefore, neither the PCA nor the driver are available to attend these IDT meetings. However, we believe these staff are often in a position to provide important details about the participants' physical and emotional condition and changes in their home environment. Information from these IDT members can be relayed through a representative, such as the PACE center manager, home care coordinator, transportation coordinator, RN, social worker, a supervisor, designated colleague, or other IDT member. Therefore, we included representatives of PCAs and drivers in § 460.102(b).

Comment: We received several requests to modify the rule to include the following positions on the IDT: qualified occupational therapy assistants (OTAs), Licensed Practical Nurses (LPNs), certified occupational therapy assistants (COTAs), and Baccalaureate-level social workers (BSWs).

Response: We believe LPNs, OTAs COTAs, and BSWs, provide dedicated quality care to PACE participants and are essential to the operation of POs. However, as we noted above, our current regulations provide ample opportunity for the POs to involve personnel with these educational qualifications in providing the best possible PACE services, without necessarily including them as part of the IDT. We do not think revising our regulation is necessary.

Comment: One commenter recommended that we include an RT on the IDT, stating the statute provides flexibility for the PO to include additional services.

Response: Composition of the IDT was based on the Protocol, which did not include respiratory therapy. However, our regulations do not prevent the inclusion of these professionals. The extent to which POs routinely include respiratory therapists on their IDT will be based on their participants' medical conditions. The IDT is required to involve any discipline necessary to treat the participant's individual needs, which includes assessment, collaboration during the development of the plan of care, and providing treatment.

Final rule actions:

In this final rule we are changing the term ''social worker'' to ''Master's-level social worker'' consistent with our changes to § 460.64.

Section 460.104 Participant Assessment

The information obtained through the participant assessment is the basis for the plan of care developed by the IDT. As such, it is important that the assessment be as comprehensive as possible in order to capture all of the information necessary for the IDT to develop a plan of care that will adequately address all of the participant's functional, psychosocial, and health care needs.

The assessment process begins before enrollment, as set forth in § 460.152, when the PO evaluates whether a potential participant can be cared for appropriately in the program. Often, POs present a proposed plan of care to the potential participant as part of the enrollment process. The initial comprehensive assessment must be completed promptly following enrollment, but individual team members' in-person assessment of the participant should be scheduled at appropriate intervals based on the participant's level of health. Because the initial assessments are thorough, this will ensure that the participant is not overwhelmed with several team members conducting assessments at one time. However, the initial comprehensive assessment must be completed quickly so that the plan of care can be completed and implemented without delay. This often is accomplished by the effective date of enrollment and should never be delayed more than a few days beyond that date. With the team concept, the goal is to obtain input from each discipline, as well as from the participant, through comprehensive assessment that identifies the services necessary to address the participant's needs and care preferences.

Section 460.104(a) requires that as part of the initial comprehensive assessment, each of the following members of the IDT must individually evaluate the participant in person and develop a discipline-specific assessment of the participant's health and social status:

- Primary care physician;
- Registered nurse;
- Social worker;
- Physical therapist or occupational therapist, or both;
- Recreational therapist or activity coordinator;
- Dietitian; and
- Home care coordinator.

We believe the specified IDT members represent the core disciplines needed to determine the specific treatment and psychosocial development needs of the participants. At the recommendation of individual team members, other professional disciplines (for example, speech-language pathologists, dentists, or audiologists) may participate in the initial comprehensive assessment if the participant's needs warrant their inclusion.

In the 1999 interim final rule, we stated that we were in the preliminary stages of developing a standardized core assessment instrument, the COCOA–B, to be used by POs for outcome-based continuous quality improvement. Until such time as this instrument was completed, we specified in § 460.104(a)(4) that the participant's assessment must include, at a minimum, the following information:

- Physical and cognitive function and ability;
- Medication use;
- Participant and caregiver preferences for treatment;
- Socialization and availability of family support;
- Current health status and treatment needs;
- Nutritional status;
- Home environment, including home access and egress;
- Participant behavior;
- Psychosocial status;
- Medical and dental status; and
- Participant language.

We believed that this information would provide a basic framework from which a comprehensive plan of care could be developed, would be appropriate for every participant, and would ensure that the plan of care focused on the participant's medical, psychosocial, and functional needs. However, this list represented the minimum information to be included in the comprehensive assessment, and the PO was encouraged to include other assessment items as necessary.

Although a core assessment instrument has been developed, since the publication of the 1999 interim final rule, our experience with the PACE program has led us to having some misgivings about its long term application. Given the need for flexibility for POs, we are concerned that specifically mandated measures may compromise the discretion of POs to use other assessment tools that may be more appropriate for their settings.

Therefore, we are not inclined to replace the information requirements contained in § 460.104(a)(4) with a specific standardized core assessment instrument. In time, we expect that POs will become more familiar with using the quality assessment and performance indicators that are contained in § 460.134 (physiological well being, functional status, cognitive ability, social/behavioral functioning, and quality of life) as a framework for participant assessments. At this time, we are finalizing the information listed in § 460.104(a)(4) as the required information POs must obtain as part of a comprehensive assessment.

The Protocol requires that the discipline-specific plans be consolidated into a single plan of care for the participant. The development of the plan of care must occur through discussion and consensus of the entire IDT. We established this requirement in § 460.104(b) by stating that the discussion must take place during team meetings, in order to facilitate group discussion of the plan of care and ensure that all members of the team are actively involved in the decision-making process, and that the plan of care must be completed promptly.

In developing the plan of care, the PACE IDT is also required by § 460.104(b) to inform female participants that they are entitled to choose a women's health specialist from the network of PACE providers. We have included this requirement to ensure compliance with the Consumer's Bill of Rights and Responsibilities (CBRR), as explained in detail in the preamble of the 1999 interim final rule.

Reassessments are necessary to provide information to adjust participants' plans of care. Periodic reassessments ensure the continued accuracy and effectiveness of the participant's plan of care. Consistent with the Protocol, we require in paragraph (c) that the following members of the IDT conduct an in-person reassessment on at least a semi-annual basis:

- Primary care physician;
- Registered nurse;
- Social worker;
- Recreational therapist or activity coordinator; and
- Other team members actively involved in the development or implementation of the participant's plan of care, for example, home care coordinator, physical therapist, occupational therapist, or dietitian.

The primary care physician, registered nurse, social worker, and recreational therapist/activity coordinator are required to perform assessments at least semiannually as they are the most critical in terms of defining outcomes of care. Other team members actively involved in the participant's plan of care must also reassess semiannually, as they have an impact on the care the participant is receiving. However, if the participant is not receiving certain services (such as home care, physical therapy, occupational therapy, dietitian services), these members of the team would not be required to conduct a semi-annual assessment for that participant.

Consistent with the Protocol, we require the following members of the IDT to conduct an in-person reassessment on at least an annual basis:

- Physical therapist and/or occupational therapist;
- Dietitian; and
- Home care coordinator.

It is important for the IDT to monitor and respond to any changes in a participant's condition or family situation or any concerns raised by the participant or his or her designated representative. The Protocol requires that the participant be reassessed by the team or by selected members of the team to develop a new plan of care when the health status or psychosocial situation of a participant changes. We believe that all members of the IDT that are required to perform the initial comprehensive assessment should reassess the participant because if fewer members participate in this reassessment, a critical component of a participant's care might be overlooked.

In addition, paragraph (c)(3) requires that if a participant's health or psychosocial status has changed or if a participant (or his or her designated representative) believes that a particular service needs to be initiated, continued, or eliminated, the appropriate IDT members must reassess the participant. The purpose of this reassessment is to evaluate whether it is necessary to increase, continue, reduce, or terminate particular services and whether a different course of treatment is needed. A complete reassessment should ensure that the participant is receiving a continuing program of care that meets his or her current needs. Requiring a reassessment based on the concerns of the participant emphasizes the active role the participant plays in the assessment process and development of his or her plan of care. The participant's adherence to the plan is critical to the successful delivery of services. Therefore, permitting the participant (or designated representative) to trigger a reassessment gives participants the opportunity to express any dissatisfaction with the manner in which care or services are furnished.

We believe the requirements in § 460.104(c)(3) are appropriate, but in this final rule, we wish to clarify that not all changes in health or psychosocial status require reassessment by the entire IDT. We are allowing the PO the flexibility to determine the appropriate staff to reassess changes that are not significant. We continue to believe that significant changes in health or psychosocial status require the in-person reassessment by the IDT members identified in § 460.104(a)(2).

Section 460.104(c)(3) also requires the PO to have explicit procedures for timely resolution of requests from participants (or their authorized representatives) to initiate, continue, or terminate a particular service. Unless an extension is granted, the IDT must notify the participant (or designated representative) of its decision to approve or deny the request as expeditiously as the participant's condition requires, but no later than 72 hours after the IDT receives the request. We considered establishing both a standard process and an expedited process for responding to participant requests; however, because of the frailty of this population, we concluded that every request is urgent and requires a quick response. We want to ensure that a participant's health is not adversely affected due to a delay in reassessing the participant's condition. The goal of the program is to maximize the participant's functioning, and a quick response is meant to ensure that all factors are evaluated, all necessary services are being furnished, and participant health is not compromised. A timely notification also allows participants adequate time to consider appeal rights, if necessary, without compromising their health.

The IDT may extend the 72-hour timeframe by no more than 5 additional days if the participant or designated representative requests the extension, or if the team documents its need for additional information and how the delay is in the interest of the participant. An extension may be warranted because not all of the appropriate members of the IDT may always be able to meet with the participant, conduct a discipline-specific reassessment, discuss the results of the reassessment with the entire IDT, and develop a response to the request within 72 hours. The PO retains the flexibility to determine the most appropriate manner in which to provide notification to the participant (or designated representative).

If, based on the reassessment, the IDT decides to deny the participant's request, the denial must be explained to the participant (or designated representative) orally and in writing. The PO must provide the specific reasons for the denial in understandable language.

If the participant (or designated representative) is dissatisfied with the outcome of the reassessment, the participant may appeal the decision in accordance with. § 460.122. Specifically, the PO must: (1) Inform the participant or designated representative of his or her right to appeal the decision; (2) describe both the standard and expedited appeals processes, including the right to and conditions for obtaining an expedited appeal of a denial of services; and (3) describe the right to and conditions for continuation of contested services through the period of the appeal.

If the IDT fails to provide the participant with timely notice of the resolution of the request for reassessment or does not furnish the services required by the revised plan of care, this failure constitutes an adverse decision, and the participant's request must be automatically processed as an appeal by the PO in accordance with § 460.122.

Team members who reassess a participant must reevaluate the plan of care. Any changes in the plan of care must be discussed and approved by the IDT and the participant (or designated representative). The plan of care reflects the team's and participant's goals for the participant's care. Obtaining the participant's approval of the proposed plan of care is important to the successful delivery of services and the participant's adherence to the plan.

In addition, we also require that any services included in the revised plan of care as a result of a reassessment must be furnished to the participant as expeditiously as the participant's health condition requires. It is critical that care not be delayed and that the participant receive comprehensive care that maintains his or her functional status. Because we recognize that some changes in the participant's plan of care (for example, installing a wheelchair ramp at the participant's home) may require more time to accomplish, we chose not to specify a timeframe for delivering services. However, we solicited comments on the necessity of requiring a specific timeframe. Whenever a participant assessment or reassessment occurs, the information must be documented in the participant's medical record.

Comment: Two commenters requested confirmation that the requirements for the initial comprehensive assessment in § 460.104(a) were not intended to govern the practice of assessment before enrollment or to prescribe which IDT members must conduct assessments before enrollment for purposes of determining whether the individual's needs can safely be met through the PACE program. One commenter requested clarification that the regulation requires that a complete assessment by the full team take place after enrollment. This commenter also asked which members of the team must have conducted assessments before enrollment.

Response: The assessment process begins before enrollment when the PO evaluates a potential participant to determine if they can be cared for appropriately in the community by the PACE program. We do not dictate the disciplines that must perform this assessment; we leave that to the discretion of the PO. The remainder of the initial comprehensive assessment can be performed before the enrollment agreement is signed or the PO can decide to wait until after the enrollment agreement is signed. The only requirement is that the assessment be completed as soon as possible after enrollment so the plan of care can be implemented after the effective date of enrollment with as little delay as possible.

As specified in § 460.104(a)(2), the initial comprehensive assessment must be performed by the following disciplines:

- Primary care physician.
- Registered nurse.
- Social worker.
- Physical therapist.
- Occupational therapist.
- Recreational therapist or activity coordinator.
- Dietitian.
- Home care coordinator, and any other professional discipline the IDT recommends be included in the comprehensive assessment process.

We believe these requirements reflect the current intake, assessment, and enrollment practices of POs. In the discussion regarding 460.102, we clarified that a MSW is a required discipline on the IDT. In order to be consistent with 460.102, we are amending 460.104(a)(2)(iii) and 460.104(c)(1)(iii) to clarify that a MSW performs assessments and reassessments.

Comment: One commenter supported the assessment and reassessment requirements but proposed a modification to § 460.104(a)(2)(i) and § 460.104(c)(1)(i) by adding ''or a nurse practitioner/physician assistant working in collaboration with a PACE PCP, as reasonable, appropriate, and allowable under State law and regulation.''

Response: We believe that the physician should perform the initial comprehensive assessment and semiannual reassessments, because these assessments are the foundation of the participant's plan of care. The NP role is an adjunct position, supportive of the physician when conducted within the NP's scope of practice and as allowable under State law. Therefore,

we are not modifying the regulatory language.

Comment: One commenter requested the requirements in § 460.104(a)(2)(iv) and § 460.104(c)(2)(i) which state, ''Physical therapist or occupational therapist or both,'' be changed to designate these disciplines into separate sections. The commenter pointed out that these disciplines are not interchangeable and both OTs and PTs should be required to participate in the initial comprehensive assessment and annual re-assessment.

Response: After reviewing the comments, we agree that PTs and OTs both needed to participate in the initial assessment and annual reassessments. Therefore, we are revising § 460.104(a)(2)(iv) and § 460.104(c)(2)(i) to require a PT and an OT to perform initial comprehensive assessments and the annual reassessments.

Comment: Two commenters requested clarification on the delivery of gynecological (GYN) services. One commenter asked whether the PO could limit GYN services to providers in their network and, if so, whether there was an assumption that the PO must have more than one GYN specialist under contract.

The other commenter requested clarification of which health professionals would meet our definition of ''qualified specialist for women's health services.'' They questioned whether PCPs would be acceptable due to the time commitment required by the geriatric and cognitive deficits of many participants. The commenter questioned whether adequate GYN services would be available to PACE participants with contracted specialists and recommended the elimination of the regulatory requirement.

Response: We first want to clarify that the PO must provide access to all specialties within its network and participants are required to receive all services through the PO. The CBRR guarantees participants the choice of providers as well as the right of female participants to choose a qualified specialist in woman's health. Therefore, we expect that when possible the PO will contract with more than one provider of gynecological services.

In response to whether the PCP is a qualified specialist for women's health services, a PCP is qualified to perform primary care including basic GYN services, but the PCP is not a ''qualified specialist for women's health services.'' Although female participants may choose their PCP for basic GYN services, if a participant requests a GYN specialist or the participant requires more complex GYN services, the participant must be provided a GYN specialist and, when possible, be provided a choice of GYN specialists.

Accordingly, we are retaining the requirement to provide participants a choice to use a woman's health specialist, consistent with the CBRR protections we adopted in the 1999 interim final rule.

Comment: The majority of commenters on this section disagreed with the regulatory language related to how to accomplish, when to perform, and who must conduct the periodic reassessments required by § 460.104(c). Recommendations ranged from deleting various requirements to requests to provide POs the flexibility over the timing and scope of reassessments. Commenters also provided proposed language changes, including some that are consistent with the Protocol.

Several commenters requested clarification of whether all team members must perform reassessments or whether only relevant team members may perform reassessments.

Response: In response to the numerous comments related to the reassessment requirements, we want to confirm that we believe that the disciplines designated in the 1999 interim final rule at § 460.104(c) are the minimum disciplines required to perform reassessments. We also expect that, should the results of the reassessments raise further issues related to other disciplines, reassessments by additional disciplines must be conducted and included in the development of the comprehensive plan of care.

In contrast, the initial comprehensive assessment must be conducted by those disciplines listed in § 460.104(a)(2), and any other professional disciplines recommended by the IDT. The results of the discipline specific assessments must be consolidated into a single comprehensive plan of care.

Again as specified in our regulation, periodic reassessments must be conducted as follows;

- At least semi-annually, and more frequently if the participant's condition dictates, by the PCP, RN, MSW, recreational therapist or activity coordinator, and other appropriate members of the IDT that are actively engaged in the development or implementation of the participant's plan of care.
- At least annually the PT, OT, dietitian, and home care coordinator must conduct in-person reassessments.

Comment: Numerous commenters remarked on the provision requiring reassessment based on change in participant status or at the request of the participant or his or her designated representative. Several commenters suggested the reassessments initiated by the PO based on changes in health status be differentiated from those requested by the participant.

Many commenters suggested that the requirement that a formal reassessment be conducted based on a change in participant health status be limited to a ''significant change.'' These commenters also suggested including a definition more consistent with the definition contained in nursing home regulations where ''a ''significant change'' means ''a major decline or improvement in the participant's status that will not normally resolve itself without further intervention by staff or by implementing standard disease related clinical interventions, that has an impact on more than one area of the participant's health status, and requires an IDT review or revision of the care plan or both.'' Another commenter recommended that we provide POs the same discretion as the nursing home regulations afford nursing homes, to determine whether and to what extent a reassessment or a change in the plan of care, or both, are necessary. Other commenters recommended that if a non-significant change occurs, the reassessment may be conducted by the discipline impacted.

One commenter recommended that this requirement be eliminated, particularly when there is agreement between the IDT and the participant or his or her designated representative.

One commenter suggested that we require the PO to have a defined process for responding to participant requests, which includes assigning appropriate team members to the reassessment.

Response: Due to the fragility of the PACE population, we do not believe it would be prudent to restrict the requirement at § 460.104(c)(3) by limiting reassessments to significant changes in participant health status. The philosophy of PACE requires the staff to be cognizant of any and all changes in participant health status so that they can take a proactive approach to the care of this frail and vulnerable population and prevent development of a major problem. We believe the suggested changes would compromise the integrity of the PACE philosophy.

Moreover, individuals that do not participate in the PACE program and reside in a NF will generally be less independent and mobile. In addition, as they reside in a more restricted environment under constant observation by staff, residents of NFs need less formally defined IDT reassessment requirements. These individuals do not require evaluation of home health or

transportation issues and generally receive more limited PT and OT services than community dwelling PACE participants. For these reasons, we believe that the requests for consistency with NF requirements is inappropriate.

PACE is based on the collaborative relationship between the participant and the PO. We believe it is in the best interest of both the participant and the PO to conduct a reassessment when there is a request for a specific service regardless of whether or not the participant and the PO agree. The reassessment might uncover other issues not previously detected.

In response to comments, we are revising § 460.104(c)(3) by renaming paragraph (c)(3) as paragraph (d) Unscheduled reassessments. We are separating the requirements for reassessments based on a change in participant status in paragraph (d)(1) from those performed at the request of the participant or designated representative in paragraph (d)(2). We are amending the requirements to require the IDT members listed in paragraph (a)(2) to perform in-person reassessments for change in participant status while permitting the IDT the flexibility to determine the appropriate IDT members when the assessment is performed at the request of a participant or his or her representative.

Comment: There was strong disagreement by one commenter regarding the PO's responsibility to inform participants about the appeal process if they are dissatisfied with a determination. The commenter stated the PO should provide appeal information with all written denials, reductions, and terminations of services or changes in the plan of care.

Response: The requirement for written notification of the PO's appeal process is discussed in § 460.122 under Subpart G, Participant rights. This section states, among other things, that participants are provided with written materials on the appeal process upon enrollment and annually thereafter and whenever there is a denial of a request for services. Denial of services includes denial, continuation, or termination of a requested service. The provisions for reassessment at the request of a participant was intended to serve as the first stage of the appeals process.

Comment: In the 1999 interim final rule, we solicited comments on whether to impose a timeframe under which POs must initiate changes in services after a revision to a participant's plan of care. Comments varied and included the following, while some commenters agreed with the existing requirement that services be furnished to the participant as expeditiously as the participant's health condition requires; others indicated that the timeframe should be left to the discretion of the PO. Those commenters stated that specifying a timeframe for service delivery merely adds a layer of regulation and oversight that in all likelihood will not be necessary. Of the comments supporting a specific timeframe, some commenters urged us to set a maximum timeframe of no more than 5 days for initiating service delivery following an approved change in the plan of care plan and permit the timeframe to be waived in specific situations. Other commenters recommended that any individualized timeframes be specified in the participant's plan of care.

Response: In response to the varied and different comments received in response to our solicitation for comment on timeframes for delivering services, we believe further consideration of this issue is needed before adopting a specific timeframe. Accordingly, we are retaining the requirement as published in the 1999 interim final rule which requires the PO to implement changes in a participant's plan of care expeditiously as the participant's health condition requires.

Final rule actions:

In this final rule, we are:

- Amending § 460.104(a)(2)(iv) and § 460.104(c)(2)(i) to require that both the PT and OT perform the initial comprehensive assessment and annual reassessments.
- Amending § 460.104(a)(2)(iii) and 460.104(c)(1)(iii) changing social worker to Master's-level social worker.
- Redesignating paragraph (c)(3) as paragraph (d) titled ''Unscheduled reassessments'' to permit the IDT the discretion to determine the disciplines necessary to perform reassessments that are requested by a participant or his or her representative.

Section 460.106 Plan of Care

Based on Part IV, section B of the Protocol, we developed requirements for the participant's plan of care. In § 460.106(a), we require that the IDT promptly develop a comprehensive plan of care that specifies all care needed to meet the participant's medical, physical, emotional, and social needs, as identified in the initial comprehensive assessment. As required by paragraph (b), the plan of care must identify measurable outcomes to be achieved and must be developed in collaboration with the participant and his or her caregiver. The specified outcomes need not be discipline-specific. Instead, these are team goals for the participant's care. Involving the participant in the plan of care is important to the successful delivery of services and the participant's adherence to the plan.

In paragraph (c), we require the team to implement, coordinate, and monitor the plan of care by providing services directly and by supervising the delivery of services furnished by contract providers. The participant's health and psychosocial status, as well as the effectiveness of the plan of care, must be monitored continuously throughout the provision of services, informal observation, input from participants and caregivers, and communications among members of the IDT and other providers.

In paragraph (d), we require that, on at least a semiannual basis, the IDT must reevaluate the participant's plan of care, including the defined outcomes, and make changes as necessary.

Semiannual review of the participant's plan of care ensures that the needs of the participant are being met. It allows the team to determine whether the participant's level of health has changed enough to warrant a change in the level of services or even the setting in which care is provided.

In paragraph (e), we require that participant plans of care be developed, reviewed, and reevaluated in collaboration with the participants or caregivers. The purpose of participant/caregiver involvement is to assure that they approve of the care plan and that participant concerns are addressed. We give POs the flexibility to determine how often care plans should be reviewed with the participant.

In paragraph (f), we require that the participant's plan of care and any changes in the plan must be documented in the participant's medical record.

Comment: We received several comments related to participant involvement in their plan of care. One commenter stated that the participant should always be included in the development of the plan of care to the extent possible and desired, but that use of the term ''or'' in ''participant or caregiver'' suggests that the team may elect not to involve the participant in the development of his or her plan of care.

Another commenter suggested we include a provision to provide for a more negotiated plan of care process incorporating discussion with the participant as part of the process.

Two respondents suggested that the participant and/or his or her representative be given the opportunity to review the plan of care at the time of the official review (semiannually), when

the plan requires significant revision and upon a request of the participant.

Response: It is our expectation that the IDT will include the participant in the plan of care development when possible and include the participant's representative when it is not appropriate to include the participant or at the instruction of the participant.

We believe that the current requirements in § 460.106 provide sufficiently for the inclusion of the participant, or the participant's representative, in the plan of care development.

Comment: One commenter requested we provide some samples of what CMS considers measurable outcomes that could be included in the plan of care.

Response: Some examples of measurable outcome measures that would be specific to an individual plan of care include the following:

- Participant will receive yearly flu shot.
- Participant will gain and maintain 1 pound each 2 week period until weight achieves 100 pounds.
- Participant will be instructed in blood sugar testing. Within 1 week, the participant will able to explain and demonstrate the use of the glucometer and recording of the results.

Final rule actions:

This final rule will finalize § 460.106 as published in the 1999 interim final rule.

Subpart G—Participant Rights

The purpose of subpart G is to establish requirements for patient rights and protections that POs must include in their program agreements and provide to PACE participants.

In accordance with sections 1894(b)(2)(B) and 1934(b)(2)(B) of the Act, the PACE program agreement requires the PO to have in effect, ''written safeguards of the rights of enrolled participants (including a patient bill of rights and procedures for grievances and appeals) in accordance with regulations and with other requirements of this title and Federal and State law that are designed for the protection of patients.'' In addition, sections 1894(f)(3) and 1934(f)(3) of the Act allow CMS the discretion to apply the requirements of Part C of title XVIII and sections 1903(m) of the Act and 1932 of the Act relating to the protection of beneficiaries and program integrity as would apply to M+C (now MA) organizations under Part C and to Medicaid managed care organizations under prepaid capitation agreements under section 1903(m) of the Act. Moreover, sections 1894(f)(2) and 1934(f)(2) of the Act require us to incorporate the requirements in the Protocol which includes a patient bill of rights.

In addition, we made every effort to assure that the rights and protections established in the PACE program agreement are in substantial compliance with the Presidential Advisory Commission's (The Commission) Consumer Bill of Rights and Responsibilities (CBRR), which appeared as an addendum to The Commission's Final Report to the President, entitled ''Quality First: Better Health Care for All Americans'' (March 1998). The President issued an Executive Memorandum to the Secretary of the Department of Health and Human Services dated February 20, 1998, which required that, by December 31, 1999, Medicare and Medicaid health care programs be brought into substantial compliance with the CBRR. The PACE program is included within that framework.

As we explained in the 1999 interim final rule, in considering how to apply these patient protections, the statute requires that we take into account the differences between the populations served and benefits provided under PACE, MA, and Medicaid managed care. We believe that the PACE program is unique in its approach to meeting the needs of the frail elderly. Unlike most managed care organizations which are responsible for meeting health care needs alone, the PACE program is an integrated partnership between the individual, the community, and the PO, which is dedicated to providing all-inclusive care to meet all medical and social needs to enable the participant to remain in the community.

We believe it is important to establish participant rights that reflect the differences in the PACE delivery approach from that of other managed care systems. For example, since PACE participants receive services most days of the week, either at the PACE center or through home visits, POs are able to monitor changes in a participant's medical condition and social service needs on a daily basis. When PACE participants are referred to contracted specialists, in most cases, the PO makes the appointment, provides transportation, and often provides an aide or other staff member to accompany the participant. While managed care organizations may provide this level of care management to some enrollees, POs do so routinely for their entire participant census. Also, while managed care organizations furnish a selected array of medical services, they do not furnish all-inclusive care, including social and recreational services intended to enhance participants' quality of life.

To reiterate the philosophy set forth in the Protocol, the PO furnishes comprehensive services designed to: (1) Enhance the quality of life and autonomy for frail, older adults; (2) maximize dignity and respect of older adults; (3) enable frail, older adults to live in their homes and in the community as long as medically and socially feasible; and (4) preserve and support the older adult's family unit. The bill of rights for PACE participants must complement and maintain this philosophy. In the 1999 interim final rule, we relied on the Protocol and incorporated the basic rights that it identifies. However, we were also guided by the M+C regulations in effect at that time and by the CBRR.

The statute also directs us to consider State law. We interpreted this to mean that a PO's participant bill of rights may include additional rights and protections as required by State or local laws and regulations or ethical considerations of particular concern, but only if these additions or modifications provide stronger rights and protections than those established in the 1999 interim final rule. Consistent with the Protocol and the CBRR, we included a provision allowing participants to choose to be represented by family members, caregivers, or other representatives. We intend that a participant may designate a representative to exercise any or all of the rights to which the participant is entitled.

In addition, we require, as did the Protocol, the PO to provide encouragement and assistance to participants in understanding and exercising their rights and in recommending changes in PACE policies and services.

In the discussion on consultations with the State Administration on Aging in section I.B.2.c. of this final rule, we referred to the State Long Term Care Ombudsman Programs. These State programs promote and monitor the quality of care in nursing homes, including identifying and resolving complaints, making regular visits to nursing homes, and generally, improving the quality of care and quality of life of nursing home residents. The role of the ombudsman is to engage in a variety of activities designed to encompass both active advocacy and representation of residents' interests. In the 1999 interim final rule, we specifically requested public comment on whether the ombudsman program could play a role in consumer assistance to potential PACE participants, as well

as to those who have disenrolled and need assistance in organizing their care. With regard to PACE participants, we were also interested in receiving public input as to whether an ombudsman could provide one-on-one consumer assistance to PACE participants and their caregivers to exercise their rights and work effectively with the IDT.

We received a very large number of comments related to participant rights.

Comment: We received 10 comments responding to our request for input regarding whether to require the use of the State Ombudsman Programs as advocates for PACE participants, prospective participants, and disenrolled PACE participants, and to monitor the quality of care provided to PACE participants. The comments related to this request varied. Some commenters recommended that the State Ombudsman Program be extended to cover PACE participants as a natural and appropriate expansion of the ombudsman program. However, the majority of commenters recommended leaving the option to State discretion rather than mandating it in regulation. The primary concern was the limited resources available to State's ombudsman programs. Commenters recommended that should the ombudsman role be expanded to include PACE, CMS should provide the appropriate funding. Other commenters indicated concerns related to funding for training and funding for pilot programs to test the efficacy of the ombudsman program in relation to PACE.

Response: We agree with the majority of commenters who recommended that CMS not mandate the use of the State Ombudsman Program for PACE. We acknowledge the limited resources available to the ombudsman program and agree that utilization of these resources is best left to the States' discretion. Additionally, our experience with the program to date indicates that the PACE grievance and appeal processes are working effectively to resolve participant concerns. We, therefore, are not revising our regulations at subpart G to mandate the use of the State Ombudsman Program for PACE.

Section 460.110 Bill of Rights

In § 460.110, we require a PO to have a written participant bill of rights that is designed to protect and promote the rights of each participant. The organization is required to inform participants upon enrollment, in writing, of their rights and responsibilities, and all rules and regulations governing participation in PACE. In addition, the organization must protect participants' rights and provide for the exercise of those rights.

Comment: Numerous commenters supported the requirement for a written participant bill of rights, and rights published in the 1999 interim final rule.

Response: We appreciate the commenters' support of the participant bill of rights, as we believe in the importance of participant rights and the protection they provide participants.

Final rule actions:

This final rule will finalize § 460.110 as published in the 1999 interim final rule.

Section 460.112 Specific Rights to Which a Participant Is Entitled

Section 460.112(a) Respect and Nondiscrimination

Right #1—

Each participant has the right to considerate, respectful care from all PACE employees and contractors at all times and under all circumstances. Each participant has the right not to be discriminated against in the delivery of required PACE services based on race, ethnicity, national origin, religion, sex, age, mental or physical disability, or source of payment.

The individual's right to respect and nondiscrimination is embedded in the basic philosophy of the PACE program. In keeping with the PACE model, we recognize the participant's right to receive comprehensive care in a safe and clean environment and in an accessible manner. The Protocol states that a PACE participant must receive treatment and rehabilitative services. We expanded this requirement to state that the participant has a right to receive comprehensive health care.

The Protocol stipulates that the participant has the right to have dignity, privacy, and humane care. We require the PO to treat the participant with dignity and respect, to afford the participant privacy and confidentiality in all aspects of care, and to provide humane care. The PO must assure that a participant's dignity and privacy are respected not only in its own facilities but also in affiliated or contract providers. Staff should be instructed that any discussions with participants regarding treatment, the participant care plan, and medical conditions should be held in private and kept confidential. While recognizing the participant's right to privacy and confidentiality, we do not advocate physical barriers because participants should be in the view of the staff at all times to ensure safety. However, in situations where there is participant body exposure during treatment, the staff should be instructed to provide temporary screens or curtains.

We adopted from the Protocol the right to be free from harm, including physical or mental abuse, neglect, corporal punishment, involuntary seclusion, excessive medication, and any physical or chemical restraints imposed for purposes of discipline or convenience and not required to treat the participant's medical symptoms. The use of restraints must be based on the assessed needs of the patient, be monitored and reassessed appropriately, and be ordered for a defined and limited period of time. The least restrictive and most effective method available must be utilized and it must conform to the patient's plan of care. Restraints may only be used as a last resort and must be removed or ended at the earliest possible time. We do not believe that restraints of any kind should ever be used as a preferred approach to care and we expect PACE organizations to ensure that their programs are ''restraint free'' to the greatest extent possible. Specific requirements regarding the use of restraint are established in § 460.114.

We adopted the rights established in the Protocol to encourage and assist the participant to exercise his or her rights, including the Medicare and Medicaid appeals processes as well as civil and legal rights. Participants are encouraged and assisted in recommending changes to PO policies and services. We also maintained the right to have reasonable access to a telephone. However, we altered the right established in the Protocol not to be required to perform services for the organization unless the services are included for therapeutic purposes in the plan of care. As we explained in the 1999 interim final rule, we do not believe that a therapeutic program should be tied to performing services for the PO.

The CBRR specifies that organizations should not discriminate on the basis of race, ethnicity, national origin, religion, sex, age, mental or physical disability, or source of payment. POs are required to comply with all Federal, State, and local laws, including discrimination statutes with regard to marketing, enrollment, and provision of services. However, we recognize that, with regard to health status considerations, POs are required as part of the intake process to assess whether a potential participant is appropriate for PACE, that is, meets the State's nursing facility eligibility standard and can be safely cared for in the community. Meeting required certification standards within the PACE context is not deemed a violation of antidiscrimination laws. However, in

order to ensure that the qualification decision is free from other, illegal forms of discrimination, we require POs to retain information on individuals who are assessed but, for whatever reason, are not enrolled.

Comment: One commenter requested that we broaden the list of demographic categories under which the PO cannot discriminate against a PACE participant to specifically include sexual orientation.

Response: We agree with the commenter that the list of demographic categories under which the PO cannot discriminate against a PACE participant should be broadened to specifically include sexual orientation. As discussed in § 460.98(b)(3), we do not believe anyone should be denied enrollment in PACE because of discrimination of any kind. Therefore, in this final rule we are amending the antidiscrimination requirement in § 460.112(a) to include sexual orientation.

Comment: Several commenters asked to what extent the PO is responsible for meeting the following assurances for an enrollee at home:

- Receiving health care in a safe and clean environment and in an accessible manner; and
- To be afforded privacy; to be free from harm, including physical or mental abuse, neglect, punishment, involuntary seclusion, excessive medication, and any physical or chemical restraints imposed for purposes of discipline or convenience and not required to treat the participant's medical symptoms.

Response: In accordance with section 1894(f)(2)(B)(v) of the Act, we may not grant a waiver of the requirement that the PO is at full financial risk and is responsible for the health and safety of the enrolled participants. In accordance with § 460.180(b), the monthly capitation amount is payment in full regardless of a change in health status, and a PO must not seek additional payment except for the limited exceptions specified in § 460.180(b)(7). We expect that locations which furnish medical care to maintain a standard of cleanliness and safety (for example, no bodily fluids on the floors, no broken plumbing, no exposed wires or broken windows). This requirement was specifically aimed at the facilities providing PACE services. However, should the IDT determine and include in the participant's plan of care that assistance is required in the home, then home care would become a required service, subject to the safety and cleanliness requirements of § 460.112. With regard to privacy, consistent with standards of practice, we expect that PO staff and contractors to furnish services in the home in a manner that respects the participant's privacy.

The requirement to be free from harm relates primarily to the behavior of and treatment by the PACE staff and contractors to the participant. However, if PACE staff or contractors identify that the participant is being abused or harmed by a family member or other caregiver, they are obligated to report this abuse to the appropriate authorities, and if acceptable to the participant, may assist the participant in acquiring new living accommodations, or otherwise resolving the abusive situation.

Comment: Another commenter asked if the right to reasonable access to a telephone means the PO is financially responsible for a participant's personal telephone bills.

Response: This requirement was not intended to make the PO financially responsible for the participant's personal telephone bill. Should the IDT determine a telephone is necessary for the health and safety of a participant and includes it in the participant's plan of care, then a telephone would become a required service and the PO would be financially responsible. In this situation, we recommend the PO investigate special telephone plans available in its area that provide only emergency service for those individuals with medical conditions that require the person to have telephone access. In addition, participants should have reasonable access to a telephone at the PACE center that can be used for local calls.

Section 460.112(b) Information Disclosure

Right #2—

Each PACE participant has the right to receive accurate, easily understood information and to receive assistance in making informed health care decisions.

As we explained in the 1999 interim final rule, in order for consumers to make rational decisions, they need accurate, reliable information that will allow them to comprehensively assess differences in their health care options, including information critical to their initial decision to enroll in PACE and whether to remain in PACE. The CBRR provides for comprehensive information to be provided to consumers in three basic categories: health plan information; health professional information; and health care facilities. Topics addressed include benefits, cost-sharing, dispute resolution, consumer satisfaction and plan performance information, network characteristics, care management information, corporate organization, etc. The CBRR indicates that certain information should be provided routinely with the remaining information available upon request.

Information that is provided to potential enrollees is addressed in more detail in the sections on marketing (§ 460.82) and enrollment (§ 460.154). With regard to participant rights, we linked the right to information disclosure to the information that is included in the enrollment agreement. The PO must explain the enrollment agreement in a manner that the participant is capable of understanding in order to ensure that all participants fully comprehend their rights and responsibilities from the beginning of their relationship with the PO.

Among the items in the enrollment agreement are an acknowledgment that the participant understands that the PO is the participant's sole service provider; a description of PACE services available and how services are obtained from the PO; the procedures for obtaining emergency and urgently needed out-of-network services; information on the grievance and appeals processes; conditions for disenrollment; description of participant premiums, if any, and procedures for payment of premiums.

The enrollment agreement also indicates that the PACE organization has a program agreement with CMS and the SAA that is subject to renewal on a periodic basis. In order to provide participants with information on the status of their organization's program agreement, in paragraph (b)(3), PACE participants have the right to examine the results of the most recent review of the PO conducted by CMS and the SAA and any corrective action plan in effect.

Comment: Several commenters requested that we eliminate the requirement for disclosure of all PACE services available, including all services delivered by providers under contract.

Response: The 2002 interim final rule provides flexibility by allowing POs to contract for all IDT members and all required PACE services. Therefore, we believe it is even more important for POs to disclose to participants which services are furnished by PACE staff and which are provided under contract with another individual or entity. Knowing who will be furnishing services is an essential component of the participant's right to make informed choices. Therefore, we are not adopting the commenter's suggestion to eliminate this requirement.

We have learned that there is confusion over the meaning of § 460.112(b)(1)(iii). That provision requires POs to notify participants when there is a change in services. Our

intention was that participants be provided information regarding a PO's contracted providers at the time a participant's needs change and a referral to a contracted provider may be necessary. This allows the participant to make an informed choice and to be able to choose from the list of the organization's contracted providers, if multiple contractors are available, and be provided the information to make an informed choice. To clarify this point, we are revising § 460.112(b)(1)(iii) to require disclosure of all PO services and services delivered by contracted providers at the time a participant's needs necessitate the disclosure and delivery of such information in order to allow the participant to make an informed choice.

Section 460.112(c) Choice of Providers

Right #3—

Each participant has the right to a choice of health care providers within the PO's network which must be sufficient to ensure access to appropriate high-quality health care. Specifically, each participant has the right:

(1) To choose his or her primary care physician (PCP) and specialists within the PACE network.

(2) To request that a qualified specialist for women's health services provide routine or preventive women's health services.

(3) To disenroll from the program at any time.

The right to access specialists must be seen in the context of the PACE model. Active involvement by participants in their care planning in conjunction with an IDT approach to care management and service delivery are fundamental aspects of the PACE model of care. In fact, although sections 1894(f)(2)(B) and 1934(f)(2)(B) of the Act provide for waiver of certain provisions of the Protocol, the use of an IDT approach may not be waived.

As we explained in the 1999 interim final rule, development of a participant's plan of care begins with a comprehensive assessment. Participant preferences for care are identified components of the assessment. Moreover, the team is required to develop, review, and reevaluate the plan of care in collaboration with the participant in order to ensure there is agreement with the plan of care and that participant's concerns are addressed. These provisions complement the participant's rights to participate in treatment decisions, to be fully informed of his or her functional status by the IDT, to participate in the development and implementation of the plan of care, and to make health care decisions, including the right to refuse treatment and to be informed of the consequences of such decisions.

It is in this context that the determination with regard to the need for specialty care is made by the IDT and the participant. If there is disagreement, then the participant has the right to engage the dispute resolution process. The IDT is expected to give ample consideration to a participant's request to see a specialist and to objectively determine whether such visits are necessary to meet the needs described in the plan of care.

We believe that access to qualified specialists for women's health services is extremely important. Therefore, we identified such a request as one of the participant preferences that must be considered in developing the plan of care.

In addition, the CBRR asserts that consumers with complex or serious medical conditions who require frequent specialty care should have direct access to a qualified specialist of their choice within a plan's network of providers. Authorizations, when required, should be for an adequate number of direct access visits under an approved treatment plan. We believe that central to the PACE model is the organization's interest in ensuring that participants obtain the care they need, including specialty care, in the easiest and most efficient manner possible. A participant who needs a course of therapy with a specialist will have that need reflected in his or her plan of care and would receive that care for the duration and number of visits specified in the plan. In light of the requirements elsewhere in this rule concerning the development and management of the plan of care, we believe it would be redundant to include an explicit requirement that would mirror this CBRR provision, and have, therefore, not included such a requirement.

In addition, CBRR provides the right to transitional care for patients who are undergoing an extensive course of treatment for a chronic or disabling condition.

With regard to having a participant's choice of PCP and specialists, the PO is required to maintain sufficient staff and contractors to meet participant needs. Given the initial participant census of POs, it is likely that choice will be limited. POs may start out with one of each type of specialist and perhaps only one PCP. Although the CBRR includes the right to choose among physicians in the provider's network, it was aimed at managed care organizations with thousands of enrollees and numerous providers. This is not always the case with the PACE model. Potential participants must weigh the limited network of POs with the benefits of a comprehensive, all-inclusive delivery system when choosing to enroll. As we discuss in more detail in the enrollment section, potential participants must be advised that the PO is the participant's sole source provider and that although the organization guarantees access to services, it does not guarantee access to a specific provider.

Comment: We received numerous and varied comments on this provision. One commenter pointed out that there is no requirement in the regulation that POs must have more than one PCP or specialist. Two commenters stated the bill of rights should clearly require disclosure when a PO has only one PCP.

One commenter requests that CMS qualify § 460.112(c)(1) as follows: ''[T]o choose his or her primary care physician and specialists from within the PACE network, as accessible and feasible * * *''

Other commenters recommended that POs be required to contract with several of the more frequently required specialists to provide choice to participants.

Response: We expect POs to have contractual arrangements with PCPs and specialists to meet the needs of their participants. CMS and the SAA determine compliance with the requirement as part of the application process and through ongoing monitoring to ensure that all participants have access to specialist services to meet their needs.

We note that there are many geographic areas that have a limited number of specialists available and providing a choice of specialists may not be possible. In addition, many PACE programs begin operations with a few participants and gradually gain participant census over time. In these cases, it would be unnecessary for the PO to employ or contract with more than one PCP or specialist in order to ensure appropriate access to specialist services. For this reason, we are not adopting the change in this final rule.

We believe that POs will have an adequate number of primary care providers and commonly-needed specialists to care for their participant population. The POs are financially responsible for all their participants' health care needs. Delays in the provision of primary care services or referrals for specialist services may have significant impact on the PO's overall financial viability. Likewise, early identification of emerging health care

problems has helped POs manage the risk associated with programs for the frail elderly. Failure to furnish timely primary care services may lead to more expensive care including the need for institutionalization.

In order to ensure that participants and potential enrollees are aware of the PO's network, § 460.112(b) requires that POs disclose all PO services and services furnished by contractors before enrollment, at enrollment, and when a change in a participant's needs necessitates the disclosure in order to allow the participant to make an informed choice. The lists will provide information about the number of PCPs and providers within each specialty and allow participants or prospective enrollees to make an informed decision about enrollment or continued enrollment in the PO.

Finally, we believe changing the regulatory language as the commenter suggested could be read as allowing a participant to choose from outside the PO's network if a PCP or specialist within the PO's network was not considered ''accessible and feasible.'' We are unsure what the commenter meant, but we do not agree that participants should have access to non-network providers. Before enrollment, when participants sign the enrollment agreement, they are informed that the PACE program is their sole health care provider. In addition, each PACE program has a network that is sufficient to ensure access to appropriate high quality care. As a result, we do not believe it would be necessary to allow access to non-network providers. This requirement is intended to ensure all-inclusive and coordinated care. Therefore, we are not amending the regulatory language.

Comment: Commenters also requested clarification as to a participant's right to request services from a qualified specialist whether or not the IDT has determined that specialist care is medically necessary.

Response: It is a participant's right to request a service they believe is necessary, which includes a request to see a specialist. If the IDT disagrees that specialist services are necessary, the participants may request a reassessment under § 460.104(d) and access the appeals process to ensure appropriate consideration is given to their request for coverage of specialist services.

Comment: One commenter recommended that we eliminate the requirement concerning women's health services and instead, allow an appropriately trained PACE PCP to serve as a qualified specialist for women's health services.

Response: As discussed in § 460.104, in developing the plan of care, female participants must be informed that they are entitled to choose a specialist in women's health services from the PO's network of providers.

Although we believe that a PCP trained in women's health care is capable of providing adequate care, we included this right to be consistent with the CBRR and Medicare managed care regulations. To further clarify the importance of access to a woman's health care specialist, we included these requests as one of the participant preferences that must be considered in developing the plan of care under § 460.104(b). We recommend that POs contract with a sufficient number of woman's health care specialists to respond to participant requests.

Section 460.112(d) Access to Emergency Services

Right #4—

Each participant has the right to access emergency health care services when and where the need arises without prior authorization by the PACE IDT.

We establish a participant's right to emergency services without prior authorization, and define emergency care, emergency medical condition, urgently needed services and post-stabilization care services in § 460.100 as these terms relate to obtaining emergency care.

Comment: One commenter requested that we define prior authorization to mean any requirement or request imposed on the participant to call or notify the PO before or during the emergency.

Response: We do not believe the term ''prior authorization'' needs to be defined as it is a well understood concept as used in the health care arena. In addition, while we generally agree with the commenter's definition, we do not believe it is needed in this context. In emergency situations, as described in § 460.100, prior authorization under any possible interpretation could delay a participant from receiving life saving critical care. Therefore, we are not revising the regulation as requested.

We note, however, that prior authorization is appropriate for urgent care outside of the service area and for post stabilization care services. The PO needs to educate its participants in the difference between emergency care (where prior authorization is not required), and urgent care (where prior authorization is appropriate). Participants need to understand when to request prior authorization and when to request urgent care. In addition, in accordance with § 460.100(e), participants must be informed that they are required to wait 1 hour after requesting prior authorization for urgent care before pursuing this care. POs need to understand their responsibility to respond to these requests within one hour or the PO relinquishes its opportunity for prior authorization for the services and will be responsible for payment of the services obtained by the participant. Section 460.100, as discussed above, further describes the concepts of urgent, emergency, and post stabilization care.

Section 460.112(e) Participation in Treatment Decisions

Right #5—

Each participant has the right to fully participate in all decisions related to his or her care. A participant who is unable to fully participate in treatment decisions has the right to designate a representative. Specifically, each participant has the right:

(1) To have all treatment options explained in a culturally competent manner, and to make health care decisions, including the right to refuse treatment, and be informed of the consequences of the decisions.

(2) To have the PO explain advance directives and to establish them, if the participant so desires, in accordance with § 489.100 and § 489.102 of this chapter.

(3) To be fully informed of his or her health and functional status by the IDT.

(4) To participate in the development and implementation of the plan of care.

(5) To request a reassessment by the IDT.

(6) To be given reasonable advance notice, in writing, of any transfer to another treatment setting and the justification for the transfer (due to medical reasons or for the participant's welfare or that of other participants). The PO must document the justification in the participant's medical record.

Active involvement by participants and their designated representatives in care planning is fundamental to the PACE model of care. As a result, we included the rights from the Protocol related to participant involvement in the development and implementation of the plan of care. We included the participant's right to be fully informed by the IDT of his or her health and functional status. In support of this right, the participant must have, upon written request, access to all records pertaining to herself or himself. Moreover, the team must provide care information in a manner that is responsive to the culturally diverse

populations whom they serve. The PO may need to develop strategies for enhancing cultural competence in its staff such as increased use of interpreters, incorporating in-house training programs, recruiting culturally diverse staff or contractors, or establishing relationships with organizations that provide technical assistance regarding cultural aspects of health care.

The Protocol states that a participant has the right to refuse treatment and be informed of the consequences of such refusal and that PACE participants may establish advance directives and make health care decisions. We restructured these two requirements in order to place greater emphasis on the participant's right to make health care decisions and to clarify that to refuse treatment is a type of health care decision. We maintained the participant's right to make advance directives, we clarified that within this right, the PO is required to fully explain advance directives to participants (in accordance with § 489.100 and § 489.102 of this chapter).

We maintained the requirement that POs provide reasonable advance notice, in writing, of any transfer to another treatment setting. In the 1999 interim final rule, we solicited comment on the necessity of specifying a timeframe for participant notification. Given the frailty of the PACE population, while some participants may require additional time to prepare for a transition to another setting, others may be able to transfer without delay.

In addition to these specific rights, there are other processes embodied in the PACE model that promote participant involvement in care planning and implementation. For example, the comprehensive assessment that serves as the basis for the plan of care includes participant and caregiver preferences for care. This input from participant and caregivers is used by the IDT to monitor the effectiveness of the plan of care. Finally, the team is specifically required to develop, review, and reevaluate the plan of care in collaboration with the participant or caregiver, to ensure that there is agreement with the plan of care and that participant concerns are addressed.

In support of effective involvement in care planning and communication between participants and providers, we note that the statute provides a specific sanction if we determine that the PO imposes a physician incentive plan that does not meet statutory requirements (see § 460.40(h)) or prohibits or otherwise restricts a health care practitioner from discussing treatment options with the participant or caregiver (see § 460.40(g)).

Comment: In response to our request for comment relating to specifying a timeframe for notification to participants of transfers to other treatment settings, we received several comments which provided general consensus that the regulation should not impose a timeframe on notification for transfers. Most commenters supported permitting the PO the flexibility to distinguish between the different types of situations and to determine whether a written notification and/or verbal advanced notice would be most appropriate based on emergency and non-emergency situations.

One commenter suggested that the term ''reasonable'' is sufficient, with the understanding that the timeframe must be justified by the documentation in the medical record.

Another commenter stated the PACE program is designed around its collaborative nature, but the ''right to be given reasonable advanced notice in writing of transfer to another treatment setting with justification'' sounded like a unilateral decision by the PO. The commenter believes that transfer decisions should also be collaborative and agreed upon by the participant.

Several other commenters supported advanced written notice for a planned transfer, while some identified situations when immediate transfers would preclude the appropriateness of an advanced written notice (for example, a heart attack).

Another commenter recommended that CMS incorporate the requirement of timely notice, by both written notice and verbal explanation, of at least 30 days. This notification timeframe would permit participants to file a grievance or appeal, as appropriate.

Response: We agree with the majority of the commenters who pointed out the difference between planned and emergent transfers, and the need for PO flexibility in determining an appropriate timeframe to notify the participant based on the individual situation. We also note that while generally a transfer may be collaborative depending on the participant's need for the transfer, the PO may need to make the decision and should be afforded the flexibility to do so without undue time restrictions. We also expect full documentation for the transfer to be reflected in the participant's medical record. Therefore, we are maintaining the current language, requiring ''reasonable advanced notice'' for transfers to any treatment setting. We urge POs to provide as much advance notice as possible for non-emergent transfers.

Section 460.112(f) Confidentiality of Health Information

Right #6—

Each participant has the right to communicate with health care providers in confidence and to have the confidentiality of his or her individually identifiable health care and other information protected, including information contained in an automated data bank (see § 460.200). Each participant also has the right to review and copy his or her own medical records and request amendments to those records.

Consistent with the CBRR and MA and Medicaid managed care organization requirements, participants have the right to communicate with any member of the IDT and contract providers in confidence and to have the confidentiality of their individually identifiable health care information protected.

In addition, the section on maintenance of records and reporting of data specifically addresses confidentiality and the safeguarding of health, financial, and other information (see § 460.200). It requires POs to establish written policies and implement procedures to safeguard the privacy of participant information and ensure appropriate use and release of participant information. POs are also required to comply with the HHS privacy standards as required by the Health Insurance Portability & Accountability Act (HIPAA) of 1996, Pub. L. 104–191, and its implementing regulations codified at 45 CFR parts 16 and 164.

Comment: We were asked to clarify that a participant's right to communicate with health care providers in confidence and to have the confidentiality of his or her individually identifiable health care information protected does not preclude IDT members and other care providers from sharing such information with each other.

Response: Members of the IDT and other care providers are permitted to discuss a participant's confidential individually identifiable health care information for treatment, payment, and health care operations, provided that such use or disclosure is consistent with other applicable requirements of the HIPAA Privacy Rule (45 CFR parts 160 and 164). Confidentiality requirements are intended to protect the participant's health information from being disclosed to individuals who are not involved with the participant's health care needs. This requirement does not prevent members of the IDT, contracted

providers, and caregivers from discussing a participant's health information, which may be essential in ensuring appropriate care.

Section 460.112(g) Complaints and Appeals

Right #7—

Each participant has the right to a fair and efficient process for resolving differences with the PO, including a rigorous system for internal review by the organization and an independent system of external review. Specifically, each participant has the right:

(1) To be encouraged and assisted to voice complaints to PACE staff and outside representatives of his or her choice, free of any restraint, interference, coercion, discrimination, or reprisal by the PACE staff.

(2) To appeal any treatment decision of the PO, its employees, or contractors through the process described in § 460.122.

We received no comment on this section. We note that comments regarding grievance and appeals procedures are addressed in § 460.120 through § 460.124.

Final rule actions:

In this final rule, we are revising § 460.112 by:

- Expanding paragraph (a) to include sexual orientation; and
- Revising paragraph (b)(1)(iii) to require the disclosure of all PO services and services delivered by contracted providers at the time a participant's needs necessitate the disclosure and delivery of such information in order to allow the participant to make an informed choice.

Section 460.114 Restraints

We revised the wording used in the Protocol regarding the use of restraints in order to emphasize that the use of restraints must be limited to those situations with adequate, appropriate clinical justification. The PO must limit use of restraints to the least restrictive and most effective method available. If the use of a restraint is needed to ensure the participant's physical safety or the safety of others, the use must be in accordance with certain conditions. First, restraints may only be used for a defined and limited period of time based on the assessed needs of the patient; second, such use must be imposed using safe and appropriate restraining techniques; third, such use may only be imposed when other less restrictive measures have been found to be ineffective to protect the participant or others from harm; and finally, such restraints must be removed or ended at the earliest possible time. As noted above, the use of restraints must be based on the assessed needs of the patient, and be continually assessed, monitored, and reevaluated.

We do not believe that restraints of any kind should ever be used as a preferred approach to care, and we expect POs to ensure that their programs are ''restraint free'' to the greatest extent possible. Specific requirements regarding the use of restraints are established in § 460.114.

We have re-examined our seclusion and restraint policy for all CMS-covered providers and have begun amending our restraint and seclusion policies. We call your attention to the discussion of the use of seclusion and restraints in the CMS interim final rule concerning the conditions of participation for hospitals (CMS–3018–IFC, published July 2, 1999, 64 FR 36070). In that regulation, we established explicit standards for the use of seclusion and restraints both in medical/surgical care and for behavior management (see § 482.13(e) and (f)). While the standards are not identical to those we included in § 460.114, they share the common principle that patients have the right to be free from restraints of any form that are not medically or psychiatrically necessary or are used as means of coercion, discipline, convenience, or retaliation by staff. In the preamble to the interim final rule for the hospital conditions of participation, we indicated our intent to examine the applicability of the hospital restraint and seclusion standards to other providers. In our 1999 PACE interim final rule, we asked for comments about how best to extend the protections established for hospital patients to participants in the PACE program.

We received no public comments on § 460.114.

Final rule actions:

This final rule will finalize § 460.114 as published in the 1999 interim final rule.

Section 460.116 Explanation of Rights

Section 460.116 requires the PO to have written policies and implement procedures to ensure that the staff, the participant, and his or her representative understand the participant's rights. The regulations also require that, at the time of enrollment, staff review participant rights with the participant and his or her representative, if any, in a manner which he or she understands. The PO is expected to assure that information is provided to the physically and mentally disabled, that translator services are available as needed for non-English speaking participants, and that interpreter services and other accommodations (such as TTY connections) are made available to the hearing-impaired.

We also incorporated the requirement that participant rights be posted in a prominent place in the PACE center in English and any other principal language of the community. This allows participants, PACE center staff, and other concerned persons to review the participant rights at any time. For those participants who speak or read in only a ''non-predominant'' language, the participants should have their rights explained to them in a manner they understand.

Comment: We received three comments related to multilingual issues. One commenter recommended that we specify that written information should be in a language easy to understand by the participant and should be given out at enrollment. Commenters also recommended that the participant bill of rights be displayed in English and other principal languages in the PO's service area. One commenter recommended that we consider providing programs serving multilingual populations with financial assistance to cover translation expenses.

Response: Our intent is that all marketing materials including the enrollment agreement be provided in a language the participant is able to understand. The regulation requires participant rights to be provided in writing, in English, and in other principal languages of the community, and to be explained in a manner the participant and his or her representative understands. In addition, § 460.116(c) requires that the PO display the participant rights in a prominent place in the PACE center. The State establishes the criteria POs use for determining a principal language of the community. We do not provide financial compensation for translation expenses, as we believe this is a cost of doing business for all entities in geographic areas where there are multilingual populations.

Final rule actions:

This final rule will finalize § 460.116 as published in the 1999 interim final rule.

Section 460.118 Violation of Rights

Section 460.118 requires the PO to have and implement documented, established procedures to respond to and rectify a violation of a participant right. This requirement is intended to ensure that the PO will address all violations of participant rights and not allow problems to continue.

We received no public comments on § 460.118.

Final rule actions:

This final rule will finalize § 460.118 as published in the 1999 interim final rule.

Section 460.120 Grievance Process

In accordance with sections 1894(b)(2)(B) and (f)(3) and 1934(b)(2)(B) and (f)(3) of the Act, we have established requirements at § 460.120 through § 460.124 requiring PACE organizations to establish procedures for grievances and appeals. We have adapted these requirements from Part II, section B of the Protocol. Rather than follow the Protocol's interchangeable use of the terms ''complaint,'' ''grievance,'' and ''appeal,'' we have distinguished between grievances and appeals. Our intent was to delineate between (1) a participant's grievance regarding dissatisfaction with service delivery or the quality of a service furnished and (2) a participant's action with respect to noncoverage of or nonpayment for a service. We believe that such a distinction is needed to clearly establish both a process to address a participant's dissatisfaction with service delivery or quality of care furnished and a process to address the PACE organization's refusal to furnish or pay for a particular service. The grievance process and the appeals process are similar, since both are based on the Protocol, with some minor differences due to the nature of the complaint.

A grievance is defined as a complaint, either written or oral, expressing dissatisfaction with service delivery or the quality of care furnished.

The PO must have a formal written process to evaluate and resolve grievances, whether medical or non-medical in nature, by PACE participants, their family members, or representatives. Having a formal written process to evaluate and resolve grievances is essential since all personnel (employees and contractors) who have contact with participants should be aware of and understand the basic procedures for receiving and documenting grievances in order to initiate the appropriate process for resolving participant concerns.

We retained the requirement from the Protocol that all participants must be informed of the grievance process in writing. This information must be provided to participants upon enrollment into the PACE program and at least annually thereafter. We believe it is critical that participants are fully and promptly informed of this process and periodically reminded of their rights, so they may exercise these rights from the beginning of their relationship with the PO.

The grievance process, at a minimum, must include procedures for:

(1) Filing a participant's grievance;

(2) Documenting the participant's grievance;

(3) Responding to and resolving the participant's grievance in a timely manner; and

(4) Maintaining confidentiality of the participant's grievance.

The PO's internal procedures should assure that every grievance is handled in a uniform manner and that there is communication among different individuals who are responsible for reviewing or resolving grievances. In addition, the PO must maintain appropriate documentation, so the information can be utilized in the organization's QAPI program. Requiring that grievances be responded to and resolved in a timely manner provides a protection to the participants. This action is intended to ensure that the PO addresses all participant concerns and does not allow the problem in service delivery to be unresolved. Finally, at all times, an organization must have procedures governing confidentiality to protect against unauthorized or inadvertent disclosure of information. Participant confidentiality is also intended to prevent reprisal against the participant.

It is critical that the PO continue to provide care to the participant during the grievance process because once enrolled, in accordance with § 460.154(p), participants must receive care solely through the PO. Continuing care also encourages participants to continue to voice concerns about service delivery without fear of reprisal.

The PO must discuss and provide to the participant in writing the steps, including timeframes for response, that will be taken to resolve the participant's grievance both at the time of the participant's enrollment and when a grievance is filed. This requirement assures the participant that there will be resolution of the issue. In addition, the organization acknowledges the participant's concern, tries to address the problem, and makes any necessary adjustments in service delivery. We recognize there will be occasions when a grievance may not be resolved to the satisfaction of the participant, but believe the PO should nonetheless set forth its best efforts. The PO must maintain, aggregate, and analyze information on grievance proceedings. This requirement is an integral part of fostering an environment of continuous improvement, and complements the QAPI requirements. We expect that once an organization has a quality improvement system in place, participant grievances will be analyzed and evaluated as grievances may be the first clue that a problem exists. By analyzing the number and types of grievances, a PO will be able to develop activities to monitor and improve the grievance resolution process, as well as identify and make improvements or modifications in the care.

Comment: One commenter was concerned that the definition of grievance found in § 460.120 could lead to confusion as to whether minor problems that present in day-to-day staff-participant contact during the provision of services would be interpreted as grievances and reported as such.

Response: The commenter has interpreted the requirement correctly. A grievance could identify a minor problem where someone is dissatisfied with the service provided. We would expect grievances to occur in day-to-day interactions and we expect to see a number of grievances simply because people have different opinions and expectations. Therefore, we are more concerned when grievances over such things as food or the choice of music are not recorded. We expect these grievances to be tracked, evaluated, and included in the QAPI process. For example, if there is a pattern of complaints about cold food, the issue should be addressed and if every time a particular dish is served many participants complain, then a change in the menu should be considered.

Comment: Two commenters expressed concern with the requirement to ''continue to furnish all required services.'' One commenter requested the regulatory language be revised to define ''required services,'' and the other commenter requested modifying the requirements regarding the PO's responsibility to continue to provide services during the grievance process. Both commenters recommended that we clarify that the PO must continue to furnish to participants all services required by their current treatment plan. If a change in health status necessitates a change in treatment plan, the PO must furnish to the participant all services required by the revised treatment plan.

Response: It appears that commenters may have confused grievances which related to quality of services with appeals that relate to coverage of services. ''Required services'' are those services indicated in the participant's plan of care. This requirement is a participant protection intended to avoid potential reprisal. We continue to

believe that it is appropriate for the PO to continue to provide all required services in the plan of care during the grievance process. Thus, we do not believe the clarification requested is necessary.

Comment: One commenter indicated the requirement did not specify a timeframes for the resolution of a grievance. The regulations require that the PO only has to provide written notice that includes the timeframes for response. The commenter recommended that all grievances be resolved within 30 days.

Response: Grievances cover a wide range of issues which may be resolved in minutes or may take much longer to resolve. Therefore, while we require the PO to have a written process to evaluate and resolve medical and non-medical grievances, we have not established a specific timeframe for resolution of grievances. The PO must acknowledge receipt of the grievance in writing and provide to the participant information as to the expected timeframe for response based on the specific situation. We expect that POs will make every effort to resolve grievances as expeditiously as possible accounting for the complexity of the particular grievance filed. Accordingly, we have not revised the regulation to set forth timeframes for resolutions.

Comment: One commenter asked whether we intended that service delivery encompass administrative complaints, such as failure to replace a lost handbook on a timely basis, failure to return phone calls related to requests for information, or breaches of confidentiality.

Response: We expect POs to acknowledge grievances in writing, to record, and to resolve any issue about which a participant expresses dissatisfaction (medical or non-medical), including administrative complaints. These grievances should be reviewed, analyzed, and included in the PO's QAPI plan.

Comment: One commenter recommended that PO actions on grievances be subject to monitoring at any time.

Response: In accordance with § 460.200, the PO must allow CMS and the SAA access to its data and records. In addition, POs report data for monitoring that includes grievance information. Thus, CMS and the SAA have access to and routinely review grievance information.

Final rule actions:

This final rule will finalize § 460.120 as published in the 1999 interim final rule.

Section 460.122 PO's Appeals Process

An appeal is defined as ''a participant's action taken with respect to a noncoverage of, or nonpayment for a service.'' The PO must have a formal written appeals process, with specified timeframes for response. We included the requirement from the Protocol that all participants must be informed of the appeals process in writing. This information must be provided to participants upon enrollment into the PACE program, at least annually thereafter, and whenever the IDT denies a request for services or payment. The appeals process, at a minimum, must include written procedures for:

(1) Timely preparation and processing of written denials of coverage or payment in accordance with § 460.104(c)(3);

(2) Filing a participant's appeal;

(3) Documenting the participant's appeal;

(4) Appointing an appropriately credentialed and impartial third party who was not involved in the original decision and who does not have a stake in the outcome of the appeal to review the participant's appeal;

(5) Responding to and resolving the participant's appeals as expeditiously as the participant's health condition requires, but no later than 30 calendar days after the PO receives an appeal; and

(6) Maintaining confidentiality of participant appeals.

The appeals process is similar to the grievance process. However, we included the requirement that an objective third party be appointed to review all appeals. In this way, information is reviewed by an individual or group that has no financial stake in the decision. This helps to prevent bias in the decision. In addition, we specified that the PO must respond to participant appeals within 30 calendar days of receipt of an appeal and established a shorter timeframe for expedited appeals. We did not include a provision for a 14-day extension of this 30-day timeframe (as allowed under the MA regulations at § 422.590(a)) in recognition of the frailty of the PACE population. We solicited comments on both the appropriateness of the 30-day timeframe and on the necessity of requiring a specific timeframe.

In § 460.122(d)(2), we adopted the Protocol requirement that the PO must give the parties involved in the appeal a reasonable opportunity to present evidence related to the dispute in person as well as in writing.

It is critical that the PO continue to furnish care to the participant during the appeal process because, in accordance with § 460.154(p), participants must receive care solely through the PO. In addition, we incorporated the Medicaid continuation of benefits provision for all Medicaid participants. Under the Medicaid continuation of benefits provision in § 460.122(e)(1), the PO may not terminate or reduce disputed services while an appeal is pending if the Medicaid participant requests that they be continued, with the understanding that the participant may be liable for the cost of those services if the appeal is not resolved in his or her favor. It is critical that all other care continue in order to maintain the participant's functional status. The goal of the program is to furnish comprehensive care to the participant and this cannot be accomplished if there is a breakdown in the provision of services.

The PO must have an expedited appeals process for situations in which the participant believes that if the service is not furnished, his or her life, health, or ability to regain maximum function would be seriously jeopardized. This process provides for prompt consideration of requests for services if the participant's health might be adversely affected if he or she had to wait for the standard appeals process to resolve the issue. As noted above, the goal of the PACE program is to maximize the participant's functioning, and the expedited appeals process ensures that all factors are evaluated so that all necessary services are being furnished and participant health is not compromised.

We included a provision at § 460.122(f)(2) pertaining to the expedited appeals process requirement that the PO must respond to the appeal as expeditiously as the participant's health condition requires, but no later than 72 hours after it receives the appeal. The 72-hour timeframe may be extended by up to 14 calendar days if the participant requests the extension or if the PO justifies to the SAA the need for additional information and how the delay is in the interest of the participant. The timeframes for responding to requests for expedited appeals are consistent with the requirements for MA expedited appeals in § 422.590(d). The PO must take appropriate action to furnish the disputed service as expeditiously as the health condition of the participant requires if, on appeal, a determination is made in favor of the participant. There may be situations in which the PO has made an incorrect or inaccurate assessment of the participant's needs or condition and has denied a service. In

these situations, it is critical that ongoing care not be delayed until the appeal is resolved, and that the participant continue to receive comprehensive care that maintains her or his functional status.

We maintained the Protocol requirement that all determinations that are wholly or partially adverse to the participant must be forwarded to CMS and the SAA. We require that the PO notify CMS, the SAA, and the participant of its actions at the time the decision is made.

We solicited comment regarding the appropriateness of a 30-day timeframe without extension, within which the PACE provider must respond to a participants' appeal, and on the necessity of requiring a specific timeframe for implementing the change in the participant's plan of care resulting from resolution of the appeal.

Comment: Several commenters supported the timeframes as published. One commenter supported the emphasis on participant rights, believed appeals would be rare and thus supported the 30-day timeframe with a shorter period for expedited appeals.

Several commenters suggested timeframes for the various components of the appeal process. Three commenters supported the 30-day timeframe in which the PO must respond to the participant's appeal. Two commenters requested the regulation specify a timeframe in which the PO must inform the participant of the determination on the appeal, while another commenter suggested that the regulation specify that services should be provided no later than 10 days after a favorable determination or immediately in the case of the expedited appeal. One commenter requested that we clarify the PO's right to implement its determination in connection with its internal appeal process.

Response: We are retaining the timeframes as required in the 1999 interim final rule. The timeframes are consistent with MA requirements in § 422.568 through § 422.570. As PACE utilizes the same timeframes as the MA requirements, we believe it is important to maintain this consistency.

Comment: One commenter stated that informing the participant of the external appeal process when the PO's internal appeal process determination is not wholly in the participant's favor was sufficient. Other commenters requested the regulation provide more detail in the denial notice provided to the participant when a request for services is denied. The commenter recommended that the notice include a description of the process used when a participant requests an item or service, the reason for the denial, the right to submit additional evidence, and information about the appeal process.

Response: Section 460.104(c)(3) requires an in-person reassessment when the participant or his or her representative believes a participant needs to initiate, eliminate, or continue a particular service. In addition, in accordance with § 460.122(b), the PO is required to have processes for timely resolution of participant requests and appeals and to provide written information on the appeals process to participants on enrollment, annually thereafter, and any time the IDT denies a request for services. We believe that the current regulation provides adequate notification requirements for the appeals process and additional changes at this time are not necessary.

Comment: We received comments requesting that we clarify what is meant by ''appropriately credentialed'' and ''impartial third party,'' as provided in § 460.122(c)(4). It was recommended that the regulatory requirement be modified to specify that the appointment be of an impartial third party credentialed in a field that is appropriate for the service at issue. Commenters questioned whether a PO's employees or contractors could serve in this capacity.

Response: An appropriately credentialed and impartial third party is an individual who was not involved in the original action and who does not have a stake in the outcome of the appeal. For example, this individual may be an outside physician or practitioner in a related field who will review the documentation related to the appeal.

To the extent that POs allow employees and contractors to review the IDT denials, it is in the context of a review committee. An employee or contractor may participate on these review committees so long as they have no connection to the original denial decision and their expertise is in the appropriate field. For example, it would not be appropriate for a social worker to review an appeal related to a physical therapy denial, or a gynecologist to review a denial of services regarding coronary surgery.

We recommend that the PO ensure that the credentialed and impartial third party reviewer make his or her determinations in a similar manner to determinations made under section 1862(a)(1)(A) of the Act. The determination is based on the participant's medical need and not on other reasons such as the cost of the disputed care, who is paying the third party reviewer's salary or fee, an individual's reputation, or other factors.

Comment: Two commenters disagreed with the regulation requirement in § 460.122(h) that CMS and the SAA be informed of every adverse determination and recommended that this requirement be deleted.

Response: We view the reporting of adverse determinations to CMS and the SAA as a participant protection. Routine reporting will enable us to track trends in coverage of services to participants and to monitor the extent to which appeals are addressed in the PO's quality improvement activities. It also alerts us to the potential for a request for an external appeal.

Comment: Several comments were submitted regarding services furnished during appeals. While one commenter recommended that we delete the requirement, other commenters indicated we should extend the protection to Medicare participants. One commenter pointed out that MA providers must continue to provide disputed services during an appeal. One commenter recommended that we require POs to continue to furnish to the participant all other services required by his or her current treatment plan. The commenter believes that in the event a change in health status necessitates a change in the treatment plan, the PO must furnish to the participant all services required by the revised treatment plan. Another commenter indicated that without the continuity of Medicare and Medicaid services, PACE participants would be subject to discrimination based on payment source.

Response: We adopted the requirement that POs continue to furnish disputed services during the appeal process to Medicaid-eligible participants in order to be consistent with the Medicaid State fair hearing (SFH) regulation at § 431.230. We did not adopt a similar requirement in the 1999 interim final rule for Medicare-eligible participants because there is no corresponding requirement for continuation of services during appeal in the Medicare Independent Review Entity (IRE) review process. For this reason, we believe it is appropriate to retain the 1999 interim final requirement at this time. We note, it is critical however, that the PO continue to furnish the non-disputed services to the participant during the appeal process, because section 1894(a)(1)(B)(1) of the Act requires that participants receive services solely through the PO and as explained in § 460.98, the required services for a participant are those services identified in their plan of care.

Comment: Commenters suggested that the appeals section apply to reductions and terminations of services in addition to denials of services.

Response: We agree with the commenters and have revised the introductory text of § 460.122 accordingly.

Comment: Commenters suggested that the expedited appeals process described in § 460.122(f) be revised. Currently, § 460.122(f) requires that POs have an expedited appeals process for situations in which the participant believes that his or her life, health, or ability to regain maximum function would be seriously jeopardized absent provision of the service in dispute. The commenters suggested that an expedited appeal process apply where a participant believes that his or her life, health, or ability to regain *or maintain* maximum function *could* be seriously jeopardized absent provision of the service in question.

Response: We agree with the commenters and have revised § 460.122(f) accordingly.

Final rule actions:

In this final rule, we are:

• Amending the regulatory language of the introductory paragraph of § 460.122 to clarify that for purposes of this section, a denial of services could include a denial, reduction, or termination of services.

• Revising § 460.122(f)(1) to require that a PACE organization must have an expedited appeals process for situations in which the participant believes that his or her life, health, or ability to regain or maintain maximum function could be seriously jeopardized, absent provision of the service in dispute.

Section 460.124 Additional Appeal Rights Under Medicare or Medicaid

As we explained in the 1999 interim final rule, the PO must inform participants in writing of their additional appeal rights under Medicaid or Medicare, assist participants in choosing which appeal process to pursue if both are applicable, and then forward the appeal to the appropriate external entity. Participants who are dually eligible for Medicare and Medicaid may utilize either the Medicare or the Medicaid managed care appeal process. In those cases where participants are covered only under one program (Medicare or Medicaid), only the applicable appeals process would apply.

Comment: We received several comments related to the additional appeal rights under Medicare and Medicaid. Several commenters indicated that the preamble description in the 1999 interim final rule does not reflect CMS's intent to allow dually eligible participants to access only one appeal route, either Medicare or Medicaid. The language does not clearly state that participants must choose one route of appeal and that the route chosen is final.

Commenters indicated that the bifurcated external appeal process was confusing, administratively burdensome, and ambiguous and that a single appeals system should be developed. These commenters also stated that the regulation should specify a timeframe for the completion of the entire appeal process suggesting a 90-day timeframe which is consistent with Medicaid requirements.

We also received comments recommending a single system of grievance, appeals, and hearings, or adapting the essentials elements of the Medicaid managed care regulations that were published in the **Federal Register** on September 29, 1998 (63 FR 52022) to the PACE program since most PACE participants are Medicaid eligible.

One commenter requested clarification on the relationship between the PO's appeal process and the external Medicare/Medicaid processes. Another commenter requested that we define ''appropriate external entity for Medicare and Medicaid,'' and respond to the following questions: First, how will the PO and participant know which appeal route is appropriate, and second, how to handle disparate decisions when a participant chooses both appeals routes.

One commenter pointed out that the reference in the regulations to the Medicare appeals process was confusing. The commenter questioned whether we intended that denials of Part A services be referred to the Part A fiscal intermediary and denials of Part B services be referred to the Part B carrier.

Lastly, other commenters indicated the reporting requirements were burdensome as all adverse determinations are to be forwarded to both CMS and the State without any guidelines or criteria to assess whether such determinations were appropriately made.

Response: Review of the comments indicated that many of the commenters misunderstood the PACE appeals process and in response to the comments, we believe a reiteration of the process would address the concerns raised. As noted previously, sections 1894(f)(3)(A) and 1934(f)(3)(A) of the Act, require that in applying certain additional beneficiary protections, we should apply Medicare and Medicaid managed care requirements while taking into consideration the differences between the population served and benefits provided under this section and under Medicare and Medicaid managed care programs. Because of this requirement, we did not intend that the PACE external appeals process involve the Medicare fee-for-service Part A intermediary or Part B carrier appeals processes. Rather, we followed the Medicare managed care process using the IRE contractor for the PACE external appeals process.

The external appeals process provides participants with an appropriate external review depending on their Medicare and Medicaid status. Medicare beneficiaries have access to the Medicare external appeals route through the IRE that contracts with CMS to resolve MA appeals, while Medicaid eligible individuals have access to the SFH process. PACE participants who are dually eligible for both Medicare and Medicaid have the choice of either process, the Medicare IRE or the Medicaid SFH process. Allowing dually eligible participants to choose to pursue an appeal through either the Medicare's IRE or Medicaid's SFH processes eliminates the possibility of conflicting determinations. Therefore, all PACE participants have one route by which to exercise their external appeal rights.

It is the PO's responsibility to assist the participants in understanding which external route is appropriate for them based on the participant's Medicare and Medicaid status. For dually eligible participants, the PO must explain the external processes of each option and assist them in initiating their choices. This is primarily a matter of personal preference as both external appeals processes are equally valid options.

Information on the Medicare IRE process is available online at *http://www.medicareappeal.com* and information on the SFH process can be obtained from the SAA. Should the participant need help with the Medicare IRE process, then in accordance with § 460.124, the PO will provide that assistance. Although Medicare does not have an external appeals process to permit challenges of disenrollment determinations, all participants may use their State's external appeals processes. As we noted in the discussion on § 460.164 (Involuntary disenrollment), the State must provide a process for Medicare-only participants for an involuntary disenrollment appeal.

Comment: Commenters asked what would happen if the PO directs the participant to the wrong entity and would the appeal rights of the participant be lost if the correct filing is not made in the required time. In

addition, one commenter stated that implementation of the 1999 interim final rule regarding appeals would be problematic for them due to a class-action litigation settlement agreement which applies a time limit on initiating appeals through the State Medicaid appeals process.

Response: CMS staff has worked closely with the POs, the SAAs, and the IRE staff responsible for PACE in order to ensure that appeals are directed to the appropriate entity. However, if an appeal should be misrouted, corrections can be accommodated.

As noted previously, dual eligible participants are allowed to choose to use either the Medicare or Medicaid external appeal processes and POs play a significant role in assisting participants in choosing the appropriate external review entity and filing the appropriate documentation. Where State law establishes a timeframe for initiating an SFH, the PO must be sensitive to those time constraints in order to ensure that the participant's rights to access the SFH is not negated by a failure to meet the State timeframes.

Comment: Another commenter recommended that Medicare participants be provided the same right as Medicare beneficiaries enrolled in an M+C plan and be allowed to go directly to an Administrative Law Judge (ALJ) hearing upon completing the internal appeals process, and not have to go through carrier or fiscal intermediary review. Another commenter indicated that the participant should not have to exhaust the internal PACE appeal process before initiating the external appeal process.

Response: According to § 422.600, beneficiaries are not permitted to circumvent the appeals process with their MA organization. Under § 422.600, beneficiaries may only be heard before an ALJ after reconsideration with their MA organization.

Comment: One commenter expressed concern that the regulation places the responsibility entirely with the PO to advise dually-eligible participants of the appropriate route of appeal without supplying guidance as to which route would best benefit the participant in different situations. This commenter believes it is essential that guidelines be established to decrease the possibility of litigation against the State or the PO and to prevent participants from accessing a second appeal route by saying they were wrongfully advised in selecting a particular route of appeal.

Response: We believe that both processes are valid options and we do not agree that a wrong choice can be made. In addition, we note that since the 1999 interim final rule was implemented, no IRE appeals and only a few SFH appeals have been filed. We will continue to monitor appeals under PACE and will propose changes in the appeals process if warranted. We have worked extensively with POs to educate them on the Medicare IRE process so that they are able to fully explain the system to participants.

Final rule action:

This final rule will finalize § 460.124 as published in the 1999 interim final rule.

Subpart H: Quality Assessment and Performance Improvement

Sections 1894(e)(3) and 1934(e)(3) of the Act require that, under a PACE program agreement, the PO, CMS, and the SAA shall jointly cooperate in the development and implementation of health status and quality of life outcome measures with respect to PACE participants. In 1999, we were considering putting into place a PACE participant assessment tool, and outcome measures that would be clinically meaningful to PACE participants and empirically valid for purposes of quality monitoring and improvement. Thus, CMS took a leadership role in developing outcome measures to be integrated into clinical and administrative practices at PACE sites.

In the 1999 interim final rule, we adopted quality QAPI requirements that are consistent with the provisions from part V of the Protocol. As noted below and as discussed in that rule (64 FR 66259), we added further requirements to prepare POs to participate in the OBCQI system that was under development pursuant to a CMS contract with the Center for Health Services and Policy Research (CHSPR) at the University of Colorado.

At the time the 1999 interim final rule was published, CHSPR was developing a core data set that was to provide the foundation for a standardized OBCQI system for PACE programs. In developing the data set for PACE, CHSPR examined existing CMS data instruments such as the Minimum Data Set (MDS) (a part of the nursing home assessment instrument), the Outcome Assessment Information Set (OASIS), (required under the home health agency conditions of participation), DataPACE (developed by On Lok, Inc., and used by the PACE demonstration programs), and the Functional Independence Measure (FIM) (an assessment data set used in rehabilitation hospitals), for data items that could be pertinent for PACE quality improvement purposes.

Since the publication of the 1999 interim final rule, the health care industry has moved beyond the problem-oriented, ''after-the-fact'' corrective approach of quality assurance to a proactive approach that focuses on continuously addressing QAPI. Consequently, many health care QAPI programs are patient-driven rather than process-driven. Given that changes in health care delivery systems are rapid and continuous, many providers requested flexibility to design QAPI programs that meet the needs of their health care settings, rather than try to comply with a ''one-size-fits-all'' program. We agree that a QAPI program should blend flexibility with appropriate accountability and in the past few years, we have been striving to balance both in a patient-centered approach. With an effective QAPI program, we believe that providers will be able to determine how its performance has affected patient experiences and outcomes. We expect a provider to focus on performance outcomes and to prioritize areas needing improvement.

While we recognize the utility of the OBCQI core outcome and comprehensive assessment data set(COCOA–B) system as a useful assessment tool for PACE participants, we have misgivings about its long-term application. Given the need for flexibility for PACE sites, we are also concerned that specifically mandated measures may compromise the discretion of POs to use other assessment tools that may be more appropriate for their settings. We decided not to impose the OBCQI requirements for POs. Therefore, POs should not expect to see the publication of specific outcome measures as was implied in the 1999 interim final rule. We are not foreclosing the possibility of requiring specific outcome measures in the future, but at this time we believe PACE organizations and their participants will benefit from a wide degree of flexibility in the QAPI approach we have chosen to present.

Section 460.130 General Rule

We require the PO to develop, implement, maintain, and evaluate an effective data-driven QAPI program. It is important that the QAPI program take into consideration the wide range of services furnished by PACE. Additionally, the program should use data to identify and improve areas of poor performance. The PO must take actions that result in improvements in its performance in all types of care.

Comment: One commenter requested that we clarify whether the requirement

to take action to improve the performance in ''all types of care'' means that the organization does not have flexibility to identify its critical processes and to prioritize and select areas of concentration in which to apply resources for improvement efforts.

Response: The requirement in § 460.130(c) states that a PO must take actions that result in improvements in its performance in all types of care. Our expectation is that POs will operate a continuous QAPI program that does not limit activity to only selected kinds of services or types of patients. We expect POs to exercise as much flexibility as is necessary in order to fully meet obligations to its participants' care. As we do not require the use of a common quality assessment tool or a set of specific outcome measures beyond the data elements for monitoring included in the program agreement, POs have the flexibility to develop the program that best meets their needs. 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 the PO's services.

Final rule actions:

This final rule will finalize § 460.130 as published in the 1999 interim final rule.

Section 460.132 QAPI Plan

The PO must have a written QAPI plan. Consistent with the Protocol, we require POs to have their QAPI plan annually reviewed by the PACE governing body and, if necessary, revised. Further, in this section we establish that a written plan must, at a minimum, specify how the PO proposes to (1) identify areas in which to improve or maintain the delivery of services and patient care; (2) develop and implement plans of action to improve or maintain quality of care; and (3) document and disseminate the results of the QAPI activities to the PACE staff and contractors.

We received a number of comments and questions regarding the QAPI plan.

Comment: Several commenters requested information regarding CMS' intention regarding prior approval and monitoring of the QAPI plan.

Response: POs are required to present their QAPI plan to their governing body for annual approval. CMS and the SAA must approve the QAPI plan prior to its inclusion in the program agreement and review the plan during monitoring visits.

Comment: One commenter indicated that the regulations do not establish an oversight responsibility for review of the plan by either the Federal or State government.

Response: The program agreement contains a description of the QAPI plan and CMS and the SAA review plan during monitoring visits.

Final rule actions:

This final rule will finalize § 460.132 as published in the 1999 interim final rule.

Section 460.134 Minimum Requirements for Quality Assessment and Performance Improvement Program

The requirements contained in § 460.134 are consistent with the Protocol, but provide more explicit information about the types of outcomes that must be used to monitor quality. We provided the following guidance regarding QAPI in the 1999 interim final rule. The PO's QAPI program must include, but need not be limited to, the use of objective measures to demonstrate improved performance with regard to the following:

(1) *Service utilization.* PACE demonstration programs collected utilization data such as hospitalizations and emergency room visits. This information can be used to evaluate fiscal well-being, as well as evaluate quality of care. It can also be used to target reviews of PACE centers whose utilization data suggest, for example, that participants may be receiving fewer services than necessary to achieve expected outcomes. The purpose of including utilization data in the PO's QAPI program is to help the PO ensure that participants receive the appropriate level of care through their PACE center. Additionally, using information regarding utilization of and reasons for emergency care and hospital and nursing home admissions, the PO can identify areas for improvement.

(2) *Caregiver and participant satisfaction.* Caregiver and participant satisfaction with services is an important element of a QAPI program. A PO must survey, on an ongoing basis, participants and their caregivers to determine satisfaction with the services furnished and the outcomes achieved. Given the large number of PACE participants who are cognitively impaired and the critical role caregivers play in keeping PACE participants in the community, it is important to survey caregivers about their satisfaction with the program. We expect the PO to use this information to identify opportunities to improve services and caregiver and participant satisfaction. We do not intend, at this point, to prescribe the specific tools for measuring participant and family satisfaction. It is the responsibility of the PO to survey the participants and family, but we are not specifying the survey tool they must use. The PO will be expected to demonstrate its satisfaction measurement system and how it is used as part of the overall internal QAPI system.

(3) *Outcome measures derived from participant assessment data.* These measures can be used to determine if individual and organization-level measurable outcomes are achieved compared to a specified previous time period. These measures should encompass the various areas needed to monitor care for PACE participants, including physiologic, functional, cognitive, mental health, social/behavioral, and quality of life outcomes. For example, POs should focus their quality improvement activities on outcomes such as stabilization in ability to bathe, from a baseline period to each follow-up period; improvement in dyspnea from admission into PACE to a follow-up period; improvement in transportation services over a specific time period; and improvement in caregiver stress from participant admission into PACE to a follow-up time period.

(4) *Effectiveness and safety of staff-provided and contracted services, including the competency of clinical staff, promptness of service delivery, and achievement of treatment goals and measurable outcomes.* For participants to experience the outcomes that the PACE benefit is intended to achieve, staff must demonstrate skills and competencies necessary to facilitate those desired outcomes. The PO is expected to include data-based, criterion-referenced performance measures of staff skills, to utilize these data to ensure that staff maintain skills, and to provide training as new techniques and technologies are introduced and as new staff are hired. Each PO will be expected to demonstrate that it has a system of appropriate complexity for keeping track of the skills and competencies of the staff and for effectively identifying and addressing staff training needs. These data should be an integral part of the PO's internal QAPI program that provides continuous feedback on staff performance.

(5) *Non-clinical areas.* The types of outcomes in this area include outcomes related to participants grievances, transportation services, and meals. For example, if a PO finds a high rate of grievances not resolved, the PO might target its activities to improve the grievance process.

We expect POs to use the most current clinical practice guidelines and

professional standards in the development of outcome measures applicable to the care of PACE participants. Continuous improvement is only possible through the identification and use of current information, techniques, and practices. While we are not imposing any specific standards of practice, this requirement establishes the expectation that the PO will utilize the current clinical and professional standards as a routine part of its daily operations.

In addition, we included a requirement that the PO must meet minimum levels of performance on standardized quality measures that will be established by CMS and the SAA and which are specified in the PACE program agreement. For example, we require all POs to achieve at least 80 percent flu immunization rate for their PACE participants. If a PO fails substantially to meet these specified requirements, the continuation of the PACE program agreement may be conditional on the execution of a CAP, or alternatively, some or all further payments for PACE program services may be withheld until the deficiencies have been corrected. We are not establishing minimum performance standards in this regulation. Rather, we will establish minimum performance standards in the program agreement based on analysis of available data sets that are applicable to PACE participants.

We also added a requirement that the PO take actions to ensure the accuracy and completeness of all data used for outcome monitoring. A data-driven QAPI program must be based on accurate data. The regulations require that POs set up mechanisms to check for the accuracy, timely collection, and completeness of all data.

Comment: One commenter described the efforts of the Performance Measure Workgroup lead by the NPA in 1999, which reviewed draft performance measures previously developed as a part of the NPA accreditation project. The final core set of 15 measures were accepted by the POs and States as measures valuable to track. This commenter recommended that CMS adopt these 15 measures or allow the States to negotiate quality measures with POs and CMS as part of the PACE program agreement.

Response: We believe that the decision to use outcome measures in addition to the five noted in § 460.134 is one that that a PO is in the best position to make. If a PO believes that tracking a specific outcome measure will benefit its participants and improve the level of service or the delivery of service, we would expect the organization to identify and collect information that will support its use.

Comment: One commenter asked when it will be known how the quality data, referred to in the 1999 interim final rule, will be collected by CMS and what the specific quality measures will be. The commenter also questioned how POs can be expected to comply with the PACE regulation prior to implementation of the OBCQI program minimum requirements for QAPI program.

Response: In 2001, we established requirements for submission of Data Elements for Monitoring, which is included in the PACE program agreement under Appendix L. The program agreement can be located at *http://www.cms.hhs.gov/PACE.* As discussed in more detail in Subpart L of this final rule, POs are required to submit the Data Elements for Monitoring quarterly via the Health Plan Management System (HPMS). POs are expected to collect, analyze, and track data from the five outcomes measures required in § 460.134, the Data Elements for Monitoring, and any other outcome measure where an identified improved performance will benefit their participants.

Comment: A commenter questioned whether levels of performance will vary by program based on such factors as the program's age, its enrollees' characteristics, its specific service model, and unique characteristics of the service area.

Response: As in other types of health care facilities, the participant population in PACE sites varies. These differences should not affect the QAPI process but may determine what performance indicators (that is, adverse patient events, satisfaction, wound healing, etc.) a PO uses to identify areas requiring continuous quality assessment and performance improvement.

Comment: One commenter supported CMS's plan, as explained in the 1999 interim final rule (64 FR 66259), not to impose standardized data collection requirements by implementing OBCQI, pending the outcome of work by CHSPR. The commenter also supports CMS continuing to work with States to collect data to be used in the development and implementation of outcome measures that would allow comparison between varied types of programs serving individuals with like needs as well as with cross-site comparison. Other commenters indicated that the application of numerous other data collection instruments such as those noted in the Preamble of the interim final rule, that is, the MDS, OASIS, DataPACE, etc., could divert resources from providing services to PACE enrollees.

Another commenter expressed concern that POs will be unduly subjected to data reporting and quality assessment requirements exceeding those imposed on other Medicare provider types. The commenter indicated it would be better to condense the data collection responsibilities of the PACE provider and establish a core set of minimum data and reporting requirements.

Response: We are concerned that specifically mandated measures such as the OBCQI may compromise the discretion of POs to use other assessment tools that may be more appropriate for their settings. At this time, CMS does not have any plans to establish a minimum data set for PACE. As stated in previous responses, we are not requiring POs to comply with the OBCQI system in this final rule. However, we believe some structure for quality-related data collection and reporting is necessary. We expect POs to exercise flexibility in determining the most appropriate methods and instruments for their participant caseloads. Those POs that have experience with data sets should be able to manage the data needs of their QAPI program.

We recognize that in some States, POs are already subject to OASIS reporting requirements because they are licensed as home health agencies and must comply with OASIS requirements. It was not our intent to subject POs to more reporting requirements than other providers. However, as more States develop specific licensure requirements for PACE, this reporting burden will be greatly reduced. We also recognize that some POs have experience in utilizing the draft performance measures developed by the NPA Performance Measure Workgroup. Although we are not requiring that POs use the OBCQI nor submit the COCOA–B data at this time, for POs still searching for guidelines to develop or improve their assessment tools or quality enhancement, the COCOA–B is available at *http://www.cms.hhs.gov/QualityInitiativesGenInfo.*

The commenters may have misunderstood the preamble discussion of QAPI in the 1999 interim final rule. We stated that the CHSPR was examining existing CMS data instruments such as MDS, OASIS, DataPACE and FIM for data items, which may be pertinent for PACE. We did not intend to imply that POs would have to comply with these other CMS data sets. However, States have differing requirements for PACE licensure and

with licensure and if the State requires a PO to be licensed as several provider types the PO would be responsible for the reporting requirements of each of the licensed provider types.

Comment: One commenter requested information about CMS's plan for working with States to establish outcome measures and minimum levels of performance.

Response: At this time, we have no specific plans to establish additional outcome measures or minimum levels of performance beyond the data elements for monitoring which were established in 2001 and are included in the program agreement as Appendix L. State licensure requirements are based on the State's designation of PACE as a particular provider type. The State designation determines the State and Federal requirements, which may include outcome measures or minimum levels of performance.

We believe that State licensure requirements together with QAPI program requirements and our reporting requirements related to the data elements for monitoring are sufficient to ensure quality care for PACE participants without being excessively burdensome for the POS. In 2001, we established the Data Elements for Monitoring. POs are required to submit quarterly data on each of the following 9 elements:

1. Routine Immunization
2. Grievance and Appeals
3. Enrollments
4. Disenrollments
5. Prospective Enrollees
6. Readmissions
7. Emergency (unscheduled) Care
8. Unusual Incidents for Participants and the PACE site (to include staff if participant was involved)
9. Deaths

Final rule actions:

This final rule will finalize § 460.134 as published in the 1999 interim final rule.

Section 460.136 Internal QAPI Activities

In § 460.136, we require that the PO must use a set of outcome measures to identify areas of good or problematic performance and must take actions targeted at reinforcing or improving care based on these outcome measures.

The PO also must incorporate any actions that result in performance improvement into its standards of practice for the delivery of care. A method of periodically tracking performance to assure that any improvements are sustained over time must also be incorporated in the program. The PO must use its own experience from its performance improvement program to change care behaviors and to ensure that these behaviors are sustained.

We require the PO to set priorities for performance improvement, considering the prevalence and severity of identified problems and giving priority to improvement activities that affect clinical outcomes. However, any identified problems that directly or potentially threaten the health and safety of participants must be corrected immediately. Prioritizing areas of improvement is essential to ensure consistency in the quality of care furnished over time. Conditions that may threaten the health and safety of participants must be immediately and directly addressed when they are identified.

Similar to the Protocol, we require the PO to designate an individual to coordinate and oversee implementation of QAPI activities. The purpose of this requirement is to ensure that the PO designates responsibility for a QAPI plan and the various activities resulting from this plan. Also, this individual is responsible for ensuring that all team members, PACE staff, and contract providers are aware of the various quality QAPI activities.

We require that the PO ensure that all team members, PACE staff, and contract providers are involved in the development and implementation of the QAPI activities and are aware of the results of these activities. The process of service delivery in PACE requires the team to identify participant problems, determine appropriate treatment objectives, select interventions and evaluate outcomes of care on an individual participant basis. The IDT is in a unique position to provide PACE management with structured feedback on the performance of the PACE program and suggest ways in which performance can be improved. Thus, we expect the PO to make full use of the IDT and other staff in contributing to its internal quality improvement program.

Finally, consistent with the Protocol, we require the PO to encourage PACE participants and caregivers to be involved in QAPI activities, including providing information about their satisfaction with services. One of the best sources of information about the strengths and weaknesses of a program is from the users of the program. In this case, it is important for PACE programs to get feedback from both PACE participants and caregivers to help identify areas that need improvement.

Comment: Many commenters expressed support for the use of an OBCQI system.

Response: We thank the commenters for their support although we are not requiring POs to comply with a specific OBCQI system at this time.

Comment: A commenter pointed out that the QAPI coordinator has a similar function similar to the medical director with regard to quality. The commenter asked if one person could hold both positions.

Response: The medical director has responsibility for patient outcomes and for the organization's QAPI program. It is the PO's choice to determine that the medical director will serve as the QAPI coordinator. The coordinator's function is to coordinate and oversee the implementation of quality assessment and performance improvement activities. We envisioned the QAPI coordinator as an individual other than the medical director. The QAPI coordinator would be responsible for day-to-day quality issues, collecting data, analyzing data, detecting trends, coordinating IDT involvement in QAPI activities, and compiling comments related to participant/caregiver satisfaction and concerns.

Final rule actions:

This final rule will finalize § 460.136 as published in the 1999 interim final rule.

Section 460.138 Committees With Community Input

Consistent with the Protocol, we require that the PO develop a committee(s) with community input to (1) evaluate data collected pertaining to quality outcome measures, (2) address the implementation of and results from the QAPI plan, and (3) provide input related to ethical decision-making including end-of-life issues and implementation of the Patient Self-Determination Act. Through this committee, the PO will be able to receive guidance regarding its QAPI program and the ethical issues faced by POs.

Comment: One commenter disagreed with the requirement, stating that it does not seem reasonable or necessary, for a small PO to be required to involve community members in one or more committees to evaluate data from the quality outcomes measures and to address implementation of the organization's QAPI plan. The commenter indicated that it should be sufficient for the SAA and CMS to evaluate the QAPI data and plan implementation on behalf of the enrollees and community.

Response: The requirement for a PO to establish committee(s) with community input was adopted from the Protocol. Section 1894(f) of the Act

requires that the Secretary ''* * * incorporate the requirements applied to PACE demonstration waiver programs under the PACE protocol.'' The use of community input is contained in that protocol. Our intention is to provide a participant protection through community involvement in the oversight of participant satisfaction and QAPI activities.

Final rule actions:

This final rule will finalize § 460.138 as published in the 1999 interim final rule.

Section 460.140 Additional Quality Assessment Activities

We require that POs participate in periodic, external quality improvement reporting requirements as may be specified by the CMS or the SAA. Examples of participation in an activity include the reporting of data items for outcome measurement purposes, participation in the survey process, and participation in a CMS-directed national quality improvement project.

Comment: One commenter asked when CMS would provide the ''external quality assessment and reporting requirements.''

Response: The only quality assessment reporting that we currently require is the Data Elements for Monitoring.

Final rule actions:

This final rule will finalize § 460.140 as published in the 1999 interim final rule.

Subpart I: Participant Enrollment and Disenrollment

The purpose of subpart I is to establish the requirements for enrollment and disenrollment of a PACE participant. We received a large number of comments related to enrollment and disenrollment in PACE.

Section 460.150 Eligibility To Enroll in a PACE Program

In accordance with sections 1894(a)(5) and (c)(1) and 1934(a)(5) and (c)(1) of the Act, we established § 460.150, to specify the requirements for eligibility to enroll in a PACE program.

Sections 1894(c)(2) and 1934(c)(2) of the Act provide that a PACE program eligible individual must have a health status comparable to the health status of individuals who participated in the PACE demonstration programs. Further, sections 1894(c)(2) and 1934(c)(2) of the Act specify that this determination will be based upon information on health status related indicators (such as medical diagnoses and measures of activities of daily living, instrumental activities of daily living, and cognitive impairment) that are part of the information collected by POs on potential PACE program eligible individuals. This provision was intended to ensure that POs continue to serve patients who are as frail as those served under the PACE demonstration program and will prevent POs from selecting enrollees who need less care and whose care is less costly.

As we explained in the 1999 interim final rule, we examined data extracted from the PACE Fact Book (Second Edition, 1996, prepared by On Lok, Inc., 1333 Bush Street, San Francisco, California, 94109) which provides a portrait of participants in the eleven fully-capitated demonstration programs as of December 31, 1995. Activities of daily living (ADLs) are personal care tasks (bathing, dressing, toileting, transferring, and eating) that a person must be able to perform to be considered independent. A person is considered to have an ADL dependency and a score of ''1'' is assigned, for each of those 5 tasks for which some or full assistance is needed to perform the task. A similar scale measured dependencies in eight instrumental activities of daily living (IADLs), which include meal preparation, shopping, housework, laundry, heavy chores, money management, taking medications, and transportation. The 2710 participants in these 11 sites at the end of 1995 had an average of 2.8 ADL dependencies (varying by site from 2.3 to 3.8) and an average of 7.5 IADL dependencies (varying from 6.9 to 7.9 by site). Additionally, these participants had an average of 7.9 medical conditions (varying from 4.9 to 11.0 by site) and an average number of 4.5 errors or unanswered questions (varying from 2.0 to 6.4) on the Short Portable Mental Status Questionnaire used to evaluate mental functioning.

The PACE Fact Book acknowledges the difficulty of maintaining a valid and consistent data set in a multisite project with sites scattered across the country. However, there are many reasons why the data would be expected to show differences across sites. Although the targeted population for all PACE demonstration programs consisted of individuals who met the NF level of care, the specific criteria used to determine if an individual needs this level of care varies by State. Actual implementation of the PACE program also differs in other ways across sites to reflect the particular community in which the site is located. Furthermore, marketing efforts vary, as do the maturity of the site and particular staffing arrangements. We are convinced that any means of determining whether individuals have a health status comparable to that of participants in the PACE demonstration programs must take into account variances among sites and differences across patients within a site. Therefore, we concluded that we could not develop a tool that would more adequately determine health status comparable to individuals in the PACE demonstration programs than the current criteria used by States to determine if an individual needs a NF level of care.

In determining how best to implement this requirement, we also considered other safeguards against selective enrollment. Sections 1894(c)(3) and 1934(c)(3) of the Act include a requirement that participants be recertified annually as requiring a NF level of care. Under the demonstration program, there was a one-time certification of a participant's meeting the NF level of care. Thus, under the demonstration program, POs could continue to serve individuals who had a short-term need for a NF level of care but whose condition had shown significant improvement. The law's annual recertification requirement ensures that participants will continue to need a NF level of care.

Additionally, we included a requirement that POs must notify CMS and the SAA of enrollment denials. CMS and the SAA can analyze this information to detect selective enrollment.

After weighing both the need to maintain State and organization flexibility to develop programs suitable to the communities in which the POs operate and the implementation of other safeguards against selective enrollment, we believe having a health status comparable to the PACE demonstration programs is inherently equivalent to needing a NF level of care. We are satisfied that applying the NF level of care requirement in conjunction with the other safeguards discussed will minimize selective enrollment while preserving program flexibility; however, we invited comments with regard to other ways to implement this provision.

Additionally, the statute requires that an individual meet any other eligibility conditions imposed under the PACE program agreement. We are aware that under the demonstration program, some PACE sites instituted some other eligibility conditions. For example, some set their minimum age limits higher than 55. However, we do not believe the intent of section 1894(a)(5)(D) of the Act was to allow for modification of the requirements of section 1894(a)(5)(A–C) of the Act, including the age criteria of 55 or older.

Thus, POs may not turn away any otherwise eligible individual who is at least age 55.

In the 1999 interim final rule, we cautioned organizations that these site-specific eligibility requirements are not intended to allow programs to discriminate against individuals with problems such as cognitive deficits, disruptive behavior, or substance abuse. Any site-specific eligibility criteria must be specified in the program agreement. We will not approve criteria that would serve as a way to selectively enroll individuals whose care is anticipated to be less costly or who are thought have easier care needs.

The eligibility requirement specified in § 460.150(c) incorporated the Protocol provision that at the point of enrollment, an individual's condition must be such that his or her health or safety would not be jeopardized by living in a community setting. We recognize that enrollment in the PACE program is not appropriate for everyone who meets the basic eligibility criteria. Determining whether or not an individual's health or safety would be jeopardized by living in the community involves assessing the individual's care support network as well as the individual's health condition. As specified in § 460.152(a)(4), this assessment is done by the PO based upon criteria developed by the SAA and specified in the program agreement.

We indicated in the statutory provisions in sections 1894(i) and 1934(j) of the Act that PACE program eligibility is not contingent upon an individual's eligibility for Medicare or Medicaid.

Comment: Two commenters disagreed with the regulatory requirement permitting enrollment of individuals 55 years of age or older. One commenter requested allowing the age limitation be established at the State's discretion. The other commenter requested more restrictive age targeting criteria which would be consistent with pre-PACE and PACE demonstration programs. This commenter would limit eligibility to those age 65 years old and older.

Response: The age requirement is consistent with sections 1894(a)(5)(A) and 1934(a)(5)(A) of the Act, which defines a PACE program eligible individual as ''55 years of age or older.''

Comments: There were numerous requests for clarification of the State responsibility related to PACE eligibility determinations. Commenters asked who determines NF level of care for PACE applicants who are not Medicaid-eligible.

Response: The SAA is responsible for determining the NF level of care for all PACE applicants, regardless of Medicaid status.

Comment: Four commenters concurred with our interpretation of health status comparable to individuals enrolled in the PACE demonstration programs. One commenter asked about the meaning of the NF certification requirement and if States have the ability to set criteria that would limit enrollment to persons who are more costly or more difficult to care for than persons who meet the State's minimum threshold level for NF level of care.

Response: Section 460.150(b) requires that an individual must meet 3 basic eligibility requirements in order to enroll in PACE. These are: (1) Be 55 years old or older, (2) be determined by the SAA to need the level of care required under the State Medicaid plan for coverage of NF services (that is, the individual's health status is comparable to the health status of individuals who participated in the PACE demonstration programs), and (3) reside in the PO's service area.

If a State establishes that its minimum threshold to qualify for a NF level of care would permit the enrollment of less frail individuals than those who participated in PACE demonstration programs (on a nationwide or State basis), we will approve the use of a more stringent or higher level of care requirement in order to ensure that the PACE permanent providers continue to serve a population that is comparable to those served under the PACE demonstration programs.

Comment: Several commenters requested clarification on the requirement that individuals with neither Medicare nor Medicaid may enroll in PACE. Commenters asked if this requirement was intended to mandate that States provide PACE as a private pay benefit or whether this would be an option. Commenters noted that establishing PACE as a private pay benefit may subject POs to State insurance laws.

Another concern was that the regulation addressed all combinations for premiums except for individuals with neither Medicare nor Medicaid. One commenter requested clarification of premium amounts for non-Medicare and non-Medicaid participants.

Response: Based on sections 1894(i) and 1934(j) of the Act, we believe the Congress intended to permit individuals with Medicare Part A, Medicare Part B, Medicaid, any combination of the above, or none of the above mentioned benefits to participate in PACE. Therefore, § 460.150(d) indicates that a potential participant is not required to be Medicare enrolled or Medicaid eligible. The statute does not specify the premium that may be charged to non-Medicare and non-Medicaid participants. However, in response to inquiring POs, we have indicated they could charge the non-Medicare and non-Medicaid participants the combined Medicare and Medicaid capitation rates as their premium.

Comment: A commenter asked if an individual who met all enrollment criteria, except the ability to live safely in a community setting could be denied enrollment. The commenter asked whether this would be the only condition under which a willing individual could be denied enrollment.

Response: Consistent with the Protocol, the only permitted reason for a denial of enrollment is when a participant's health or safety would be jeopardized by living in a community setting. The criteria used to determine if an individual's health or safety would be jeopardized by living in a community setting are often developed by the SAA and must be included in the PACE program agreement in accordance with sections 1894(c) and 1934(c) of the Act. PACE staff must assess the potential participant to establish that the participant can be cared for appropriately in a community setting and that he or she meets all requirements for PACE eligibility specified in this part. The SAA is responsible for oversight of this process and has ultimate responsibility for the determination. If a PO denies enrollment because based on their assessment, that is, they do not believe the individual can be safely maintained in the community, the PO must notify CMS and the SAA.

Comment: When determining whether an individual can be maintained safely in the community, one commenter asked if we intended to include all possible community settings or merely the one in which the individual resides at the time of application.

Response: The intent of the requirement is that POs consider the individual's residence at the time of application. However, if the individual cannot be maintained safely in their current residence but the PO believes they could live safely in another community setting, the option of moving should be presented to the individual before enrollment is denied.

Comment: Several commenters recommended regulatory revisions that: (1) Provide the SAA flexibility to ensure that selective enrollment is avoided; (2) permit denial of enrollment to those with End-Stage Renal Disease (ESRD) (alternatively, CMS should reconsider a proposed change in financing for

enrollees with ESRD); and (3) specifically exclude conditions prohibited elsewhere in the regulation from being approved as an additional program specific eligibility requirement. Commenters noted that specific mention of important protections against discriminatory exclusion would be beneficial. Lastly, commenters requested that we provide an example of an optional eligibility criterion.

Response: The regulations include several provisions intended to prevent selective enrollment. First, participants must have a health status comparable to the health status of individuals who participated in the PACE demonstration program. This is incorporated into the requirement that eligible individuals must meet the State's NF level of care requirements. If a State establishes that its minimum threshold to qualify for a NF level of care would permit the enrollment of less frail individuals than those who participated in the PACE demonstration program (on a nationwide or State basis), the State may request the use of a more stringent or higher level of care requirements in order to ensure that the POs continue to serve a population that is comparable to that served under the PACE demonstration. Other safeguards include a requirement that participants be recertified annually as requiring a NF level of care as well as a requirement that POs must notify both CMS and the SAA of enrollment denials.

It is the SAA's responsibility to establish the criteria used by the PO in assessing an individual's ability to live safely in the community. These criteria are included in the program agreement. The PO's assessment is used by the SAA in their final enrollment/denial determination. Although we believe that the States will be open to PO assessments regarding a participant's ability to live safely in the community, the decision to permit a denial of enrollment is ultimately delegated to the State. If the PO determines that the individual must be denied enrollment, the PO must inform CMS and the SAA. In addition, the PO is required to inform the individual in writing of the reason for the denial.

We understand individuals with ESRD are among the most frail and complex persons to care for and in the past POs have had reservations about enrolling this population due to additional cost of their care. However, we believe that PACE is a care delivery model well-suited to meeting the needs of this population. Thus, we do not believe that it is appropriate for POs to deny enrollment to individuals solely based on ESRD status.

In January 2005, we implemented a risk-adjusted capitation model exclusively for ESRD. The ESRD CMS–HCC model accounts for the additional costs of providing ESRD patients with the costly and highly specialized care needed. This model is exclusively for ESRD patients and has three categories of ESRD acuity: those that are on dialysis, those that have had kidney or kidney and pancreas transplant(s), and those that have had kidney grafts.

We agree with the commenter's suggestion that any condition that is specifically excluded in statute or regulation not be included in a program agreement as an additional program specific eligibility condition. As all additional program specific eligibility conditions must be approved by CMS and the SAA, we do not believe that additional regulatory language is needed.

Although we have not yet approved any site-specific eligibility requirements, we anticipate that the most likely proposal would be to develop a disease or condition-specific program, such as programs for participants with Alzheimer's disease. Site-specific requirements may not modify the three basic eligibility requirements and may not serve as a way to selectively enroll participants. We will consider other proposals on a case-by-case basis.

Comment: Several commenters asked which IDT members are required to assess the participant to determine the participant's ability to live safely in the community. Another commenter requested that the PO's ability to safely transport a participant be considered in the determination of whether a participant could live safely in the community.

Response: We did not specify particular IDT members that must assess the participant's ability to live safely in the community because we believe that the PO is in the best position to assign this responsibility. It is our expectation that individuals' health condition and their social support system will be considered in their assessment. In addition, as transportation is a major activity, whether to the PACE center, or to off-site providers, we expect this assessment to include the PO's ability to transport individuals safely.

Comment: One commenter requested that for POs located in areas where there are a disproportionate number of Medicaid-only elderly, they be permitted a waiver or modification of the mandate to enroll all individuals meeting the eligibility requirements. The commenter indicated that a PO in this situation will have a serious financial burden from the substantial loss of revenues related to the prohibition from collecting the Medicare capitation amount from these participants.

Response: With implementation of the Part D benefit, all States will have to develop Medicaid rates that vary depending on whether the participant is dually eligible (Medicare and Medicaid eligible) or is a Medicaid-only individual. The costs utilized as the basis for the calculation of the Medicaid rate will vary for these two comparable populations due to service utilization and will result in a higher rate for the Medicaid-only population. Therefore, the Medicaid capitation payment is adjusted to account for the difference in costs between the dually-eligible individual and the Medicaid-only individual. We recognize that an organization may receive more for a dually-eligible participant, due to the receipt of both Medicare and Medicaid capitation payments rather than only the Medicaid capitation for a Medicaid-only participant. However, we believe the Medicaid capitation payments are adequately adjusted to account for the difference in costs, and we are not inclined to grant a waiver of the requirement to enroll the Medicaid-only population.

Final rule actions:

This final rule will finalize § 460.150 as published in the 1999 interim final rule.

Section 460.152 Enrollment Process

We established § 460.152 to specify the PO's responsibility during the intake process and actions required in the event a potential PACE participant is denied enrollment because his or her health and safety would be jeopardized by living in a community setting.

Although we recognize that the intake process must be flexible to meet the needs of POs and potential PACE enrollees, in the 1999 interim final rule, we specified certain steps that must, at a minimum, be included in the process. These are not intended to be sequential steps and may in fact occur concurrently. Potential participants need reliable, accurate information on the PACE delivery system in order to make a rational decision whether to enroll. There is both a legal and an ethical obligation to inform potential participants about how the PO controls and affects the delivery of health care and other services, albeit in full partnership with the participant.

The following discussion describes the information that is made available to the potential participant routinely and upon request. One-on-one assistance is

provided throughout the intake process. In all situations, the information is provided in a culturally competent manner, including providing information in a language understood by the participant.

The most basic disclosure is that all health care services must be received through the PO. Once that disclosure is made and understood by the potential participant, other key disclosures related to what is included within and what is excluded from the PACE program, what costs would be borne by the participant, how to access emergency services, and how the grievance and appeals processes work. Additional information that should be disclosed upon request includes the process that the PO uses to decide that drugs, devices, and procedures are experimental and whether the PO uses a drug formulary.

The uniqueness of the PACE model depends upon the partnership formed between the participant and the IDT. Therefore, a potential participant should also be made aware of how the team works, who is on it, and what choices exist for participant selection of a primary care physician. The participant must also know how the organization provides access to services not provided directly by the IDT. These services may include contractors who furnish specialty services, health care facilities such as hospitals and nursing homes, and providers of home health care. Also, participants may request information regarding whether there are financial incentives to PO staff and contractors that may impact care. Finally, upon request, the following information must be disclosed: Information regarding board certification and other credentialing requirements; clinical protocols; medical practice guidelines, consumer satisfaction survey results; or the results of the organization's most recent Federal or State review.

With regard to specific intake tasks, we did not include the Protocol requirement for a complete assessment by the IDT prior to the denial of enrollment based on health and safety issues. We believe that such a determination can generally be made without a complete IDT assessment. In establishing enrollment requirements, our intent was to clarify, not change, the enrollment process as described in the Protocol.

If a prospective participant is denied enrollment because his or her health or safety would be jeopardized by living in the community, we require the PO to inform CMS and the SAA as well as make the documentation available for review; notify the individual in writing of the reason for the denial; as appropriate, refer the individual to alternative services; and retain supporting documentation of the reason for the determination.

We received the following comments related to the PACE enrollment process.

Comment: Commenters asked if the State review was limited to certifying a potential participant's eligibility for NF level of care. Commenters also asked if the State was prohibited from reviewing other eligibility criteria such as the ability for the potential participant to be maintained safely in the home.

Response: In addition to certifying NF level of care, States are responsible for establishing the criteria used for the PO assessment to determine if an individual's health and safety would be jeopardized by living in a community setting. States are also responsible for oversight of the PO's intake process.

Comment: A commenter asked if Federal financial participation (FFP) is available to States for administrative costs related to the State performing preadmission screening for NF level of care determinations for participants, particularly if they are not Medicaid eligible.

Response: FFP is provided to States for all administrative costs for administering the PACE program. Because the State NF level of care determination is a statutory eligibility requirement for the PACE program, the State may claim FFP for this administrative function regardless of whether the participant is ultimately determined eligible for Medicaid or Medicare.

Comment: Commenters requested we identify which members of the IDT must conduct assessments prior to enrollment.

Response: We have not specified which IDT members must conduct assessments prior to enrollment. We believe the PO is best able to identify staff qualified to perform the assessment to determine whether the participant can live safely in the community and provide a preliminary explanation of the services that an individual would receive from the program. An initial comprehensive assessment as described in § 460.104 must be completed by all members of the IDT promptly following enrollment.

Comment: We received several comments related to denials of enrollment that we believe indicate some confusion regarding the differences between ''withdrawal'' by a participant, ''screen-out'' by the PO when the prospective enrollee does not meet eligibility requirements, and ''denial of enrollment''.

Response: We wish to clarify the difference between ''withdrawal,'' ''screen-out,'' and ''denial of enrollment.''

When a prospective enrollee begins the intake process, the PO must determine whether or not the prospective enrollee meets the three basic eligibility criteria:

(1) Age 55 or older,

(2) Lives in the service area of the PO, and,

(3) Requires the State's NF level of care.

- If the potential enrollee does not meet any of these three basic eligibility criteria, we consider the result to be a ''screen-out'' by the PO.
- If the prospective enrollee meets the three basic eligibility criteria but decides not to enroll in the PACE program, we consider the enrollee's action to be a ''withdrawal.''
- If the potential enrollee meets the three basic eligibility criteria, they are then assessed to ensure they can safely live in the community and be provided a preliminary explanation of services that would be provided. If the enrollee then chooses not to enroll, it is still considered a ''withdrawal.'' Neither screen-outs nor withdrawals are required to be reported to CMS or the SAA by our regulations.
- A ''denial of enrollment'' may occur when the person is determined to be unable to live in the community without jeopardizing his or her health and safety. The PO must report this denial of enrollment to CMS and the SAA and provide the individual with a written explanation of the denial of enrollment. Consistent with the Protocol, the only permitted reason for a denial of enrollment is that living in a community setting would jeopardize an individual's health and safety.

Comment: Commenters asked about the purpose of notifying CMS and the State of each denial of enrollment, and how this notification was to occur. We were also asked if the intent of reporting a denial of enrollment is to communicate the presence of an ''at risk'' individual living in the community, for which the State already has established reporting requirements and protocols for addressing such situations. Commenters also asked if potential participants could appeal denials of enrollment.

Response: The purpose for notifying CMS and the SAA of each enrollment denial is to prevent selective enrollment by the PO. We believe this reporting is another participant protection preventing the practice of enrolling those individuals with less expensive care needs or implementing

discriminatory practices. The CMS requirement is fulfilled through the quarterly HPMS reporting. The SAA is responsible for the oversight of the denial process and may specify additional reporting requirements.

Denials of enrollment are may be appealed by potential participants through the State fair hearing process, and this process is applicable for all enrollment denials, regardless of the participant's Medicare and Medicaid status.

Comment: Two commenters recommended that we modify requirements to explicitly permit qualified M+C (now MA) enrollees to disenroll from MA at any point in the year for the purpose of enrolling in PACE.

Response: Medicare has an operational process called the Special Election Period (SEP) which allows Medicare managed care enrollees to disenroll from MA plans at any time in order to enroll in PACE. The SEP for PACE is in the Medicare Managed Manual, section 30.4.4., and can be located on the CMS Web site at *http://www.cms.hhs.gov/manuals/downloads/mc86c02.pdf*. Moreover, after disenrolling from PACE, under the SEP, individuals are allowed two months to enroll in an MA plan or revert to the original Medicare program. As SEPs are an operational practice of the MA program, we do not believe it is appropriate to include SEP provisions in PACE regulations.

Comment: One commenter recommended that the regulation be revised to require POs to explain to potential enrollees which services or benefits are excluded and how the PACE service delivery model differs from the other service alternatives.

Response: The intake process is an extensive and interactive activity between the PO, the participant and their family or caregiver. During these encounters the PO staff explains PACE, what it encompasses and the differences between PACE and other service delivery alternatives including what services generally are not covered. The PACE benefit includes all Medicare services, all Medicaid services, and services the IDT determines is necessary for a particular participant. Therefore, we believe regulatory language requiring POs to provide information on excluded services would be inappropriate because PACE services are participant-specific and excluded services for one participant may become required services for another participant.

Comment: One commenter recommended that the information supplied to prospective participants include a review of post-eligibility treatment of income, which was not expressly included in the 1999 interim final rule.

Response: Although not specified in this section of the regulation, we require that information regarding post-eligibility treatment of income is included in the enrollment agreement (see § 460.154(g).

However, we agree with the commenter and as an additional participant protection, we are adding a requirement to § 460.152(a) that POs review post-eligibility treatment of income with prospective enrollees.

Comment: Commenters asked if the State could delegate review of denials of enrollment and review of proposed involuntary disenrollments to local departments of social services.

Response: The PO must provide written notification to individuals denied enrollment. We note that a denial occurs when an individual meets the basic eligibility criteria of age, living in the service area and requiring NF level of care but is determined to be unable to live safely in the community. The SAA is ultimately responsible for oversight of this process and for prior review of involuntary disenrollments. While the SAA can delegate these activities, the SAA must maintain adequate and appropriate oversight and review of any delegated activities/responsibilities.

Final rule actions:

In this final rule, we are adding a requirement that POs review post-eligibility treatment of income with prospective enrollees.

Section 460.154 Enrollment Agreement

While the program agreement contains the specific enrollment and disenrollment procedures to be followed by the PO, in § 460.154, we specify general requirements, which must be met by all POs. Although the statute is silent as to any general enrollment requirements, it requires that the regulations should incorporate, to the extent possible, the requirements applied to the PACE demonstration programs under the Protocol. Thus, we adopted the Protocol enrollment and disenrollment provisions with the exceptions noted below.

We removed the reference to the Member Handbook because we found the distinction between the Member Handbook and the enrollment agreement to be confusing. We define the minimum information that must be included in the enrollment agreement to incorporate those materials that would generally be expected to be included in a Member Handbook. Although some POs may use a cover sheet to obtain the participant's signature and a ''handbook'' to provide the required information, the cover sheet alone does not constitute the enrollment agreement and must be accompanied by the additional minimum information specified when provided to the participant.

In the 1999 interim final rule, we emphasized that an individual who accepts PACE as his or her sole source of services could not then make an election of hospice care under section 1812(d) of the Act and 42 CFR 418.24 or section 1905(o)(2) of the Act. However, hospice-type services are available from the PO as the PACE model of care is designed to furnish a continuum of services which meet health care needs. We included a requirement that the enrollment agreement include notification that Medicaid recipients and individuals dually-eligible for Medicare and Medicaid enrolled in PACE are not liable for any premiums, but they may be held liable for any applicable spenddown liability under 42 CFR 435.121 and 435.831 and any amounts due under the post-eligibility treatment of income process under § 460.184.

We also included a requirement for the enrollment agreement to include information on the consequences of subsequent enrollment in other optional Medicare or Medicaid programs following disenrollment from PACE. This provision was intended to ensure that participants are informed in advance of conditions that might apply if they are disenrolled from PACE and elect, for example, to enroll in another managed care plan.

We added a requirement that any changes to the information contained in the enrollment agreement must be provided to the participant in writing and fully discussed with the participant and his or her representative or caregiver. We believe it is essential that all participants are made aware of any changes in this information in order to protect and exercise their rights.

Comment: We received four comments related to the enrollment agreement. One commenter expressed concern that in § 460.154(h) our requirement that the enrollment agreement contain a notice that a Medicare participant may not disenroll from a PACE program at a Social Security office seems likely to create confusion and could be more appropriately handled by proper education of Social Security Administration staff.

Response: Social Security Administration staff are unable to make an eligibility determination for PACE enrollment. The PO and SAA make the required determinations that a prospective PACE enrollee meets the State's NF eligibility criteria and can be safely cared for in the community.

Because most Medicare beneficiaries are familiar with the Social Security office in their community as the place where they signed up for their Social Security and Medicare benefits, it is reasonable to assume that Medicare beneficiaries would think that the Social Security office is the logical place to enroll or disenroll from PACE. We included this requirement in our regulations to ensure that all PACE participants understand that, unlike other Medicare benefits, they cannot enroll in or disenroll from PACE at a Social Security office.

We are clarifying this requirement by revising the regulatory language to state that enrollees may not enroll or disenroll at a Social Security office.

Comment: Two commenters requested we modify § 460.154(k) to require POs to include in the enrollment agreement all services that are covered and not covered through the PACE providers.

Response: We disagree with the commenters; PACE services are participant-specific as determined by the IDT and specified in the participant's plan of care. Therefore, identifying covered and non-covered services could be misleading and potentially confusing for participants and their family or representative.

Comment: One commenter requested we modify § 460.154(t) to specify that the enrollment agreement contain the signature of the applicant or his or her designated representative, and the date.

Response: We agree with this commenter, and are amending § 460.154(t) to include ''or his or her designated representative'' to sign the enrollment agreement.

Final rule actions:

In this final rule we are revising:

- § 460.150(h) by clarifying that individuals may not enroll or disenroll at a Social Security office.
- § 460.154(t) to read ''The signature of the applicant or his or her designated representative and the date.''

Section 460.156 Other Enrollment Procedures

We established this section to specify the documentation that must be provided to a PACE participant who signs an enrollment agreement. Specifically, a PACE participant must be given a copy of the enrollment agreement, a PACE membership card, emergency information to be posted in his or her home which includes the phone number of the PO, and when applicable, stickers for the PACE participant's Medicare or Medicaid cards (or both) that indicate the individual is a PACE participant and include the phone number of the PO.

In addition, the PO must submit participant information to CMS and the SAA in accordance with established procedures.

We also included a requirement that, in the event there are changes in the enrollment agreement information at any time during the participant's enrollment, the PO must provide to the participant an updated copy of the information and explain the changes to the participant and their representative in a manner they understand.

Comment: One commenter requested clarification of the ''established procedures'' POs are required to use for submitting enrollment information to CMS and the SAA.

Response: The ''established procedures'' refers to CMS and SAA procedure for enrollment and payment. CMS and the SAA notify the PO how to submit information regarding enrollment.

Final rule actions:

This final rule will finalize § 460.156 as published in the 1999 interim final rule.

Section 460.158 Effective Date of Enrollment

Consistent with the Protocol, this section established that a participant's enrollment in the PACE program is effective the first day of the calendar month following the date the PO receives the signed enrollment agreement.

Comment: Three commenters indicated that unless we require that PACE enrollment be effective on the same date for both Medicare and Medicaid, there is the potential that a participant could be enrolled in Medicare a month earlier than they are enrolled in Medicaid. The commenters indicated that as written, this requirement is problematic for States that set the enrollment date for PACE on a day other than the first day of the month following the date of the signed enrollment agreement. Commenters indicated that potential PACE participants may very likely be in situations where they need to enroll before the beginning of the next month. The commenters explained that since capitation payment is tied to pull down dates for the Medicaid Management Information System and the effective date of enrollment impacts the effective date of the capitation payment, they need flexibility in establishing the effective date for Medicaid enrollment, and should be permitted to adjust that first month's capitation payment.

Response: Our regulation at § 460.158 requires that a participant's enrollment in the program is effective on the first day of the month following the date the PO receives the signed enrollment agreement. This is applicable for all participants regardless of Medicare or Medicaid eligibility. Therefore, the effective date for Medicare and Medicaid payment will be the same, even if the participant is eligible for both programs.

In an instance where there is a lag time between the signing of the enrollment agreement and its effective date, the PO may choose to provide services to the newly signed enrollee. However, any services provided are not considered ''PACE'' services until the effective date of enrollment. Therefore, services would only be covered to the extent an individual's existing health plan (for example, Medicare fee-for-service or Medicaid) provided the coverage. Should the PO choose to provide services outside the individuals existing benefits package prior to the effective date of enrollment in PACE, the PO would be liable for the cost of providing these services.

A State may choose to pay the PO for services for a participant prior to the effective date of enrollment whether on a fee-for-service or pro-rated capitated basis. However, the participant's effective date of enrollment as a PACE participant is not established until the first of the following month.

Comment: A commenter asked what the PO's responsibilities are for covering nursing home care in the event that a participant's condition necessitates such placement before the effective date of enrollment.

Response: Section 460.150(c) requires that at the time of enrollment into PACE, an individual must be able to live in a community setting without jeopardizing his or her safety. If a participant's condition or situation changes prior to the effective date of enrollment such that they can no longer be maintained safely in the community, the PO, with SAA concurrence, may deny the enrollment. Since the enrollment was never implemented, there is no need to involuntarily disenroll the enrollee. However, once the enrollment status has become effective, a participant may not be disenrolled due to health status.

Final rule actions:

This final rule will finalize § 460.158 as published in the 1999 interim final rule.

Section 460.160 Continuation of Enrollment

In this section, we specify that a PACE participant's enrollment continues until death regardless of changes in health status unless the PACE participant voluntarily disenrolls in accordance with § 460.162 or is involuntarily disenrolled in accordance with § 460.164.

We incorporated the statutory requirement contained in sections 1894(c)(3) and 1934(c)(3) of the Act for an annual recertification of need for NF level of care. We believe that the law contemplated that reevaluations would be conducted by the SAA for all participants, whether Medicaid eligible or not.

The statute provides that the annual recertification may be waived for those individuals for whom the SAA determines there is no reasonable expectation of improvement or significant change in condition. As a waiver may not be granted until the first annual recertification is due, a participant for whom this requirement is waived would have been receiving services under the PACE program for at least a year. We believe it is unlikely, especially in view of the average age and frailty of PACE participants, that a person who has not shown significant improvement in the past year would show enough improvement in the future to no longer need a NF level of care. The law permits a waiver ''during a period in accordance with regulations'' in those cases where the SAA determines there is no reasonable expectation of improvement. Therefore, we provided in the 1999 interim final rule that such a waiver should be for the life of the participant. However, the reasons for the waiver must be explicitly documented in the medical record. We indicated that we did not provide a mechanism for reinitiating the recertification process once a waiver was granted, and we invited comments on this issue.

Finally, sections 1894(c)(4) and 1934(c)(4) of the Act allow for the continuation, or deemed eligibility, of participants who are determined, through the annual recertification process, to no longer meet the NF level of care requirement but who, in the absence of continued coverage under PACE, would reasonably be expected to again meet the NF level of care within the next 6 months. We indicated that the determination is made by the SAA, which may solicit input from the PACE organization and that the deemed eligibility continues until the next annual recertification. While it is the SAA's responsibility to determine the need for NF level of care, the PO has a detailed knowledge of the day-to-day care and service requirements of the participants and would, therefore, be better able to predict a participant's reaction to the loss of PACE services. We invited comments on whether this responsibility should be shared or carried out solely by either the SAA or the PO.

Comment: Eight commenters supported differing requirements related to continuation of enrollment. The commenters generally agreed with annual recertification of NF eligibility. Half of the commenters supported deeming the annual recertification a State responsibility after working with the PO to make the determination. The remaining commenters viewed deeming a PO responsibility subject to State review or a joint State/PO activity.

One commenter did not support annual recertification, stating that disenrolling a participant from the program penalizes the participant and IDT team for reaching their goals.

Five commenters responded to our request for input regarding whether deemed eligibility should continue until the next annual recertification. They unanimously agreed that the period of deemed eligibility should continue for 12 months until the next annual recertification is due.

Response: With the publication of the 1999 interim final rule and the transition of PACE programs from demonstration programs to permanent provider status, the provisions regarding continued enrollment in the program changed. Under the demonstration program, the NF level of care determination was a one-time certification prior to enrollment and PACE participants were not recertified as needing a NF level of care. While sections 1894(c)(3) and 1934(c)(3) of the Act, implemented a new annual certification requirement, the law balanced this requirement with an important beneficiary protection in the continued eligibility provisions of section 1894(c)(4) and 1934(c)(4) of the Act. The continued eligibility provisions take into account that a participant's condition may have improved such that he or she no longer meets the NF level of care solely due to the services being received from the PACE program. Thus, being disenrolled from the program could result in a decline in which the person quickly needs a NF level of care once again and would be eligible to re-enroll in the program. The continued eligibility provisions at § 460.160(b)(2) avoid this unnecessary and disruptive cycling in and out of eligibility by allowing participants to remain in the program even though they do not currently meet the NF level of care requirement if a determination is made that, in the absence of PACE services, they would reasonably be expected to meet the requirement within the next 6 months.

In the 1999 interim final rule, we solicited comments on whether the determination of continued eligibility should be a responsibility that should be shared or carried out solely by either the State administering agency or the PACE organization. In considering the comments received, and in light of the fact that it is the State's responsibility to determine the need for nursing facility level of care, we have concluded that all States should develop appropriate criteria and implement a process whereby continued eligibility determinations can be made. However, we recognize that the PO has knowledge of the care and service requirements of the individual participants and should be consulted in making the determination of continued eligibility based on these criteria. For this reason, we are revising § 460.160(b)(3)(i) to specify that the SAA must establish criteria, in consultation with the PO, make a determination of deemed continued eligibility based on a review of the participant's medical record and plan of care.

With regard to the comments on annual recertification, we understand the argument presented by the commenter that disenrolling a participant who does not meet the NF level of care at the time of recertification penalizes the participant and the IDT for reaching their goals. However, the annual recertification required at § 460.160(b) is a statutory requirement (sections 1894(c)(2)–(4) and 1934(c)(2)–(4) of the Act). The recertification process is an important safeguard to ensure that PACE programs continue to serve individuals who have a health status comparable to those who participated in the demonstration program. We believe the provisions allowing the waiver of this requirement on a case-by-case basis as well as the use of the deemed continued eligibility provisions provide important flexibility and safeguards for States in administering the program and would not result in penalizing the participant or the PO.

Regarding whose responsibility it is to determine or deem a participant's continued eligibility, we believe that establishing whether a participant meets

the State's criteria for NF level of care is a State responsibility. We believe this activity includes pre-enrollment or post-enrollment eligibility. We also acknowledge that due to the gravity of continued eligibility determinations, the SAAs should solicit input and assistance from the PO in making these determinations, but the SAA retains the ultimate responsibility.

Comment: Several commenters agreed that a mechanism for reinitiating the recertification process once a waiver had been granted was not necessary because waivers would only be granted in cases where the possibility of improvement is extremely remote.

Response: We agree with the commenters and therefore have not developed a mechanism for reinitiating the recertification process once a waiver has been granted.

Final rule actions:

In this final rule we are revising paragraph (b)(3)(i) to clarify that the SAA must establish criteria for use in making deemed eligibility determinations.

Section 460.162 Voluntary Disenrollment

In accordance with sections 1894(c)(5)(A) and 1934(c)(5)(A) of the Act, this section specifies that a PACE participant may voluntarily disenroll from the program without cause at any time. We received no public comments on § 460.162.

Final rule actions:

This final rule will finalize § 460.162 as published in the 1999 interim final rule.

Section 460.164 Involuntary Disenrollment

In accordance with sections 1894(c)(5)(B) and 1934(c)(5)(B) of the Act, we established this section to specify the conditions under which a PACE participant can be involuntarily disenrolled from a PACE program. The Protocol, in Part III, section D.1, describes various circumstances under which a participant may be involuntarily disenrolled.

The statutory language at sections 1894(c)(5)(B) and 1934(c)(5)(B) of the Act provides that a participant may only be involuntarily disenrolled for nonpayment of premiums on a timely basis or for engaging in disruptive or threatening behavior. In our regulations at § 460.164(a)(1), we adopted the requirement that a participant may be involuntarily disenrolled if they fail to pay or to make satisfactory arrangements to pay any premium due the PO after a 30-day grace period.

We also incorporated the following reasons for involuntary disenrollment from the Protocol:

(a) The participant moves out of the PO's program service area or is out of the service area for more than 30 days unless the PO agrees to a longer absence due to extenuating circumstances;

(b) The PO is unable to offer health care services due to loss of State licensure or contracts with outside providers.

We added as a reason for involuntary disenrollment that the PO agreement with CMS and the SAA is not renewed or is terminated. We also incorporated, at § 460.164(a)(4), as a reason for involuntary disenrollment the statutory provision regarding the annual recertification of NF level of care. In all of these situations the disenrollment is not a subjective determination made by the PO but is necessary due to the application of objective criteria.

We did not incorporate the following reasons for disenrollment from the Protocol: the participant refuses to provide accurate financial information, provides false information, or illegally transfers assets. As these situations would affect the determination of Medicaid eligibility, we believe they would actually prevent enrollment in the first place. However, if the individual is already enrolled when these situations occur or are discovered, they may affect the participant's payment responsibility and thus lead to either voluntary disenrollment or involuntary disenrollment based on failure to pay premiums.

In order to incorporate the statutory provision regarding disruptive or threatening behavior, we felt the need to balance two concerns: (1) To protect participants who are exhibiting difficult behaviors from being disenrolled by the PO, and (2) to provide a safeguard for the PO, by permitting them to disenroll a competent but noncompliant participant whose behavior disrupts the organization's ability to furnish adequate services to that individual for reasons beyond the organization's control. Therefore, after consulting with SAAs, we defined a person who engages in disruptive or threatening behavior as:

a. A person whose behavior is jeopardizing his or her health or safety or that of others; or

b. A person with decision-making capacity who consistently refuses to comply with his or her individual plan of care or the terms of the enrollment agreement.

However, in accordance with paragraphs (c)(5)(B)(ii) of sections 1894 and 1934 of the Act, a PO may not involuntarily disenroll a PACE participant on the grounds that the individual has engaged in noncompliant behavior if such behavior is related to a mental or physical condition of the individual unless the individual's behavior is jeopardizing his or her health or safety or that of others. The term ''noncompliant behavior'' includes repeated noncompliance with medical advice and repeated failure to keep appointments.

While we believe this definition provides a necessary safeguard, we are not suggesting that a participant should be disenrolled at the first sign of difficulty. We caution organizations to use this authority only as a last resort when all reasonable remedies (which must be documented in the medical record) have been exhausted.

Based on sections 1894(c)(5)(B)(iii) and 1934(c)(5)(B)(iii) of the Act, we specified that proposed involuntary disenrollments are subject to a timely review and final determination by the SAA prior to the effective date of the proposed disenrollment. This provision protects the participant from being inappropriately disenrolled and provides for the continuation of services until a final determination is made. We invited comments on whether the regulations should specify a timeframe in which the review must be conducted and, if so, what an appropriate timeframe would be.

We received a large number of comments regarding involuntary disenrollment.

Comment: Several commenters requested that we expand the reasons for involuntary disenrollment to include the failure to pay any allowable fees and share of costs including amounts required as part of a participant's spenddown liability and post-eligibility treatment of income amounts.

Response: Sections 1894(c)(5)(B) and 1934(c)(5)(B) of the Act explicitly state that the PO may involuntarily disenroll a participant for only one payment-related issue, which is nonpayment of premiums.

However, CMS has the authority to provide BIPA 903 waivers in instances where the POs are unable to comply with regulatory requirements (see § 460.26). We have approved several BIPA 902 grandfathering requests and BIPA 903 waiver requests regarding this issue. However, to retain flexibility in application of these waivers, we are not expanding the reasons for involuntary disenrollment for non-payment of premiums in this final regulation.

Comment: Three commenters requested that we eliminate the requirement for State review of an

involuntary disenrollment due to failure to pay a premium.

Response: We believe the commenters' concern about the SAA review of a proposed involuntary disenrollment due to failure to pay premiums may be that the process would cause further delay and present a financial hardship for the POs. The intent of this requirement is oversight by the SAA to ensure that the disenrollment documentation reflects adequate grounds for involuntary disenrollment. The review was established as a check in the process to ensure an important participant protection. We are confident the SAAs have established procedures that ensure the State review is completed prior to the effective date of the proposed disenrollment.

Comment: One commenter requested that we include the disruptive or threatening behavior of family members, where they are involved in health care or decisions at the participant's request, as a reason for involuntary disenrollment.

Response: It is not our intention to jeopardize the safety of those providing care. However we expect POs to make every effort to resolve such situations before considering disenrollment. Sections 1894(c)(5) and 1934(c)(5)of the Act specify the reasons a PACE Program eligible individual may be disenrolled, including ''for engaging in disruptive or threatening behavior, as defined in such regulations (developed in close consultation with State administering agencies).''

In consultation with SAAs, we have defined disruptive or threatening behavior in our regulations at § 460.164(b) as including consistent refusal by a competent participant to comply with the plan of care. If PO staff or contractors cannot furnish necessary care because of the threatening behavior of someone other than the participant, then we expect the PO to establish alternative arrangements that would not disrupt the PO's ability to provide adequate services and to include those arrangements in the participant's plan of care. Such arrangements might include providing services at the PACE center, arranging for alternative living arrangements, or obtaining the participant's agreement to control the actions of the caregiver or family member during the time PO staff are on the premises. Should the participant refuse to cooperate with the plan of care and all efforts fail, as a last resort the PO may submit a proposal to involuntarily disenroll a competent participant for refusal to comply with their plan of care, as provided in § 460.164(b). As required by § 460.164(d) and (e), all pertinent documentation must be submitted to the SAA for review before the PO may implement an involuntary disenrollment.

Comment: One commenter agreed that the breakdown in the physician/IDT and participant relationship is not a reason for involuntary disenrollment.

Response: We appreciate the commenters support. We believe that a breakdown in the IDT/participant relationship is an unacceptable reason for involuntary disenrollment and would undermine the participant's right to participate in treatment decisions. Our expectation in this situation is that the PO would work with the participant and the IDT to establish a mutually acceptable resolution. Should the participant remain dissatisfied after the PO attempts to reestablish an acceptable working relationship, it would be the participant's right to voluntarily disenroll. We view this breakdown as an incident the PO would review as a part of its QAPI plan.

Comment: Commenters supported a variety of timeframes for SAA review of involuntary disenrollments. Recommended timeframes included no required timeframe, in a timely manner, 72 hours, up to 30 days (depending on the cause of the disenrollment, especially where the participant's health and safety may be in jeopardy or the participant has not paid their premiums). Commenters suggested that the involuntary disenrollment be deemed approved if the SAA does not respond within a reasonable timeframe.

Response: Our experience to date has been that States have developed adequate procedures and are in a position to know when a particular situation warrants an expedited review. While we understand the concerns behind the suggestion that involuntary disenrollments should be deemed approved if the SAA has not responded within an appropriate timeframe, we are not including this provision in this final rule. We view the State review as an important beneficiary protection and are concerned that a specific timeframe might unduly constrain or limit the State's ability to provide an adequate review. Therefore, we are retaining § 460.164(e) and will require SAA review in a timely manner for involuntary disenrollments.

Comment: One commenter suggested we give the State the authority to consider all relevant evidence in their review of proposed involuntary disenrollment, not to limit review to the sufficiency of reasons shown in the records.

Response: Documentation provided to the SAA by the PO should include all relevant information supporting their reason for initiating an involuntary disenrollment. Our regulations do not preclude the SAA from requesting additional documentation if it feels that the organization has not provided adequately documented grounds for disenrollment.

Comment: One commenter expressed support for CMS' attempt to distinguish between behavior that jeopardizes health and safety and noncompliant behavior. They requested further clarification as to whether a PO may disenroll a participant for noncompliant behavior if the behavior is not related to a mental or physical condition of the participant. The commenter questioned whether noncompliant behavior would be considered disruptive behavior if the participant is competent and the noncompliance was addressed in the participant's care plan.

Response: We note that § 460.164(b) does not distinguish between disruptive behavior and noncompliant behavior, but rather defines noncompliant behavior as disruptive behavior, consistent with the statute. The PO may involuntarily disenroll a participant for noncompliance with their plan of care provided the noncompliance is not related to a mental or physical condition.

Comment: Two commenters requested that we eliminate noncompliance as a reason for involuntary disenrollment. Other commenters were concerned that we unduly expanded the definition of disruptive or threatening behavior to include a competent participant who consistently refuses to comply with his or her individual plan of care or terms of the PACE enrollment agreement.

Another commenter indicated that this type of disenrollment violates the participant's right to refuse treatment. Therefore, they requested that noncompliance be eliminated as a reason to disenroll a participant.

Response: We disagree with the commenters' suggestion that we delete noncompliance as a reason to involuntarily disenroll. We do not believe that a disenrollment based upon noncompliance by a competent participant violates their right to refuse treatment.

The competent participant actively participates in establishing their plan of care, and it is at this juncture that the participant should raise any objections to the components of their plan of care and refuse treatment. At the time the participant refuses the proposed treatment, the IDT should present and discuss other treatment options. If the

participant has issues with the treatment after the establishment of the plan of care, there should be discussion with his or her IDT. Because of the cooperative nature of establishing the plan of care, once the participant has agreed with the plan of care they are committed to following it. If the participant later refuses to comply with the agreed upon plan of care and the IDT and the participant are unable to agree to an alternative treatment, the PO can involuntarily disenroll that participant. We believe that the noncompliant behavior will disrupt the provision of care to the participant and jeopardize their health or safety.

Additionally, potential participants are informed of the terms of the enrollment agreement during the enrollment process and signing of the enrollment agreement indicates the person's willingness to comply with those terms. We believe we must provide this safeguard to allow POs to disenroll competent but willfully noncompliant participants if their behavior disrupts the organization's ability to furnish adequate services and safeguard the participant's health and safety.

Comment: One commenter questioned the requirement that the State review involuntary disenrollments initiated by the PO without respect to the enrollee payer status and asked if the SAA review was considered to be a final determination that can be appealed.

Response: As specified in § 460.164(e), the SAA must review all proposed involuntary disenrollments, regardless of payer status, in order to determine that the PO has adequately documented acceptable grounds for disenrollment. This was one of the issues specifically discussed with the State workgroup in developing the 1999 interim final rule. At that time, the States correctly predicted that this provision would not lead to a major increase in workload. If the State supports the PO's decision to involuntarily disenroll the PACE participant, the participant may pursue an external appeal. States must provide an alternative to the Medicaid State Fair Hearing process for Medicare-only participants because Medicare's independent review entity does not hear involuntary disenrollment appeals.

The SAA review of involuntary disenrollments is a final determination, which would allow a Medicaid-eligible participant to pursue a Medicaid Fair Hearing. POs should contact their SAA for details on their State's Fair Hearing process. Medicaid regulations regarding the State Fair Hearing process are located at 42 CFR 431.200 through 431.250.

Comment: One commenter indicated that there is no need for SAA review of proposed disenrollments due to nonpayment of premiums.

Response: As a participant protection, we believe the SAA should review all involuntary disenrollments, including involuntary disenrollment related to nonpayment or failure to make satisfactory arrangements to pay premiums.

Final rule actions:

In this final rule, we are finalizing § 460.164 as published in the 1999 interim final rule.

Section 460.166 Effective Date of Disenrollment

We require that the PO must use the most expedient process allowed for by Medicare and Medicaid procedures to ensure that the disenrollment date is coordinated between Medicare and Medicaid for participants who are dually eligible for both programs and that reasonable advance notice is given to the participant. In addition, until such time the enrollment is terminated, PACE participants must continue to use PO services and remain liable for any premiums, and the PO must continue to furnish all needed services.

Comment: One commenter recommended that an involuntary disenrollment should not be effective until Medicare and/or Medicaid eligibility has actually been established and alternative providers are available to provide the services in the participant's care plan.

Response: We believe the disenrollment date must be the same for Medicare and Medicaid participants. We intend that no disenrollment would become effective until the participant is appropriately reinstated into other Medicare and Medicaid programs and alternative services are arranged.

Final rule actions:

In this final rule, we are finalizing § 460.166 as published in the 1999 interim final rule.

Section 460.168 Reinstatement in Other Medicare and Medicaid Programs

We established this section to prescribe the PO's responsibility to facilitate a participant's reinstatement in other Medicare and Medicaid programs after disenrollment. We require that the PO make appropriate referrals and ensure that medical records are made available to new providers in a timely manner. In addition, we require that the PO work with the SAA and CMS to reinstate the participant in other Medicare and Medicaid programs for which the individual is eligible.

We received no comments on this section.

Final rule actions:

This final rule will finalize § 460.168 as published in the 1999 interim final rule.

Section 460.170 Reinstatement in PACE

Section 460.170 provides that a previously disenrolled participant may be reinstated in the PACE program. However, we did not adopt the Protocol provision limiting a participant to a one-time-only reinstatement following a voluntary disenrollment. We believe that frail elderly individuals may experience living arrangement changes that take them in and out of a PO's service area and result in unavoidable disenrollments. However, we included the Protocol provision that a PACE participant may be reinstated in the PACE program with no break in coverage if the reason for the disenrollment was failure to pay premiums and the PACE participant pays the premium before the effective date of the disenrollment.

Comment: One commenter recommended that the State be granted the flexibility to set criteria for multiple re-enrollments of participants after involuntary disenrollment. Two other commenters indicated that it would be appropriate to restrict the number of times an individual may be reinstated.

One commenter suggested a one-time reinstatement or, alternatively, that the PO be granted the discretion to determine whether to reinstate a participant multiple times based upon the unique circumstances of the previous disenrollment. The commenter recommended that the PO identify the circumstances for reinstatement and establish policies and procedures prior to implementation of the PACE program.

Response: We believe the decision to allow participants the ability to be reinstated repeatedly is appropriate in some cases, especially for participants who voluntarily disenroll. Therefore, we are not inclined to limit the number of allowable reinstatements. However, if a participant has been involuntarily disenrolled, and wishes to re-enroll in the PO, the issue that caused the involuntary disenrollment must be resolved, before the participant can be reinstated.

Final rule actions:

This final rule will finalize § 460.170 as published in the 1999 interim final rule.

Section 460.172 Documentation of Disenrollment

We established § 460.172 to specify that a PO must have procedures to document the reasons for all voluntary and involuntary disenrollments, make the documentation available for review by CMS and the SAA, and use the information on voluntary disenrollments in the PO's internal QAPI plan.

Comment: One commenter recommended that the information on all disenrollments be used in quality assurance.

Response: It is our intent to use only the voluntary disenrollment information in QAPI as these disenrollments are more likely to be impacted by participant impressions of the quality of their care and their satisfaction. Involuntary disenrollment is not usually initiated because a participant is unhappy with their care but rather the participant has not met their responsibilities to the PO. Therefore, we only require that voluntary disenrollment information be used in QAPI.

Final rule actions:

This final rule will finalize § 460.172 as published in the 1999 interim final rule.

Subpart J: Payment

The 1999 interim final rule described Medicare payment as follows. Sections 1894(d) and 1934(d) of the Act requires that payment to a PO be based on a capitation amount. The Medicare capitation amount is based upon the M+C (now MA) payment rates established under section 1853 of the Act. The Medicaid capitation amount is negotiated between the State and the PO.

The following basic principles distinguish the PACE financing model.

- Obligation for payments is shared by Medicare, Medicaid, and individuals who do not participate in Medicare and Medicaid.
- Medicare, Medicaid, and private payments for acute, long-term care, and other services are pooled.
- The capitation rates paid by Medicare and Medicaid are designed to result in cost savings relative to expenditures that would otherwise be paid for a comparable NF-eligible population not enrolled under the PACE program.
- The PO accepts the capitation payment amounts described in this section as payment in full from Medicare and Medicaid.

Section 460.180 Medicare Payment to PACE Organizations

Section 1894(d)(1) of the Act requires that POs be paid monthly payments of a capitation amount for each eligible enrolled PACE program individual, in the same manner and from the same sources as payments that are made to a M+C (now MA) organization under section 1853 of the Act. In accordance with section 1894(d)(2) of the Act, PACE capitation amounts are based upon payment rates established for the purposes of payment under section 1853 of the Act and shall be adjusted to take into account the comparative frailty of PACE enrollees and other factors the Secretary determines appropriate. Payments of a capitated amount are to be adjusted in the manner described in section 1853(a)(2) or section 1876(a)(1)(E) of the Act; that is, retroactively adjusted to take into account any difference between the actual number of participants and the estimated number of participants to be enrolled in determining the amount of the advance payment.

Consistent with the basic methodology applied to M+C (now MA) plans at the time of publication of the 1999 interim final rule, Medicare paid monthly payments based on an interim per capita rate per participant. Under that methodology, separate rates were established for Part A and Part B. The PO received payments based on each participant's entitlement to Medicare Part A and Part B. Therefore, if the participant was entitled to Part A benefits, but was not enrolled under Part B, the PO received only the monthly capitation rate established for Part A. For Medicare Part A-only participants who are also eligible for Medicaid, the State is obligated to pay Medicare Part B premiums under section 1902(a)(10) of the Act. Therefore, POs needed to verify at the time of enrollment whether the participant was dually eligible for Medicare and Medicaid and whether the participant has Medicare Part A and Part B. As required in 1999 and still currently required, payment for a participant begins upon the effective date of enrollment (see § 460.158).

Under section 1894(d)(2) of the Act, the capitation amount should be adjusted to take into account the comparative frailty of PACE participants and other factors the Secretary determines to be appropriate. As explained below, a frailty factor and an adjustment factor for PACE participants who have ESRD were applied to the appropriate demographic payment rate.

Under the PACE demonstration program, the Medicare capitation rate for each PO was calculated using CMS' standard Adjusted Average Per Capita Cost (AAPCC) methodology (also referred to as the demographic rate methodology) developed in accordance with the 1982 Tax Equity and Fiscal Responsibility Act to pay risk-based health maintenance organizations for Medicare enrollees. However, instead of using the usual adjustments for age, sex, welfare status, institutional status, employment status, and disability, there was one frailty adjuster of 2.39 for all PACE participants except those diagnosed with ESRD. Therefore, in accordance with 1894(d)(2) of the Act, as of January 1, 1998, the Medicare capitation rate paid to PACE demonstration programs was calculated using the M+C (now MA) AAPCC rates with an additional frailty adjuster of 2.39 to account for the higher costs related to caring for this frail population.

Subsequently, the BBA mandated M+C (now MA) plans to implement a risk adjusted methodology starting January 1, 2000. However, PACE payment continued to be based on the frailty adjusted demographic rate methodology until refinements to the risk adjustment methodology specific to PACE were completed. Implementation of the risk adjustment payment methodology with PACE specific adjustments began January 1, 2004.

Changes to PACE payment methodology are proposed in the annual Advance Notice of Methodological Changes for Medicare Advantage Payment Rates (Advance Notice), along with changes to MA methodology. After publication of the Advance Notice, the public is given a two-week period to provide comments. The final changes are described in the Announcement of Medicare Advantage Payment Rates (Announcement). The Announcement is published the first Monday in April, and the Advance Notice is published 45 days before that. Any changes that have been made to PACE payment methodology since the publication of the 1999 proposed rule were dealt with through that process.

Many of the changes to the PACE payment methodology since 1999 are based on the January 1, 2004 implementation of the CMS-Hierarchical Conditions Category (CMS–HCC) based MA risk adjustment payment methodology with refinements for PACE. These changes are reflected throughout § 460.180. The risk adjustment payment methodology, history and authority are initially described in the Advance Notice and

Announcement for calendar year 2004, with the refinements described in subsequent Advance Notices and Announcements. Advanced Notices and Announcements can be found on the CMS Web site at *http://www.cms.hhs.gov.*

The purpose of risk adjustment is to use health status indicators to improve the accuracy of payments and establish incentives for plans to enroll and treat less healthy Medicare beneficiaries. The risk adjustment model was phased-in for all MA plans. The gradual phase-in provided a safeguard against abrupt changes in payments and effects related to risk adjustment. However, due to the additional refinements that were made to the PACE payment, the implementation of the risk adjustment phase-in was delayed for PACE. The phase-in schedule for PACE will lag the phase-in of MA risk adjustment by one year. The additional refinements to the risk adjustment model for PACE, mentioned above, surrounded the frailty adjuster. A deferral was needed so that CMS could study the applicability and impact of risk adjustment on capitated payments for the frail elderly.

On January 1, 2004, PACE began the phase-out of the demographic payment methodology adjusted by the 2.39 frailty adjuster and phase-in of the new MA risk-adjusted payment methodology. To ease the transition, the rates will blend a gradual decreasing amount of the demographic payment methodology adjusted by the 2.39 frailty adjuster and a gradual increasing amount of the new MA risk-adjusted payment methodology. The blended phase-in rates for PACE are provided in the following table.

Calendar year	Percent frailty adjusted demographic rate (AAPCC times 2.39)	Percent risk adjusted rate (CMS–HCC times frailty score)
2004	90	10
2005	70	30
2006	50	50
2007	25	75
2008	0	100

The demographic payment methodology referenced above, which is the payment methodology that is being phased out, was used at the time of the interim final rule in 1999. Under that methodology, the Medicare capitation rate paid to PACE demonstration programs was calculated using the MA AAPCC rates with an additional frailty adjuster of 2.39 to account for the higher costs related to caring for this frail population.

As discussed above, section 1894(d) of the Act mandated that the Medicare capitated payments to POs be based on MA rates and be adjusted to account for the comparative frailty of PACE enrollees. The CMS–HCC payment approach described herein is a further refinement to the risk adjustment payment methodology to ensure that capitated payments to POs that serve frail community-based populations are accurate.

The CMS–HCC payment model described above is the basis of the new PACE payment. The individual participant risk score for MA and PACE is calculated using the appropriate CMS–HCC model (community, long-term institutionalized, ESRD or new enrollee) based on the participant's status. Risk adjustment explains the future Medicare expenditures of individuals based on diagnoses and demographics. The risk score is computed for each participant for a given year and applied prospectively. The risk score generally follows the beneficiary for one calendar year. But risk adjustment does not explain all of the variations in expenditures for frail community populations. We determined that it was appropriate to augment risk adjustment with a frailty adjustor for functionally impaired community residents in PACE. The purpose of the PACE frailty adjustment is to predict the Medicare expenditures of community populations with functional impairments that are unexplained by risk adjustment. Therefore, we developed a payment approach that adjusts the risk adjustment payment to an organization according to the frailty of the organization's enrollees. To clarify, the PACE frailty adjustment currently is made in addition to the risk adjustments made under the MA payment methodology.

The PACE frailty adjustment is based on activities of daily living (ADLs), a proxy for functional impairment, and applies only to community-based and short-term institutionalized participants (that is, the frailty adjustment for long-term institutionalized participants is zero).

The prospective frailty adjustment was designed to adjust for the average difference between the predicted and actual expenditures for each group. The prior year's functional impairment data are used to predict the next year's payment adjustment. Functional data are submitted to CMS, where they are calculated to establish the PO's frailty score, which is then applied to each participant's risk adjusted payment. The frailty adjustment approach is applied in conjunction with the CMS–HCC risk adjustment model. The frailty adjustment and factors were initially described in the CY 2004 Advance Notice and Announcement of MA Payment Rates. The CY 2004 Advance Notice and Announcement of MA Payment Rates can be found on the CMS Web site at: *http://www.cms.hhs.gov/MedicareAdvtgSpecRatesStats/Downloads.* We continue to refine our risk adjusted payment methodology to ensure that capitated payments to POs are accurate and take into account the comparative frailty of PACE enrollees. Any changes to our current PACE payment methodology will be described in subsequent Advance Notices and Announcements.

Comment: We received numerous comments, recommendations and concerns related to the Medicare payment methodology provided in the 1999 interim final rule. Overall, the commenters disapproved with changing the established payment methodology, discontinuing the 2.39 frailty adjustment, and speculation regarding how the Principal Inpatient-Diagnostic Cost Group (PIP–DCG) methodology risk adjustment payment methodology would work, including the rate amounts and how an MA payment methodology would be appropriate for calculating the PACE capitation payments. They also requested we continue to explore methods to capture the frailty status of PACE participants. Several commenters also inquired how ESRD payment would be calculated.

Response: The PIP–DCG risk adjustment methodology has been replaced by the CMS–HCC risk

adjustment model, that provides numerous adjustments related to participant demographics, characteristics, and diagnosis. CMS provided extensive technical assistance and training to the NPA and POs prior to the phase-in of risk adjustment for PACE. We also provided guidance and training on the ESRD payment methodology.

We believe that the comments presented have been answered to the satisfaction of the commenters. Further information and specific MA risk adjustment rate updates and MA documentation pertinent to risk adjustment methodology can be found on the CMS Web site at *http://www.cms.hhs.gov.* Annual rate updates are also published in the Advanced Notice of Methodological Changes for Calendar Year (CY)—Medicare Advantage (MA) Payment Rates and are also located on the CMS Web site.

End-Stage Renal Disease (ESRD) Adjustment Under the PACE Demonstration Program

Under the PACE demonstration program, POs were paid in two ways for Medicare ESRD participants. Each month for each ESRD participant, the PACE program was paid the AAPCC Part A and Part B ESRD rate. The rate was not adjusted by the 2.39 frailty factor. Instead, PACE programs received additional payment each month for the actual cost of services in excess of the AAPCC ESRD payment rate. As section 1894(d) of the Act does not authorize payment of actual cost, we conducted an analysis of 1994 Medicare claims data for ESRD patients. The analysis shows that Medicare expenditures for ESRD patients who are 75 or older are significantly higher than expenditures for all ESRD patients. This finding was fairly constant over time. The group of ESRD patients who are 75 or older tend to be very frail and in most cases would be considered NF-eligible. This group of elderly ESRD patients were used as a proxy for ESRD patients who are NF-eligible. ESRD patients who are 75 or older have 46 percent higher Part A expenditures relative to all ESRD patients, while their Part B expenditures are 36 percent higher. We applied this information to calculate adjusters for ESRD patients enrolled in PACE. Thus, the Part A ESRD adjuster was 1.46 and the Part B ESRD adjuster was 1.36. These ESRD adjustment factors were established at the time the 1999 interim final rule was published as an interim measure pending development of a risk adjustment methodology.

New ESRD Risk Adjustment Model

Simultaneous with the implementation of the CMS–HCC model for risk adjustment, we have implemented a new approach to improve payments on behalf of enrollees with ESRD. The approach is the same for both PACE and MA plans. Section 605 of BIPA required CMS to adjust the approach to computing ESRD payment rates to reflect the method used in the ESRD social HMO (S/HMO) demonstration program then in place. We interpreted this to mean that ESRD payments to MA organizations should employ the same basic approach used under the ESRD demonstration referenced in section 605. To implement the BIPA provision for 2002, CMS increased the base rates by three percent and began adjusting payments with age and sex factors, while continuing to review other options.

Effective January 2005, MA enrollees with ESRD were incorporated into diagnosis-based risk adjustment using a different version of the CMS–HCC model. (A list of coefficients for each disease group can be found at *http://www.cms.hhs.gov.*) The new ESRD payment model aligned us further with the method used in the ESRD S/HMO demonstration program by allowing us to capture co-morbidity information in addition to demographic information and basic disease markers for ESRD beneficiaries. ESRD status is recognized in the payment year. The data for 100 percent of ESRD beneficiaries were used to develop the model. The CMS–HCC model for ESRD is described in the Advance Notice and Announcement for Calendar Year 2005, which is available on the CMS Web site. Any updates will be described in future Advance Notices and Announcements.

In this final rule, we are revising § 460.180(b)(4) to reflect the new ESRD risk adjustment model.

We are also revising § 460.180(b)(1) to require that the PACE program agreement contain the ''methodology'' for establishing the monthly capitation rather than the ''amount'' of the monthly capitation. Section 1894(d)(2) of the Act, requires that capitation amount be specified in the program agreement. As such, under the new risk adjustment methodology, specifying the capitation amount in the program agreement is operationally impractical. We believe that continuing to include the capitation amount would require CMS, the SAA, and the PO to establish and sign new program agreements each time a new individual enrolled in the PACE program. We believe that the change from including the capitation amount to the methodology used to calculate the risk adjusted capitation payment amount is consistent with the statutory intent that the program agreement should specify how the PO will be paid. Because of the change in the MA payment methodology enacted by the Congress, it is no longer feasible to include the amount of payment. We will therefore include the payment methodology in the program agreement as a way to give effect to the intent of the PACE statute.

Under the demographic rate methodology, the capitation amount per person was the same for all participants (except participants with ESRD) and was multiplied by the number of participants. Under the new risk adjusted methodology each participant receives a individualized diagnosis-related payment. There is no way for CMS, the SAA, or the PO to predict what diseases or number of diseases future participants will have. Therefore, we have replace the capitation amount with the methodology for calculating the capitation amount in the PACE program agreement in Appendix M.

Comment: Commenters suggested that the actual fee-for-service cost factors be utilized in developing the new MA capitation rates and that the regulation should include language which allows alternatives to the MA methodology. Commenters also requested that CMS continue to explore methodology options and test the validity of various methods of capturing the true frailty status of PACE participants.

Response: Section 1894(d) of the Act directs that PACE payment be based on MA payment rates, adjusted for frailty of PACE enrollees and other factors as appropriate. The differences in the cost of caring for the community based frail population led to the implementation of a frailty adjustor being added to the risk adjustment methodology of the CMS–HCC model.

Comment: In the 1999 interim final rule, we also solicited comment related to the data collection that would be required to develop a specific risk adjustment methodology for PACE.

Numerous commenters presented their concerns that CMS sets Medicare payments to PACE providers based on the rate CMS pays to a MA organization. The commenters questioned whether the MA payment methodology is an appropriate foundation for calculating capitation payments for PACE providers considering the inherent problems with applying the PIP–DCG methodology to PACE and the decision to delay implementation of risk adjustment for PACE. They also believe that a risk-adjustment methodology that relies on

inpatient diagnosis as a determinant for payment is an inappropriate payment methodology for innovative programs such as PACE that diligently strive to minimize inpatient days through aggressive preventative and primary care and serve a frail elderly population with multiple chronic and complex health conditions.

Response: The Congress, through BIPA, required the implementation of a payment model for M+C organizations using not only diagnoses from inpatient hospital stays, but also from ambulatory settings, beginning in 2004. In addition, as described previously, CMS applies a frailty adjuster to an individual participant's risk-adjusted payment to account for the frailty of PACE participants.

Comment: The commenters also indicated that risk adjustment for PACE must account for PACE participants' functional status and cognitive impairment as well as other factors that may systematically impact Medicare utilization and costs in the fee-for-service environment and the need to base payment methodology (and related reporting requirements) for PACE programs on Medicare expenses incurred by comparable individuals outside PACE, not utilization of Medicare covered expenses by PACE participants themselves.

Because the 1999 interim final regulation was not specific in regard to the manner in which MA rates will be established in the future or the manner in which CMS will adjust MA rates for frailty and other factors determined by CMS to be appropriate, they requested that any process that CMS employs to modify the current rate-setting methodology for PACE, include consistent and timely communication with POs.

They also recommended that CMS consult with NPA regarding the reasonableness and impact of proposed changes well in advance of a final determination regarding a particular rate-setting approach and its implementation.

Response: In response to our solicitation for comment we received numerous comments on the data collection required to develop a PACE-specific risk adjustment methodology. The 1999 interim final rule discussed a MA payment methodology that no longer applies to PACE payment since that MA payment methodology is in the process of being phased out as required by BIPA.

Implementation of a new risk adjusted payment methodology based on the CMS–HCC model began in 2004. The transition to 100 percent payment using the new risk adjusted payment methodology will occur over a 5-year period. Implementation of the MA risk adjustment payment methodology for PACE programs was delayed until 2004 to provide CMS with sufficient time to evaluate differences in cost of care for the frail elderly community dwelling population.

In response to the commenters, the risk adjustment methodology for PACE, includes a frailty adjustment based on the functional status of the PO's participant population.

After the development of the MA risk adjustment model and of PACE specific modifications to the MA payment methodology, CMS had discussions with NPA regarding implementation of the new PACE payment methodology.

Comment: A commenter asked if the Medicare capitation rate would be based on the location of the program or the residence of the participant if the program spanned more than one county.

Response: The Medicare capitation rate is based on the county in which the participant resides.

Final rule actions:

In this final rule, we are amending § 460.180 to:

- Reflect statutory changes in the capitation payment methodology used to determine payment amounts for MA plans, and thus payment amounts for POs; and
- Require that the PACE program agreement contain the payment methodology for establishing the monthly capitation rate, rather than specifying a payment amount, in accordance with the changes to the MA capitation payment methodology.

Section 460.182 Medicaid Payment

Section 1934(d) of the Act requires a State to make prospective monthly capitated payments for each PACE program participant eligible for medical assistance under the State plan. The capitation payment amount must be specified in the PACE program agreement and be less, taking into account the frailty of PACE participants, than the amount that would otherwise have been paid under the State plan if the individuals were not enrolled in a PACE program.

A national Medicaid rate-setting methodology for PACE has not been established. Rather, each State that elects PACE as a Medicaid State plan option 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.

As the statutory requirements do not differ from the Protocol requirements regarding Medicaid payments under the PACE demonstration program, the regulations mirror the Protocol requirements. We received three comments pertaining to Medicaid payment.

Comment: One commenter stated that considering the relationship between PACE payments and M+C (now MA) methodologies, there should be ample safeguards to assure that PACE entities can reasonably be expected to provide high quality services at these (Medicaid) payment levels. The commenter was also concerned that Medicaid payments are set at the state, not national level, and suggested we should examine the variation in state payments in relation to outcomes.

Response: We believe this commenter was indicating their opinion that the Medicaid payment amount in conjunction with the Medicare payment was ample to provide the highest quality care.

Medicaid costs vary depending on the State plan and home and community-based services offered in the State. The Medicaid capitation payment must be less than the amount that would otherwise have been paid under the State plan if the participant were not enrolled in a PACE program. As costs and benefits vary by State, we do not believe it would be appropriate to set Medicaid rates at a national level.

Comment: A commenter indicated that to date POs have operated with a fixed rate that does not change based on the participant's health status and suggested testing alternative approaches. The commenter offered to assist CMS with testing an alternative approach involving a rate change (at specified intervals) if there is significant change in a participant's health status. The commenter also requested that waivers be considered to facilitate testing this payment approach.

Response: We appreciate the commenter's offer, however, the statute does not address risk adjustment for Medicaid rates in PACE. As explained above, CMS does not want to impose a rate setting methodology on States. States have flexibility to implement a risk adjusted payment methodology that would recognize differences in health status among participants should they choose to do so consistent with the requirements of 1934(d)(2) of the Act.

Comment: The third commenter asked if the requirement at § 460.182(b) precludes the establishment of multiple

rate cells, with different payment levels that may change based on an annual reassessment, that address the frailty level and health status of the participant.

Response: States are afforded the flexibility to establish various payment levels reflective of frailty levels as long as payment is prospective and does not change before the annual renegotiation of the Medicaid capitation rate due to a change in health status. Section 460.182(b)(4) permits capitation rates to be renegotiated on an annual basis. It would be the responsibility of the State Medicaid Agency to ensure that payments for participants are accurately made for the appropriate payment level.

Comment: A commenter asked if the requirement at § 460.182(c) precludes risk sharing on losses and profits on the Medicaid services.

Response: Under sections 1894 and 1934(f)(2)(B)(v) of the Act, the PO must be at full financial risk. The State may not share risk with the PO.

Accordingly, § 460.182(c) states that the PO must accept the capitation payment as payment in full for Medicaid participants and may not bill, charge, collect, or receive any other forms of payment from the SAA. Therefore, the PO cannot share the risk with the State under stop-loss provisions.

POs are permitted to purchase stop-loss insurance from entities in the form of reinsurance, which is discussed in § 460.80(c)(2). States can offer stop-loss or reinsurance as a product to be purchased by the PO. Stop-loss provisions should be established based on the total costs for a participant and may not be based on a particular aspect of the benefit package.

Final rule actions:

This final rule finalizes § 460.182 as published in the 1999 interim final rule.

Section 460.184 Post-Eligibility Treatment of Income

Section 1934(b)(1)(A)(i) of the Act states that a PO shall provide, to eligible individuals, all covered items and services without application of deductibles, copayments, coinsurance, or other cost sharing that would otherwise apply under Medicare or Medicaid. Section 1934(i) of the Act permits States to use post-eligibility treatment of income in the same manner as it is applied for individuals receiving services under a waiver under section 1915(c) of the Act.

The post-eligibility treatment of income provision reduces the amount of Medicaid payments to a PO by the amount remaining after specified deductions are made from the income of the PACE participant. The income that remains after these deductions are applied is the amount a participant is liable to pay toward the cost of the PACE services. Therefore, an argument could be made that sections 1934(b) and (i) of the Act are in conflict since under section 1934(i) of the Act, PACE participants may incur limited liability for part of the cost of their services. However, we have concluded that the type of Medicaid participant liability permitted by section 1934(i) of the Act is not cost sharing prohibited by section 1934(b)(1)(A)(I) of the Act.

Section 1902(a)(17) of the Act permits an individual (or family) who has more income than allowed for Medicaid eligibility to reduce excess income by incurring expenses for medical or remedial care to establish Medicaid eligibility. However, this spenddown process is used in establishing Medicaid eligibility rather than being the type of cost sharing prohibited by section 1934(b)(1)(A)(I) of the Act.

We interpret section 1934(b)(1)(A)(i) of the Act, to refer to deductibles, copayments, coinsurance or other cost sharing beyond participant liabilities related to Medicaid eligibility. Any other reading of the law would make section 1934(i) of the Act merely surplusage and not meaningful. Therefore, to give significance to these sections of the Act, we provided in § 460.184, which implements section 1934(i) of the Act, references to 42 CFR 435.726 and 435.735. Sections 435.726 and 435.735 lay out the post-eligibility treatment of income requirements that may be applied to PACE participants in the same manner as applied to individuals receiving home and community-based services.

Conforming Amendments

The BBA made conforming amendments to sections 1924(a)(5) and 1903(f)(4)(C) of the Act pertaining to eligibility for medical assistance. Section 1924(a)(5) of the Act, was revised to indicate that special treatment of income and resources for institutionalized spouses in determining eligibility for medical assistance is applied to individuals receiving services under a PACE program under sections 1934 or 1894 of the Act. Further, section 710 of the Omnibus Appropriation Bill (Pub. L. 105–277) enacted October 21, 1998, permits PACE program eligible individuals enrolled in a PACE program under section 1934 of the Act to be eligible for Medicaid under the optional categorically needy eligibility group at section 1902(a)(10)(A)(ii)(IV) of the Act. Under this authority, States can determine eligibility for PACE enrollees using institutional rules, including use of the special income level group described at section 1902(a)(10)(A)(ii)(IV) of the Act.

We received no public comments on § 460.184.

Final rule actions:

This final rule will finalize § 460.184 as published in the 1999 interim final rule.

Section 460.186 PACE Premiums

Neither section 1894 nor section 1934 of the Act addresses the premiums a PO can charge a PACE participant. As a result, we have adopted most of the PACE premium requirements in this section from Part VI, section D of the Protocol. It is important to note that the term ''premiums'' as used in this regulation does not include spenddown liability under 42 CFR 435.121 and 435.831, or post-eligibility treatment of income under § 460.184. This use of the word premiums is narrower than the way the word is used in the Protocol, where a participant's ''share of cost'' responsibility under Medicaid is referred to as a type of premium. In addition, POs may continue to collect any liability due them under Medicaid spenddown and post-eligibility processes, but that liability is not a premium.

We specify that a participant's monthly premium responsibility depends upon his or her eligibility under Medicare and Medicaid.

The Protocol says that the premium for Medicare-only participants is equal to the Medicaid capitation amount. Nearly all Medicare participants have both Part A and Part B, and the capitation amount that Medicare pays is the sum of the Part A and Part B capitation rates. However, section 1894(a)(1) of the Act permits an individual who is entitled to Medicare benefits under Part A or enrolled under Part B to enroll in the PACE program. For those rare persons who are eligible under only one part, the Medicare capitation amount will be only the portion for that part. Such a participant is required to make up the difference, that is, pay an additional premium amount equal to the missing piece of the Medicare capitation amount. We specify the premiums for Medicare-only participants as follows—

- For a participant who is entitled to Medicare Part A and enrolled under Medicare Part B, but is not eligible for Medicaid, the premium equals the Medicaid capitation amount.
- For a participant who is entitled to Medicare Part A, but is not enrolled under Part B and is not eligible for Medicaid, the premium equals the

Medicaid capitation amount plus the Medicare Part B capitation rate.

• For a participant who is enrolled only under Medicare Part B and is not eligible for Medicaid, the premium equals the Medicaid capitation amount plus the Medicare Part A capitation rate.

We specify that no premium may be charged to a participant who is dually eligible for both Medicare and Medicaid or one who is only eligible for Medicaid.

We received four comments regarding PACE premiums.

Comment: Commenters requested clarification on the premiums for those with neither Medicare nor Medicaid. One commenter recommended that POs not be permitted to establish private pay premiums for Medicare covered services in excess of the Medicare capitation amount. Two commenters suggested that private pay premiums for non-Medicaid eligible participants be no less than the Medicaid capitation rate.

Response: We believe it was congressional intent to permit individuals with Medicare Part A, Part B, Medicaid, any combination of the above or none of the above to participate in PACE based on sections 1894(i) and 1934(j) of the Act. Therefore, POs must enroll any individual who meets the enrollment criteria even if they participate in neither Medicare nor Medicaid.

However, as we noted previously, the statute does not address the amount a private pay PACE enrollee can be charged in premiums. Therefore, we will leave the premium amount to the discretion of the POs, based on their individual population and service needs.

Comment: One commenter recommended that, through the waiver process, POs be allowed to explore alternate methods of establishing premiums for non-Medicaid participants, who have Medicare so long as the premiums are set to be actuarially equivalent to, those established for the Medicaid populations.

Response: In accordance with BIPA 903, the 2002 interim final rule provides a waiver process that can be accessed by a PO, that is unable to meet a regulatory requirement or, if they are an experienced PO, waivers to explore alternative practices (see § 460.26 and § 460.28 regarding waiver process). Additional information regarding the waiver process is on the PACE Web site, *www.cms.hhs.gov/PACE.*

As explained above, CMS requires that the premium for Medicare-only participants enrolled in both Medicare Part A and Part B be equal to the Medicaid capitation amount. The PO does not have the discretion to establish a higher premium amount for these participants. CMS specifies the premium amount that may be charged to these PACE participants so that premiums correlate with (Medicaid) costs and are equal for participants with the same eligibility. CMS and States go through an extensive process to calculate Medicaid rates that take into account the frailty of PACE participants. Therefore, the Medicaid capitation rate, should be an acceptable amount for a premium.

Final rule actions:

This final rule will finalize § 460.186 as published in the 1999 interim final rule.

Subpart K: Federal/State Monitoring

Section 460.190 Monitoring During Trial Period

Sections 1894(e)(4)(A) and 1934(e)(4)(A) of the Act provide for annual close oversight during the trial period, which is a PO's first 3 contract years. We established § 460.190 to address the requirements for monitoring during the trial period. During the trial period, CMS in cooperation with the SAA conducts comprehensive annual reviews of a PO.

In accordance with the statute and as specified in § 460.190 the review includes an on-site visit to the PO, a comprehensive assessment of the organization's fiscal soundness, a comprehensive assessment of the organization's capacity to furnish all PACE services to all enrolled participants, a detailed analysis of the organization's substantial compliance with all significant requirements of sections 1894 and 1934 of the Act and these regulations, and any other elements that CMS or the SAA find necessary.

No public comments were received on § 460.190.

Final rule actions:

This final rule will finalize § 460.190 as published in the 1999 interim final rule.

Section 460.192 Ongoing Monitoring After Trial Period

In accordance with paragraph (e)(4)(B) of sections 1894 and 1934 of the Act, we specified that at the conclusion of the trial period, CMS, in cooperation with the SAA, would continue to conduct reviews of a PACE program, as appropriate. These reviews must take into account the performance level of the PO with respect to the quality of care provided and compliance of the organization in meeting the PACE program requirements. Such reviews include an on-site visit at least every two years.

No public comments were received on § 460.192.

Final rule actions:

This final rule will finalize § 460.192 as published in the 1999 interim final rule.

Section 460.194 Corrective Action

We require the PO to take action to correct deficiencies identified during the reviews. CMS or the SAA will monitor the effectiveness of corrective actions. Failure to correct deficiencies can result in sanctions or terminations in accordance with subpart D.

Comment: One commenter inquired how it would be determined whether the CMS or the State would monitor a CAP.

Response: CMS works in partnership with the SAA to monitor POs. Information received by either agency in response to the CAP is shared with the other agency. As indicated in § 460.194, either CMS or the SAA will monitor the CAP. The determination of which agency will monitor the CAP will vary depending on the issues addressed by the CAP. Since CMS and the SAA have their own regulations, each agency is monitoring for deficiencies in relation to their regulations as well as any general deficiency they identify that needs correction. CMS and the SAA discuss the monitoring review findings and the actions that need to be taken, to assure the PO has corrected or is in the process of correcting the deficiencies, prior to releasing the official CAP report to the PO. During those discussions, they will decide who will be the lead for monitoring the progress of the CAP. One of the factors involved in that decision is the number of follow-up visits that will be required and the proximity of the SAA and CMS offices. Often times, quarterly calls between CMS, the SAA, and the PO can include specific CAP items on the agenda. Follow-up visits can be conducted by the SAA, CMS, or the results can be reviewed at the next monitoring visit.

Final rule actions:

This final rule will finalize § 460.194 as published in the 1999 interim final rule.

Section 460.196 Disclosure of Review Results

In accordance with paragraph (e)(4)(C) of sections 1894 and 1934 of the Act, we specified requirements for disclosing the results of monitoring reviews. CMS and the SAA promptly report the results of reviews under § 460.190 and § 460.192 to the PO, along with any recommendations for changes to the organization's program. The results are made available to the public upon

request. In addition, we require that the PO post a notice of the availability of the results of the most recent review and any CAPs or responses related to the most recent review. The PO must also make the results available for examination in a place readily accessible to participants.

Comment: One commenter stated that access to the information by the public would be greatly expanded by requiring the SAA to post the results of PACE monitoring reviews on the agency's Web sites.

Response: We believe the decision regarding whether the State posts the results of PACE monitoring reviews is a State determination. We encourage access to information for the public but do not believe it is necessary to dictate specific methods in regulations.

Comment: Another commenter questioned if the definition for ''promptly'' means within 45 days.

Response: CMS and the SAA expect to complete the analysis of monitoring review findings and provide them to the PO within 30 days after completion of the review and, if this timeframe is not possible, then as close to 30 days as possible. Due to the in-depth review performed by the CMS and SAA monitoring review teams, it is not always possible to complete an extensive report quickly. Therefore, we have decided to retain the term promptly and not provide a specific timeframe.

Final rule actions:

This final rule will finalize § 460.196 as published in the 1999 interim final rule.

Subpart L: Data Collection, Record Maintenance, and Reporting

The purpose of subpart L is to establish the requirements for data collection, record maintenance, and reporting. This subpart describes in detail the manner in which POs must collect, maintain and report data including participant health outcomes, organization financial information, and medical records.

Section 460.200 Maintenance of Records and Reporting of Data

In accordance with sections 1894(e)(3)(A) and 1934(e)(3)(A) of the Act, we require POs to collect data, maintain records, and submit reports. We describe data and records to include participant health outcome data, financial books and records, medical records, and personnel records. We require the documents to be accessible to CMS and the SAA upon request and be stored in a manner consistent with the PO's written policies that protect them from loss, destruction, unauthorized use or inappropriate alteration.

We established several requirements intended to safeguard the privacy of any information that identifies a particular participant. The PO must establish written policies and implement procedures to ensure that information from, or copies of, records are released only to authorized individuals and that original medical records are released only in accordance with Federal or State laws, court orders, or subpoenas. In addition, a participant's written consent must be obtained before the release of identifiable information to persons not otherwise authorized to receive it. The written consent may limit the degree of information and the persons to whom information may be released. Participants are guaranteed timely access to review and copy their own medical records and may request amendments to their records. Finally, the PO must abide by all Federal and State laws regarding confidentiality and disclosure of participant mental health and medical records and other health information.

The Protocol did not specify a minimum record retention timeframe. In order to enable adequate oversight and to be consistent with the requirements established for M+C plans, we require POs to retain records for the longest of the following periods: the period specified by State law; six years from the date of the last entry made in the record; or for medical records of disenrolled participants, six years after the date of disenrollment. If any litigation, claim, financial management review, or audit is started before the expiration of the retention period, we are requiring that those records be retained until completion of the litigation, or until claims or audit findings involving the records have been resolved and final action taken.

We note that for purposes of Medicare Part D, POs are required to retain Part D related records for a period of 10 years in accordance with 42 CFR 423.505(d).

Comment: One commenter asked when data collection, maintenance, and reporting requirements would be issued by CMS and the SAA.

Response: In the fall of 2001 the PACE demonstration programs were instructed to submit Data Elements for Monitoring on a quarterly basis via the HPMS. This reporting requirement remains in effect for POs.

Prior to signing the program agreement, which contains these reporting requirements, POs are provided with instructions on the HPMS: The HPMS Connectivity Guide, HPMS User's Guide and HPMS Connectivity for States. These materials can also can be found on the PACE Web site at *http://www.cms.hhs.gov/PACE/09_AdditionalResources.asp*.

The Data Elements for Monitoring include information on the number of grievances and appeals; reasons for disenrollment; and vaccination rates for flu and pneumonia.

Appendix M of the PACE program agreement indicates that Medicare payment is also reliant on information reported to CMS. As discussed in the payment section, the risk score for PACE participants is based on the CMS–HCC, which is based on the diagnostic information submitted by the PO. The PO's frailty score is based on the responses received from community-dwelling participants on the Modified HOS (Health Outcomes Survey), which identifies participant difficulty in performing ADLs.

To the extent the SAA establishes additional reporting requirements, the requirements would be identified in a separate contract between the SAA and the PO.

Final rule actions:

This final rule will finalize § 460.200 as published in the 1999 interim final rule.

Section 460.202 Participant Health Outcomes Data

In the 1999 interim final rule, we modified the requirement in Part VII, section B of the Protocol for data collection and reporting. We require POs to maintain a health information system that collects, analyzes, integrates, and reports data necessary to measure their performance and to develop their QAPI. As discussed above, POs are expected to collect data for monitoring and report it at quarterly intervals via HPMS. HPMS information may be used by CMS, SAAs, and POs.

Each PO must collect, evaluate, and report the data as part of managing its QAPI. These data will assist the PO in its efforts to identify opportunities to improve participant care and outcomes, and to evaluate the results of its performance improvement activities.

Additionally, we have a requirement that the PO must furnish data and information in the manner and at the time intervals specified by CMS and the SAA, pertaining to its participant care activities. The items to be collected are specified in the PACE program agreement and will be subject to the confidentiality requirements specified in § 460.200.

Finally, we require that each PO conduct an annual satisfaction survey of its participants and caregivers. The

findings should be used by the PO to identify opportunities for improvement.

Comment: Four commenters commented on health outcomes data, and although they were supportive of requirements for participant health outcomes data, they maintain that flexibility is important in developing State or site specific systems. Commenters asked that CMS focus on the specific data elements that will be required but leave the decision about which tool to use to the States or providers.

One commenter indicated that it is important for States to know, up front, the participant health outcome data reporting requirements to assist them in making PACE a State plan option.

Response: Although the reporting requirements discussed above were not available when we published the 1999 interim final rule, we established the requirement shortly after publication. We also provided training to the POs. States should now be aware of the reporting requirements for PACE.

Comment: One commenter indicated that if encounter data were going to be used for uses other than risk adjustment, then a broader range of data requirements would be needed. This commenter was interested in CMS developing consistency in reporting requirements in order to minimize the reporting burden for POs.

Response: Currently, encounter data is only being used to determine reimbursement under the risk adjustment payment methodology. As discussed in the QAPI section, we are no longer pursuing development of a standardized assessment tool for PACE.

Comment: Several commenters stressed the importance of streamlining all Federal and State reporting requirements. Two commenter opposed CMS' application of a broad range of reporting requirements to POs which were developed for, and are more appropriate to, managed care entities and more limited provider types, such as, home health agencies or nursing homes. One commenter discouraged whole scale application of these types of requirements and encouraged the development of OBCQI requirements unique to PACE providers.

Response: At the time we published the 1999 interim final rule, several PACE demonstration programs were licensed under State law as home health agencies. In these cases, the POs were subject to the additional reporting requirements based upon their licensure. We understand many States are now developing licensure programs for PACE. When this occurs, the POs would no longer be required to submit additional OASIS information. The encounter and functional status reporting are necessary for PACE payment under risk adjustment methodology.

Final rule actions:

This final rule will finalize § 460.202 as published in the 1999 interim final rule.

Section 460.204 Financial Recordkeeping and Reporting Requirements

In § 460.204, we require that a PO must provide CMS and the SAA with accurate financial reports that are prepared using an accrual basis of accounting and verifiable by auditors.

In addition, we require that the PO maintain an accrual accounting recordkeeping system that accurately documents all financial transactions, provides an audit trail to source documents, and generates financial statements.

Further, except as stipulated under Medicare principles of reimbursement set forth in 42 CFR part 413, a PO must follow standardized definitions and accounting, statistical, and reporting practices that are widely accepted in the health care industry.

We also require that a PO must permit CMS and the SAA to audit or inspect any books and records of original entry that pertain to any aspect of services performed, reconciliation of participants' benefit liabilities or determination of Medicare and Medicaid amounts payable.

We note the statute does not provide for risk-sharing arrangements between CMS and POs. It places the organization at full financial risk for all services, thus our emphasis is on the need for accurate accounting records.

Comment: One commenter recommended that CMS require POs that are a subdivision of a larger parent organization, to maintain a balance sheet, statement of income and expenses, and documentation of the sources and uses of its funds that is separate and distinct from the parent organization's financial record keeping.

Response: We agree. We believe it is important for us to receive the financial information for the PO in order to determine the PO's solvency. However, where the PO's financial solvency is based on a guarantee by the PO's parent organization, we request this information as well.

Final rule actions:

This final rule will finalize § 460.204 as published in the 1999 interim final rule.

Section 460.208 Financial Statements

CMS, in cooperation with the SAA, has the responsibility of assessing fiscal soundness as described in § 460.80. The financial information required to assess the fiscal soundness of a PO is information from basic financial statements, balance sheets, statement of revenues and expenses, and sources and uses of funds statement. An organization that has completed its trial period is required to submit financial statements annually. An organization that is in the trial period is required to submit quarterly financial statements in addition to the annual certified financial statements. An organization may use the ''Annual Statement'' (also known as the ''orange blank''), which was developed by the National Association of Insurance Commissioners for reporting by HMOs. For information contact NAIC 2301 McGee Street, Suite 800 Kansas City, MO 64108 (816–842–3600).

We require that, not later than 180 days after the end of the organization's fiscal year, the PO submit the annual financial statement that includes appropriate footnotes. This financial statement must be certified by an independent certified public accountant. At a minimum, the certified financial statement must include a certification statement, a balance sheet, a statement of revenues and expenses, and a source and use of funds statement.

Throughout the trial period, we require that not later than 45 days after the end of each quarter of the organization's fiscal year, a PO must submit a quarterly financial statement. Quarterly financial statements are not required to be certified by an independent certified public accountant.

At the conclusion of the trial period, CMS or the SAA may require a PO to submit monthly or quarterly financial statements, or both, if CMS or the SAA determines that an organization's performance requires more frequent monitoring and oversight due to concerns about fiscal soundness. These additional reports do not have to be certified by a certified public accountant.

Sections 1894(e)(3) and (4) and 1934(e)(3) and (4) of the Act require CMS and the SAA to work in consultation to determine what data, cost and financial reports the PO must submit so these agencies can monitor the cost and effectiveness of a PO and perform necessary reviews.

We consulted with representatives from various State organizations that serviced PACE demonstration programs. We have determined that data collection

and financial reporting requirements vary among the State organizations. The data collection and financial reports we require for purposes of assessing fiscal soundness can also assist the SAA in their monitoring and oversight requirements. Of course, States have the authority to request any data and reports that they consider to be necessary in implementing the PACE program. We solicited comments on consistency in reporting requirements in the 1999 interim final rule.

Comment: Two commenters asked whether financial statements and reports should be routed to CMS via the SAA or if they should go to CMS and the SAA simultaneously.

Response: Financial reports should go to CMS and the SAA simultaneously.

Comment: Commenters asked whether there is any flexibility in CMS requirements at § 460.208 for submission of financial reporting documents to CMS and the State, if the State establishes a different reporting cycle.

Response: The financial statements are due to CMS within the required timeframes of 45 days from the end of the quarter (during the trial period) and 180 days after the fiscal year end. There is no flexibility in CMS' timeframes, but States may have discretion regarding their timeframes for reporting requirements if they are different than the Federal requirements.

Comment: Several commenters asked if CMS has standard reporting formats and if States have flexibility to develop their own financial reporting documents.

Response: CMS does not have a standard format for financial reporting for POs. As specified in § 460.204, financial reports are required to be prepared using an accrual basis of accounting and must be verifiable by qualified auditors.

There is flexibility for States to develop their own financial reporting formats if they choose to do so.

Final rule actions:

This final rule will finalize § 460.208 as published in the 1999 interim final rule.

Section 460.210 Medical Records

The participant's medical record presents a total picture of the care provided. The medical record is a useful tool in diagnosing, treating and caring for the participant. The medical record: (1) Facilitates communication among the various health care professionals providing services to the participant; (2) provides a focal point for coordinating the actions of the IDT; (3) provides an accurate picture of the participant's progress in achieving care goals; and (4) provides the team members with data for evaluating and documenting the quality and appropriateness of care delivered. Because care for the PACE population will be provided by a variety of sources (for example, PACE center employees, contracted personnel, hospital staff, nursing home staff, etc.), it is critical that all information on the participant be documented in the medical record to ensure quality and continuity of care. As a result, in the 1999 interim final rule, we retained with few modifications the minimum elements specified in the Protocol to be included in the participant's medical record.

To facilitate continuity of care, we require in § 460.210 that the PO maintain a single comprehensive medical record for each participant at the PACE center they attend. Participant medical records should be complete, accurately documented, easily retrievable, systematically organized, and available to all staff. We recognize that a PO may have more than one PACE center, however, participant medical records must be located at the PACE center where the participant receives services so that staff has access to pertinent information. This requirement also should prevent time lost in obtaining records and facilitate timely review and documentation of the medical record.

At a minimum, the participant medical record must include:

- Appropriate identifying information;
- Documentation of all services furnished, including:

+ A summary of emergency care and other inpatient or long-term care services. (We included this last phrase to ensure that any services furnished to the participant outside the scope of the PACE center's direct care is documented in the medical record. It is critical to the continuity of care that the IDT be informed of all outside services furnished to the participant. Once the participant returns to the PACE center, the course of treatment can be reevaluated and adjusted based on any changes in the participant's status.);

+ Services furnished by employees of the PACE center; and

+ Services furnished by contractors and their reports (This item is intended to ensure that anyone who furnishes services to the participant, employees of the PO or contractors, shares the information with the IDT for documentation in the medical record. Again, this requirement is intended to facilitate communication between providers.);

+ Interdisciplinary assessments, reassessments, plans of care, and treatment and progress notes that are signed and dated;

+ Laboratory, radiological and other test reports (This change from the Protocol clarifies that all tests should be included in the participant medical record.);

+ Medication records;

+ Hospital discharge summaries, if applicable;

+ Reports of contact with informal support (for example, representatives/ care givers, legal guardian, or next of kin);

+ Enrollment Agreement signed by the participant;

+ Physician orders;

+ Disenrollment justification, if applicable;

+ Advance directives, if applicable (For example, when a participant has executed an advance directive, that fact should be prominently displayed. If the PO cannot implement an advance directive as a matter of conscience that fact also should be prominently displayed and explained to prospective enrollees.);

+ A signed release permitting disclosure of personal information; and

+ Accident and incident reports. (Accident and incident reports were included because we believed they may be an indicator of changes in the participant's functional status, problems or changes in the participant's home environment, or physical problems with the PACE center or its staff.)

We also require the PO to provide for the prompt transfer of copies of appropriate medical record information between treatment facilities to ensure continuity of care whenever a participant is temporarily or permanently transferred to another facility. Examples of appropriate medical record information include, but are not limited to, the reason for the transfer, the name and phone number of the attending physician, participants' demographics, active diagnosis and treatment plan including current medications and ADL status, special dietary considerations, etc. It is essential that the medical history and plan of care follow the participant. This requirement is intended to ensure communication between providers. We solicited comments on whether a specific timeframe for the transfer of participant medical record information should be required.

We included a requirement for authentication of the medical record to ensure that the appropriate individuals have reviewed and completed the participant's medical records. All

entries must be legible, clear, complete, and appropriately authenticated and dated.

Authentication must include signatures or a secured computer entry by a unique identifier of the primary author who has reviewed and approved the entry.

Comment: Three commenters indicated that it is inappropriate for accident and incident reports to be kept in the medical record. They suggest that changes in a participant's health status resulting from an accident and other incident not be noted in the medical record. Rather the commenter believed that accident or incident reports should be maintained in a secure, confidential location that is available to CMS and the SAA for review.

Response: Our intent at the time of drafting the 1999 interim final rule was that POs would record changes in health status resulting from accidents or incidents in the medical record and all records would be consolidated into one medical record. However, we agree with the commenters that specific accident or incident reports should be maintained in a secure confidential location and should be available to CMS and the SAA for review. We believe the purpose of including such items in the medical record is served by noting the change in medical condition. We do not think that the origin of the change is required in the medical record but agree that accident and incident reports should be available to CMS and the SAA for purposes of program review. Changes in participant health status and related participant assessments and modifications to care plans are required to be included in the medical record. We will, however, no longer require that accident and incident reports be filed in participant medical records.

Therefore, we are amending § 460.210 by deleting paragraph (b)(13) from the required content of medical record.

Comment: Two commenters responded to our request for comments regarding whether to impose specific timeframes for the transfer of participant medical record information between the PO and another treatment facility or provider. One commenter did not recommend the imposition of a timeframe for transfer of records, while the other commenter recommended implementing a timeframe requirement only when providing the participant with a copy of their medical record when requested.

Response: We believe that a comprehensive treatment history equips providers to deliver appropriate care. We also believe that POs are cognizant of the importance of prompt transfer of medical records in order to assist other providers and facilities in coordinating PACE participant care.

Therefore, we believe that POs will provide for the prompt transfer of appropriate medical record information between treatment facilities to ensure continuity of care whenever a participant is temporarily or permanently transferred to another facility and a timeframe for doing so is not necessary. Accordingly, we are not imposing a timeframe for transferring medical records in this final rule.

Comment: Two commenters questioned whether the PO must maintain a hardcopy of all electronically maintained medical records. The commenters requested clarification of the requirement for electronic record integrity and back-up.

Response: CMS does not require the hardcopy backup of electronic medical records. We are not mandating a specific system for electronic medical record backup but the PO needs to develop and maintain a backup system for their electronic medical records to ensure that they can reproduce their medical records should there be a systems dysfunction or physical destruction such as a fire. The electronic medical records should be periodically and systematically backed-up, secure, and located off site in case of a physical disaster. The PO must be able to provide a copy of participants medical records upon request by CMS or the SAA.

Final rule actions:

This final rule will amend § 460.210 by deleting paragraph (b)(13) ''Accident and incident reports'' from the required contents of the medical record.

IV. Provisions of Final Rule

Part 460 Authority Citation

We are adding sections 1894(f) and 1934(f) of the Social Security Act to the authority citation for part 460 because they specifically require the Secretary to promulgate regulations for these sections.

Subpart A—Basis, Scope, and Definitions

Section 460.2 Basis—No Change

Section 460.4 Scope and Purpose—No Change

Section 460.6 Definitions

We are amending this section to redefine the term ''PACE center'' as ''a facility which includes a primary care clinic, areas for therapeutic recreation, restorative therapies, socialization, personal care, and dining which serves as the focal point for coordination and provision of most PACE services.'' We are also amending this section by adding the definition of ''PACE program''.

Subpart B—PACE Organization Application and Waiver Process

Section 460.10 Purpose—No Change

Section 460.12 Application Requirements

The October 2002 interim final with comment removed and reserved § 460.12(a)(2). In this final rule, we are redesignating § 460.12(a)(3) as § 460.12(a)(2). We are also removing the cross reference to § 460.14 in newly redesignated paragraph (a)(2)(i) of § 460.12, and the cross reference to § 460.16 in newly redesignated paragraph (a)(2)(ii) of § 460.12, since § 460.14 and § 460.16 are being removed in this rule.

Section 460.14 Priority Consideration

In this final rule, we are deleting § 460.14 which no longer applies since August 5, 2000 timeframe has passed and all PACE demonstration programs have transitioned to permanent providers. We are reserving this section.

Section 460.16 Special Consideration

In this final rule, we are deleting § 460.16 which no longer applies since the August 5, 2000 timeframe has passed and all PACE demonstration programs have transitioned to permanent providers. We are reserving this section.

Section 460.18 CMS Evaluation of Application—No Change

Section 460.20 Notice of CMS Determination—No Change

Section 460.22 Service Area Determination—No Change

Section 460.24 Limit on Number of PACE Program Agreements—No Change

Section 460.26 Submission and Evaluation of Waiver Requests

In this final rule, we are amending § 460.26 by redesignating paragraph (a) as paragraph (a)(1) and adding paragraph (a)(2) permitting non-operational entities submitting a PACE provider application to submit a waiver request at the same time. The waiver request must be submitted as a separate document and follow all other requirements as stated in this section. We are also amending paragraphs (b) and (b)(1) by adding ''or PACE applicant.''

Section 460.28 Notice of CMS Determination on Waiver Requests

We are amending (a)(2) by adding ''or PACE applicant,'' thereby requiring

CMS to notify the PO or PACE applicant in writing of the decision to deny the submitted wavier request.

Subpart C—PACE Program Agreement

Section 460.30 Program Agreement Requirement—No Change

Section 460.32 Content and Terms of PACE Program Agreement

We are amending paragraph (a)(12) to require the PACE program agreement to include the Medicaid capitation rate and the methodology used to calculate the Medicare capitation rate.

Section 460.34 Duration of Program Agreement—No Change

Subpart D—Sanctions, Enforcement Actions, and Termination

Section 460.40 Violations for Which CMS May Impose Sanctions—No Change

Section 460.42 Suspension of Enrollment or Payment by CMS—No Change

Section 460.46 Civil Money Penalties—No Change

Section 460.48 Additional Actions by CMS or the State—No Change

Section 460.50 Termination of PACE Program Agreement—No Change

Section 460.52 Transitional Care During Termination—No Change

Section 460.54 Termination Procedures—No Change

Subpart E—PACE Administrative Requirements

Section 460.60 PACE Organizational Structure

In this final rule, we are amending § 460.60(d)(3) by changing ''60'' to ''14'' days. Together with the following deletions of paragraphs (d)(4) and (d)(5) of this section, we are reducing administrative burden for POs.

We are deleting paragraph (d)(4) that states ''changes in organizational structure must be approved in advance by CMS and the SAA.''

We are also deleting paragraph (d)(5) that states, ''changes in organizational structure approved by CMS and the SAA must be forwarded to the consumer advisory committee, described in § 460.62(c) for dissemination to participants as appropriate.''

Section 460.62 Governing Body

In this final rule, we are clarifying the requirements for community involvement on issues relating to participants. We are revising the name of the ''Consumer Advisory Committee'' to be the ''Participant Advisory Committee'' to more adequately reflect the intent of the PO having an advisory committee that is comprised of participants and participant representatives who are focused on their issues. The Participant Advisory Committee provides the Participant Representative with issues as recorded in minutes of their meeting to present at the PO governing body meeting required in the new paragraph (c)(3).

Section 460.64 Personnel Qualifications for Staff With Direct Participant Contact

We are amending the title of § 460.64 and the personnel qualifications to clarify that the qualifications apply to all PACE staff with direct participant contact and decrease the burden in hiring and contracting for adequate numbers of staff members. We are removing the educational requirements and other qualifications at § 460.64(c) that we established for professions where no States require licensure, certification, or registration. All PACE staff with direct participant contact must meet the general personnel qualifications.

The amended requirements also clarify that physicians must meet the requirements for Federally-defined qualifications for a physician in addition to the general personnel requirements.

Section 460.66 Training

We are clarifying the training requirement for personal care attendants by requiring that their competency must be exhibited before performing personal care services independently.

Section 460.68 Program Integrity

We are amending the conflict of interest prohibitions. We provided a mechanism for disclosure and recusal in the event that a PO experiences any direct or indirect conflict of interest by a member of the governing body or an immediate family member.

Section 460.70 Contracted Services

We are reducing operational burden by amending this regulation to remove the requirement that POs submit each signed contract for inpatient care.

Section 460.71 Oversight of Direct Participant Care

We are amending this requirement to be consistent with the general personnel qualifications by clarifying that all direct participant care staff and contractors be free of communicable diseases and have all immunizations up to date before performing direct participant care.

Section 460.72 Physical Environment

We are amending this requirement to clarify that POs must perform the manufacturers' recommended maintenance.

Section 460.74 Infection Control—No Change

Section 460.76 Transportation Services—No Change

Section 460.78 Dietary Services

In this section, we are clarifying that each participant's dietary requirements are determined by assessment and included in the participant's plan of care. It also clarifies that the PO must ensure that each participant receives meals that are specific to their dietary needs. If the PO needs to provide meals, which are included in the participant's plan of care, the meals must be nourishing, palatable, well-balanced, and meet the participant's daily nutritional and special dietary needs.

Section 460.80 Fiscal Soundness—No Change

Section 460.82 Marketing Materials—No Change

Subpart F—PACE Services

Section 460.90 PACE Benefits Under Medicare and Medicaid—No Change

Section 460.92 Required Services

We are amending the list of required services to clarify that the PACE benefit package include all Medicare-covered items and services, Medicaid-covered items and services specified in the State's approved Medicaid plan, and other services determined necessary by the IDT to improve and maintain the participant's overall health status.

Section 460.94 Required Services for Medicare Participants

We are amending the requirement to clarify that payment for PACE program services is for services that are provided to the PACE participants.

Section 460.96 Excluded Services

We are correcting a technical error published in § 460.96(e)(1) by replacing the word ''through'' with the word ''and'' so that paragraph (e) reads ''Services furnished outside of the United States, except as follows: (1) In accordance with § 424.122 and § 424.124 of this chapter.''

Section 460.98 Service Delivery

We are expanding participant rights by amending this requirement to include sexual orientation in the list of

categories under which PO must not discriminate.

Section 460.100 Emergency Care

We are defining urgent care and post-stabilization care outside of the service area.

We are also expanding participant protection by amending this requirement to clarify that the PO must explain to the participant or caregiver that they can obtain emergency care without prior authorization.

Section 460.102 Interdisciplinary Team

We are clarifying the position and responsibilities of the social worker on the IDT by amending it to ''Master's level social worker (MSW).'' This will make the requirement consistent with other Medicare regulations.

Section 460.104 Participant Assessment

We are amending this provision to require that the in-person assessment and reassessments be performed by both a physical therapist and an occupational therapist, thus clarifying one discipline cannot replace the other discipline.

We are clarifying that a MSW performs assessments and reassessments.

We are also redesignating paragraph (c)(3) as new paragraph (d) and changing the heading from ''Reassessment based on change in participant status or at the request of the participant or designated representative'' to ''Unscheduled reassessments.'' We are identifying separate requirements in paragraph (d) for reassessments based on a change in participant status or requested by a participant or his or her representative.

We are decreasing the operational burden by removing the requirement that all reassessments be performed by the IDT minus the personal care attendant, driver, and PACE center manager. We are amending this requirement to require the IDT members listed in paragraph (a)(2) to perform in-person reassessments for change in status and permit the IDT to determine which IDT members must perform reassessments when requested by the participant or their designated representative. However, we added a requirement that if a significant change in the participant's health or psychosocial status occurs, the in-person reassessment must be performed by the entire IDT minus the personal care attendant, driver, and PACE center manager.

Section 460.106 Plan of Care—No Change

Subpart G—Participant Rights

Section 460.110 Bill of Rights—No Change

Section 460.112 Specific Rights to Which a Participant Is Entitled

We are amending this requirement by expanding the Participant's rights to include sexual orientation in the list of categories that a PO must not discriminate against.

Also we are revising paragraph (b)(1)(iii) to require the disclosure of all PO services and services delivered by contracted providers at the time a participants needs necessitate the disclosure and delivery of such information to allow the participant to make an informed choice.

Section 460.114 Restraints—No Change

Section 460.116 Explanation of Rights—No Change

Section 460.118 Violation of Rights—No Change

Section 460.120 Grievance Process—No Change

Section 460.122 PACE Organization's Appeals Process

We are amending this requirement to clarify that noncoverage of services including denials, reduction, or termination of services are included as a basis for appeal.

We are also expanding participant protections by changing ''would'' be seriously jeopardized to ''could'' be seriously jeopardized and revising ''regain'' maximum function to ''regain or maintain'' maximum function.

Section 460.124 Additional Appeal Rights Under Medicare or Medicaid—No Change

Subpart H—Quality Assessment and Performance Improvement—No Change

Subpart I—Participant Enrollment and Disenrollment

Section 460.150 Eligibility To Enroll in the PACE Program—No Change

Section 460.152 Enrollment Process

We are expanding participant protection by amending the requirement that POs must explain and provide information related to post-eligibility treatment of income during the intake process.

Section 460.154 Enrollment Agreement

We are clarifying the requirement that a participant may not enroll or disenroll at a Social Security office.

We are also expanding participant protection by amending this requirement allowing the participant or their designated representative to sign and date the reenrollment agreement.

Section 460.156 Other Enrollment Procedure—No Change

Section 460.158 Effective Date of Enrollment—No Change

Section 460.160 Continuation of Enrollment

We are revising paragraph (b)(3)(i) to clarify that the SAA must establish criteria for use in making deemed eligibility determinations.

Section 460.162 Voluntary Disenrollment—No Change

Section 460.164 Involuntary Disenrollment—No Change

Section 460.166 Effective Date of Enrollment—No Change

Section 460.168 Reinstatement in Other Medicare and Medicaid Programs—No Change

Section 460.170 Reinstatement in PACE—No Change

Section 460.172 Documentation of Disenrollment.—No Change

Subpart J—Payment

Section 460.180 Medicare Payments to POs

We are amending this section to reflect the new Medicare risk adjustment payment methodology and are requiring that the PACE program agreement contain the ''methodology'' for establishing the monthly capitation rather than the ''amount'' of the monthly capitation rate.

Section 460.182 Medicaid Payment—No Change

Section 460.184 Post-Eligibility Treatment of Income—No Change

Section 460.186 PACE Premiums—No Change

Subpart K—Federal/State Monitoring

Section 460.190 Monitoring During Trial Period—No Change

Section 460.192 Ongoing Monitoring After Trial Period—No Change

Section 460.194 Corrective Action—No Change

Section 460.196 Disclosure of Review Results—No Change

Subpart L—Data Collection, Record Maintenance, and Reporting

Section 460.200 Maintenance of Records and Reporting Data—No Change

Section 460.202 Participant Health Outcomes Data—No Change

Section 460.204 Financial Recordkeeping and Reporting Requirements—No Change

Section 460.208 Financial Statements—No Change

Section 460.210 Medical Records

We are amending this section by removing the requirement that accident and incident reports be contained in the medical record. The origin of a change in the status of a medical condition is not required in the medical record, but should be available for CMS and the SAA for review.

V. Collection of Information Requirements

Under the Paperwork Reduction Act of 1995, we are required to provide 30-day notice in the **Federal Register** and solicit public comment before a collection of information requirement is submitted to the Office of Management and Budget (OMB) for review and approval. In order to fairly evaluate whether an information collection should be approved by OMB, section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995 requires that we solicit comment on the following issues:

- The need for the information collection and its usefulness in carrying out the proper functions of our agency.
- The accuracy of our estimate of the information collection burden.
- The quality, utility, and clarity of the information to be collected.
- Recommendations to minimize the information collection burden on the affected public, including automated collection techniques.

We are soliciting public comment on each of these issues for the following sections of this document that contain information collection requirements (ICRs):

Section 460.30 Program Agreement Requirement

Section 460.30(c) states that CMS may only sign program agreements with PACE organizations that are located in States with approved State plan amendments electing PACE as an optional benefit under their Medicaid State plan.

The burden associated with this requirement is the time and effort for a State to develop its State plan amendment to elect PACE as an optional Medicaid benefit. We estimate that 25 States will each take 10 hours to complete this requirement for a total annual burden of 250 hours. We estimate the total burden for these requirements to be 358 hours.

Section 460.68 Program Integrity

Section 460.68(b)(1) requires PACE organizations to develop written policies and procedures for handling direct or indirect conflict of interest by a member of the governing board or an immediate family member.

The burden associated with this requirement is the time and effort for a PACE organization to develop written policies and procedures for handling direct or indirect conflict of interest by a member of the governing board or an immediate family member. We estimate that each organization will spend 1 hour developing and writing these policies and procedures. There will be approximately 54 organizations for a total annual burden of 54 hours.

Section 460.68(b)(2) requires that in the event of a direct or indirect conflict of interest the PACE organization must document the disclosure of the exact nature of the conflict.

We estimate each organization will spend 30 minutes documenting a conflict of interest disclosure. There will be approximately 54 organizations for a total burden of 27 hours.

Note: The following ICRs are subject to the PRA. However, we believe that the burden associated with these ICRs is exempt from the PRA in accordance with 5 CFR 1320.3(b)(2) because the time, effort, and financial resources necessary to comply with these requirements would be incurred by persons in the normal course of their activities.

Section 460.52 Transitional Care Following Termination

Section 460.52(b) states that an entity whose PACE program agreement is terminated must provide assistance to each participant in obtaining necessary transitional care through appropriate referrals and making the individual's medical records available to new providers.

Section 460.70 Contracted Services

Section 460.70(a) states that the PACE organization must have a written contract with each outside organization, agency, or individual that furnishes administrative or care-related services not furnished directly by the PACE organization.

Section 460.70(c) states that a list of contractors must be on file at the PACE center and a copy must be provided to anyone upon request.

Section 460.72 Physical Evironnment

Section 460.72(c)(1) states that the PACE organization must establish, implement, and maintain documented procedures to manage medical and nonmedical emergencies and disasters that are likely to threaten the health or safety of the participants, staff or the public.

Section 460.72(c)(4) states that the organization must have a documented plan to obtain emergency medical assistance from sources outside the center when needed.

Section 460.74 Infection Control

Section 460.74(b) states that the PACE organization must establish, implement, and maintain a documented infection control plan.

Section 460.82 Marketing

Section 460.82(a) states that a PACE organization must inform the public about its program and give prospective participants the following written information: An adequate description of the PACE organization's enrollment and disenrollment policies and requirements; PACE enrollment procedures; description of benefits and services; premiums; and other information necessary for prospective participants to make an informed decision about enrollment.

Section 460.82(d) states that marketing materials must inform a potential participant that he or she must receive all needed health care (other than emergency or urgently needed services) from the PACE organization or from an entity authorized by the PACE organization. All marketing materials must state clearly that PACE participants may be fully and personally liable for the costs of unauthorized or out-of-PACE program agreement services.

Section 460.98 Service Delivery

Section 460.98(a) states that a PACE organization must establish and implement a written plan to furnish care that meets the needs of each participant in all care settings 24 hours a day, every day of the year.

Section 460.100 Emergency Care

Section 460.100(a) states that a PACE organization must establish and maintain a written plan to handle emergency care.

Section 460.102 Interdisciplinary Team

In summary, *section 460.102(d)* states that the interdisciplinary team is responsible for the initial assessment, periodic reassessments, plan of care, and coordination of 24 hour care delivery. Each team member must regularly inform the interdisciplinary team of the medical, functional, and psychosocial condition of each participant; and document changes in a participant's condition in the participant's medical record consistent with documentation policies established by the medical director.

Section 460.104 Participant Assessment

In summary, *section 460.104(d)* states that the interdisciplinary team must explain why it denies a participant's request for services, inform participants of additional appeal processes available, and document all assessment and reassessment information in the participant's medical record.

Section 460.106 Plan of Care

Section 460.106(f) states that the team must document the plan of care, and any changes made to it, in the participant's medical record.

Section 460.110 Bill of Rights

Section 460.110(a) states that a PACE organization must have a written participant bill of rights designed to protect and promote the rights of each participant.

Section 460.110(b) states that upon enrollment, the organization must inform a participant in writing of her or his rights and responsibilities, and all rules and regulations governing participation.

Section 460.112 Specific Rights to Which a Participant Is Entitled

Section 460.112(b)(1) states that a participant has the right to be fully informed in writing of the services available from the PACE organization.

Section 460.112(b)(2) states that a participant has the right to have the enrollment agreement fully explained in a manner understood by the participant.

Section 460.112(e)(2) states that a participant has the right to have the PACE organization explain advance directives and to establish them, if the participant so desires.

Section 460.112(e)(3) states that a participant has the right to be fully informed of his or her health and functional status by the interdisciplinary team and to participate in the development and implementation of the plan of care.

Section 460.112(e)(6) states that a participant has the right to be given reasonable advance notice, in writing, of any transfer to another treatment setting, and the justification for it, due to medical reasons or for the participant's welfare, or that of other participants. The PACE organization must document the justification in the participant's medical record.

Section 460.116 Explanation of Rights

Section 460.116(a) states that a PACE organization must have written policies and implement procedures to ensure that the participant, his or her representative, if any, and staff understand these rights.

Section 460.116(b) states that upon enrollment, the staff must fully explain the rights to the participant and his or her representative, if any, in a manner understood by the participant.

Section 460.122 PACE Organization's Appeals Process

Section 460.122(d) states that a PACE organization must give all parties involved in the appeal appropriate written notification and a reasonable opportunity to present evidence related to the dispute in person, as well as in writing.

Section 460.152 Enrollment Process

Section 460.152(a)(1) requires that at a minimum, the intake process must include the following steps: the PACE staff must explain to the potential participant and his or her representative or caregiver: the PACE program; the requirement that the PACE organization is the participant's sole service provider; monthly premiums, if any; any Medicaid spend-down obligations, and post-eligibility treatment of income, if any.

Section 460.152(a)(2) states that the potential participant must sign a release to allow the PACE organization to obtain his or her medical and financial information and eligibility status for Medicare and Medicaid.

Section 460.152(b)(1) states that if a prospective participant is denied enrollment because his or her health or safety would be jeopardized by living in a community setting, the PACE organization must notify the individual in writing of the reason for denial.

Section 460.152(b)(2) states that if a prospective participant is denied enrollment because his or her health or safety would be jeopardized by living in a community setting, the PACE organization must refer the individual to alternative services, as appropriate.

Section 460.152(b)(3) states that if a prospective participant is denied enrollment because his or her health or safety would be jeopardized by living in a community setting, the PACE organization must maintain supporting documentation of the reason for the determination.

Section 460.154 Enrollment Agreement

Section 460.154 states that if the potential participant meets the eligibility requirements and wants to enroll, he or she or their representative must sign an enrollment agreement in accordance with the requirements in this section.

Section 460.156 Other Enrollment Procedures

Section 460.156(c) states that if there are changes in the enrollment agreement information at any time during the participant's enrollment, the PACE organization must give an updated copy of the information to the participant; and explain the changes to the participant and his or her representative or caregiver in a manner they understand.

Section 460.168 Reinstatement in Other Medicare and Medicaid Programs

Section 460.168(a) states that in order to facilitate a participant's reinstatement in other Medicare and Medicaid programs after disenrollment, the PACE organization must make appropriate referrals and ensure medical records are made available to new providers in a timely manner.

Section 460.172 Documentation of Disenrollment

Section 460.172(a) states that a PACE organization must have a procedure in place to document the reasons for all voluntary and involuntary disenrollments.

Section 460.200 Maintenance of Records and Reporting of Data

Section 460.200(e) states that a PACE organization must safeguard the confidentiality of any information that identifies a particular participant; establish and implement procedures that govern the use and release of a participant's information before releasing personal information that is not required by law to be released.

Section 460.200(f)(1) states that a PACE organization must retain records for the longest of the following periods: the period of time specified in State law; six years from the last entry date; or for medical records of disenrolled participants, six years after the date of disenrollment.

Section 460.204 Financial Recordkeeping and Reporting Requirements

Section 460.204(b) states that a PACE organization must maintain an accrual accounting recordkeeping system.

Section 460.210 Medical Records

Section 460.210(a) states that a PACE organization must maintain a single, comprehensive medical record for each participant, in accordance with accepted professional standards.

Section 460.210(c) states that the PACE organization must promptly transfer copies of medical record information between treatment facilities.

Section 460.210(d) states that all entries must be legible, clear, complete, and appropriately authenticated and dated. Authentication must include signatures or a secured computer entry by a unique identifier of the primary author who has reviewed and approved the entry.

Note: We believe the following requirements are not subject to the PRA in accordance with CFR 1320.3(c)(4) since they do not require information from ten or more entities on an annual basis.

Section 460.60 PACE Organizational Structure

Section 460.60(d)(3) states that a PACE organization planning a change in organizational structure must notify CMS and the State administering agency, in writing, at least 14 days before the change takes effect.

Section 460.82 Marketing

Section 460.82 states that once a PACE organization is under a PACE program agreement, any revisions to existing marketing information and any new information is subject to CMS' time period for approval. CMS approves or disapproves marketing information within 45 days after receipt from the organization.

Note: In accordance with 5 CFR 1320.4(a)(2), we believe the following ICRs are exempt from the PRA since it is in response to an administrative action, investigation, or audit against specific individuals or entities.

Section 460.68 Program Integrity

Section 460.68(c) states that a PACE organization must have a formal process in place to gather information related to paragraphs (a) and (b) of this section, and must be able to respond in writing to a request for information from CMS within a reasonable amount of time.

Section 460.172 Documentation of Disenrollment

Section 460.172(b) states a PACE organization must make documentation available for review by CMS and the State administering agency.

Section 460.192 Ongoing Monitoring After Trial Period

Section 460.192(a) states that at the conclusion of the trial period, CMS, in cooperation with the State administering agency, will continue to conduct reviews of a PACE organization, as appropriate, taking into account the performance level of the organization with respect to the quality of care provided and the organization's compliance with all requirements of this part.

Section 460.194 Corrective Action

Section 460.194(a) states that a PACE organization must take action to correct deficiencies identified during reviews.

Section 460.200 Maintenance of Records

Section 460.200(f)(2) states that if litigation, a claim, a financial management review, or an audit arising from the operation of the PACE program is started before the expiration of the retention period, specified in paragraph (f)(1) of this section, the PACE organization must retain the records until the completion of the litigation, or resolution of the claims or audit findings.

Section 460.204 Financial Recordkeeping and Reporting Requirements

Section 460.204(d) states that a PACE organization must permit CMS and the State administering agency to audit or inspect any books and records of original entry that pertain to the following: any aspect of services performed; reconciliation of participant's benefit liabilities; or determination of Medicare and Medicaid amounts payable.

Section 460.208 Financial Statements

Section 460.208(c) states that if CMS or the State administering agency determines that an organization's performance requires more frequent monitoring and oversight due to concerns about fiscal soundness, CMS or the State administering agency may require a PACE organization to submit monthly or quarterly financial statements, or both.

Note: There is additional burden associated with Sections 460.12, 460.26, 460.30(a) & (b), 460.70, 460.71, 460.72, 460.82, 460.102, 460.104, 460.116, 460.120(b) & (e), 460.122, 460.124, 460.132, 460.152, 460.156, 460.160, 460.164, 460.190, 460.196, 460.202, 460.208, 460.22, 460.32, 460.52, 460.60(d)(1) & (2), 460.68, 460.80, 460.104, 460.118, 460.120, 460.122, 460.132, 460.200, 460.204; however, that burden is currently approved under OMB # 0938–0790 with an expiration date of 2/28/2009.

In the 2002 IFC, § 460.12 was redesignated as § 460.30(c) and the burden was approved at that time. It continues to be currently approved under OMB#0938–0790 with an expiration date of February 28, 2009.

If you comment on these information collection and record keeping requirements, please mail copies directly to the following: Centers for Medicare & Medicaid Services, Office of Strategic Operations and Regulatory Affairs, Division of Regulations Development, Attn.: Melissa Musotto, CMS–1201–F, Room C5–14–03, 7500 Security Boulevard, Baltimore, MD 21244–1850. Office of Information and Regulatory Affairs, Office of Management and Budget, Room 10235, New Executive Office Building, Washington, DC 20503, Attn: Carolyn Lovett, CMS Desk Officer, CMS–1201–F, *carolyn_lovett@omb.eop.gov.* Fax (202) 395–6974.

VI. Regulatory Impact Statement

We have examined the impact of this rule as required by Executive Order 12866 (September 1993, Regulatory Planning and Review), the Regulatory Flexibility Act (RFA) (September 19, 1980, Pub. L. 96–354), section 1102(b) of the Social Security Act, the Unfunded Mandates Reform Act of 1995 (Pub. L. 104–4), and Executive Order 13132.

First, Executive Order 12866 directs agencies to assess all costs and benefits of available regulatory alternatives and, if regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety effects, distributive impacts, and equity). A regulatory impact analysis (RIA) must be prepared for major rules with economically significant effects ($100 million or more in any 1 year). This rule does not reach the economic threshold and thus is not considered a major rule.

Next, the RFA requires agencies to analyze options for regulatory relief of small businesses. For purposes of the RFA, small entities include small businesses, nonprofit organizations, and small governmental jurisdictions. Most hospitals and most other providers and suppliers are small entities, either by nonprofit status or by having revenues of $6 million to $29 million in any 1

year. Individuals and States are not included in the definition of a small entity. Although PACE organizations (POs) are nearly always small entities, the industry is limited in scope with a growth rate of new POs averaging fewer than six per year. Currently, there are 36 POs that have program agreements. In addition, the requirements contained in this rule are largely similar to the requirements that have been applicable to the existing organizations through the 1999 and 2002 interim final rules. Other entities that have contemplated or already have started developing PACE programs have been aware of those requirements and would have designed their potential programs to comply with them. Because the basic effect of this rule is to finalize prevailing industry standards, its impact is not significant.

While we do not have data on which to base an estimate of overall costs or savings to the Medicare and Medicaid programs, we believe that any incremental difference would be so small as to be negligible. PACE services substitute for services that would otherwise be covered, and payment rates are adjusted so that the total payment level is less than the projected payment that would have been made if the participants were not enrolled in PACE. Thus, the overall result should be a slight savings for this small population. PACE services substitute for services that would otherwise be covered, and payment rates are adjusted so that the total payment level is less than the projected payment that would have been made if the participants were not enrolled in PACE. Thus, the overall result should be a slight savings for this small population. Because this rule will not have a significant economic impact on a substantial number of small entities, we are not preparing an analysis for the RFA.

In addition, section 1102(b) of the Act requires us to prepare a regulatory impact analysis if a rule may have a significant impact on the operations of a substantial number of small rural hospitals. This analysis must conform to the provisions of section 604 of the RFA. For purposes of section 1102(b) of the Act and relating to Medicare payment, we define a small rural hospital as a hospital that is located outside of a Metropolitan Statistical Area and has fewer than 100 beds. In terms of Medicaid payment, we define a small rural hospital as a hospital that is located outside of a Core-Based Statistical Area and has fewer than 100 beds. We are not preparing an analysis for section 1102(b) of the Act, because we have determined that this rule will not have a significant impact on the operations of a substantial number of small rural hospitals.

Next, Section 202 of the Unfunded Mandates Reform Act of 1995 also requires that agencies assess anticipated costs and benefits before issuing any rule whose mandates require spending in any 1 year of $100 million in 1995 dollars, updated annually for inflation. That threshold level is currently approximately $120 million. Consistent with our approach in the 1999 and 2002 PACE interim final rules, we are not preparing an analysis of section 202. Even as we factor in the growth rate of PACE since the two previous interim final rules, the mandates of this rule do not require spending $100 million or more in any 1 year. This rule will have no consequential effect on State, local, or Tribal governments or on the private sector.

Finally, Executive Order 13132 establishes certain requirements that an agency must meet when it promulgates a proposed rule (and subsequent final rule) that imposes substantial direct requirement costs on State and local governments, preempts State law, or otherwise has Federalism implications. Under Executive Order 13132, this regulation will not significantly affect the States beyond what is required and provided for under the BBA. It follows the intent and letter of the law and does not usurp State authority beyond what the BBA requires. This regulation describes the processes that must be undertaken by CMS, the States, and POs in order to implement the PACE benefit.

As noted previously, sections 4801 and 4802 of the BBA clearly describe a cooperative relationship between the Secretary and the States in the development, implementation, and administration of the PACE benefit. The following are some examples of areas in which we engaged in partnership with States to establish policy and procedures:

1. Establishing procedures for entering into, extending, and terminating PACE agreements—sections 1894(e)(1)(A) and 1934(e)(1)(A) of the Act.

2. Establishing procedures for excluding service areas already covered under other PACE program agreements in order to avoid unnecessary duplication of services and also to avoid impairing the financial and service viability of the existing program—sections 1894(e)(2)(B) and 1934(e)(2)(B) of the Act.

3. Establishing procedures for the POs to make available PACE program data—sections 1894(e)(3)(A)(i)(III) and 1934(e)(2)(A)(i)(III) of the Act.

4. In conjunction with the PO, developing and implementing health status and quality of life outcome measures—sections 1894(e)(3)(B) and 1934(e)(3)(B) of the Act.

5. The statute requires the Secretary and State to conduct a comprehensive annual review—sections 1894(e)(4)(A) and 1934(e)(4)(A) of the Act.

6. Establishing the frequency of the monitoring reviews—sections 1894(e)(4)(B) and 1934(e)(4)(B) of the Act.

7. Establishing a mechanism for communicating CMS Secretary's findings and State action when a PO is failing to comply with Federal requirements—sections 1894(e)(6)(A) and 1934(e)(6)(A) of the Act.

8. Establishing the entity responsible for the annual eligibility recertification—sections 1894(c)(3) and 1934(c)(3) of the Act; and continuation of eligibility requirements—sections 1894(c)(4) and 1934(c)(4) of the Act.

For this reason, we obtained State input in the early stages of policy development through conference calls with State Medicaid Agency representatives. The 8 agencies that volunteered to participate in these discussions represented a balanced view of States; some with PACE demonstration program experience and some that were not involved with PACE at that time, but were interested in providing input to establish a new long term care optional benefit. The calls were very productive in understanding the variety of State concerns inherent in implementing a new program. In addition, in order to formulate processes to operationalize the PACE benefit, we maintained ties with State representatives through conference calls to obtain information on a variety of topics including the applications review and approval process, data collection needs, and enrollment/disenrollment issues, join CMS/State onsite surveys. We are committed to continuing this dialogue with States after publication of this regulation to ensure this cooperative atmosphere continues as the PACE matures.

Since this regulation finalizes costs associated with PACE and does not impose any new costs on State or local governments, the requirements of E.O. 13132 are not applicable.

In accordance with the provisions of Executive Order 12866, this regulation was reviewed by the Office of Management and Budget.

List of Subjects in 42 CFR Part 460

Aged, Health care, Health records, Medicaid, Medicare, Reporting and recordkeeping requirements.

■ For the reasons set forth in the preamble, the Centers for Medicare & Medicaid Services confirms as final the interim final rules amending 42 CFR Chapter IV, published on November 24, 1999 (64 FR 66234) and October 1, 2002 (67 FR 61496), as final with the following changes:

PART 460—PROGRAM OF ALL-INCLUSIVE CARE FOR THE ELDERLY (PACE)

■ 1. The authority citation for part 460 is revised to read as follows:

Authority: Secs. 1102, 1871, 1894(f), and 1934(f) of the Social Security Act (42 U.S.C. 1302, 1395, 1395eee(f), and 1396u–4(f)).

§§ 460.72, 460.74, 460.98, and 460.102 [Amended]

■ 2. In the following paragraphs in part 460, remove the word ''center'' and add the phrase ''PACE center'' in its place:
■ § 460.72(b)(1) at the end of the first sentence
■ (b)(2)(ii)
■ (b)(4)
■ § 460.74(c)(1)
■ § 460.98(d) heading
■ (d)(3)
■ (e) heading and in the body of the paragraph § 460.102(a)(1)

Subpart A—Basis, Scope, and Definitions

■ 3. Section 460.6 is amended by revising the definition of ''PACE center'' and by adding a definition of ''PACE program'' to read as follows:

§ 460.6 Definitions.

* * * * *

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.

* * * * *

PACE program means a program of all-inclusive care for the elderly that is operated by an approved PACE organization and that provides comprehensive healthcare services to PACE enrollees in accordance with a PACE program agreement.

* * * * *

§ 460.12 [Amended]

■ 4. Section 460.12 is amended by—
■ A. Redesignating paragraph (a)(3) as paragraph (a)(2).
■ B. In newly redesignated paragraph (a)(2)(i), removing the phrase '', as provided in § 460.14.''
■ C. In newly redesignated paragraph (a)(2)(ii), removing the phrase '', as provided in § 460.16.''

§ 460.14 [Removed and Reserved]

■ 5. Section 460.14 is removed and reserved.

§ 460.16 [Removed and Reserved]

■ 6. Section 460.16 is removed and reserved.

■ 7. Section 460.26 is amended as follows:
■ A. Redesignating paragraph (a) as paragraph (a)(1).
■ B. Adding paragraph (a)(2).
■ C. Revising paragraph (b) introductory text.
■ D. Revising paragraph (b)(1).
The revisions read as follows:

§ 460.26 Submission and evaluation of waiver requests.

(a)(1) A PACE organization must submit its waiver request through the State administering agency for initial review. The State administering agency forwards the waiver requests to CMS along with any concerns or conditions regarding the waiver.

(2) Entities submitting an application to become a PACE organization may submit a waiver request. The entity must submit its waiver request through the State administering agency for initial review. The State administering agency forwards the waiver requests to CMS along with any concerns or conditions regarding the waiver. The waiver request is submitted as a document separate from the application but may be submitted in conjunction with and at the same time as the application.

(b) CMS evaluates a waiver request from a PACE organization or PACE applicant on the basis of the following information:

(1) The adequacy of the description and rationale for the waiver provided by the PACE organization or PACE applicant, including any additional information requested by CMS.

* * * * *

■ 8. Section 460.28 is amended by revising paragraph (a)(2) to read as follows:

§ 460.28 Notice of CMS determination on waiver requests.

(a) * * *

(2) Denies the request and notifies the PACE organization or PACE applicant in writing of the basis of the denial.

* * * * *

■ 9. Section 460.32 is amended by revising paragraph (a)(12) to read as follows:

§ 460.32 Content and terms of PACE program agreement.

(a) * * *

(12) The Medicaid capitation rate and the methodology used to calculate the Medicare capitation rate.

* * * * *

§ 460.60 [Amended]

■ 10. Section 460.60 is amended as follows:
■ A. Paragraph (d)(3) is revised.
■ B. Paragraphs (d)(4) and (d)(5) are removed.
The revisions read as follows:

§ 460.60 PACE organizational structure.

* * * * *

(d) * * *

(3) A PACE organization planning a change in organizational structure must notify CMS and the State administering agency, in writing, at least 14 days before the change takes effect.

■ 11. Section 460.62 is amended by—
■ A. Revising paragraph (b).
■ B. Revising paragraph (c).
The revisions read as follows:

§ 460.62 Governing body.

* * * * *

(b) *Participant advisory committee.* (1) A PACE organization must establish a participant advisory committee to provide advice to the governing body on matters of concern to participants. Participants and representatives of participants must constitute a majority of the membership of this committee.

(2) The participant advisory committee must provide the liaison to the governing body with meeting minutes that include participant issues.

(c) *Participant representation on the governing body.* (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.

(3) *Duty of the participant representative.* The participant representative must present issues from the participant advisory committee to the governing body.

■ 12. Section 460.64 is revised to read as follows:

§ 460.64 Personnel qualifications for staff with direct participant contact.

(a) *General qualification requirements.* Each member of the PACE organization's staff that has direct participant contact, (employee or contractor) must meet the following conditions:

(1) Be legally authorized (for example, currently licensed, registered or certified if applicable) to practice in the State in which he or she performs the function or action;

(2) Only act within the scope of his or her authority to practice;

(3) Have 1 year of experience with a frail or elderly population;

(4) Meet a standardized set of competencies for the specific position description established by the PACE organization and approved by CMS before working independently.

(5) Be medically cleared for communicable diseases and have all immunizations up-to-date before engaging in direct participant contact.

(b) *Federally-defined qualifications for physician.* In addition to the qualification specified in paragraph (a) of this section, a physician must meet the qualifications and conditions in § 410.20 of this chapter.

■ 13. Section 460.66 is amended by adding paragraph (c) to read as follows:

§ 460.66 Training.

(c) Personal care attendants must exhibit competency before performing personal care services independently.

■ 14. Section 460.68 is amended by–

■ A. Revising paragraph (b).

■ B. Redesignating paragraph (d) as paragraph (c).

■ C. Revising the heading of newly redesignated paragraph (c).

The revisions read as follows:

§ 460.68 Program integrity.

* * * * *

(b) *Direct or indirect interest in contracts.* The PACE organization shall identify members of its governing body or any immediate family member having a direct or indirect interest in any contract that supplies any administrative or care-related service or materials to the PACE organization.

(1) PACE organizations must develop policies and procedures for handling any direct or indirect conflict of interest by a member of the governing body or by the member's immediate family.

(2) In the event of a direct or indirect conflict of interest by a member of the PACE organization's governing body or his or her immediate family member, the board member must—

(i) Fully disclose the exact nature of the conflict to the board of directors and have the disclosure documented; and

(ii) Recuse himself or herself from discussing, negotiating, or voting on any issue or contract that could result in an inappropriate conflict.

(c) *Disclosure and recusal requirements.* * * *

§ 460.70 [Amended]

■ 15. Section 460.70 is amended by—

■ A. Removing paragraph (d).

■ B. Redesignating paragraph (e) as paragraph (d).

■ C. Redesignating paragraph (f) as paragraph (e).

■ 16. Section 460.71 is amended by republishing paragraph (b) introductory text and revising paragraph (b)(4) to read as follows:

§ 460.71 Oversight of direct participant care.

* * * * *

(b) The PACE organization must develop a program to ensure that all staff furnishing direct participant care services meet the following requirements:

* * * * *

(4) Are free of communicable diseases and are up to date with immunizations before performing direct patient care.

* * * * *

§ 460.72 [Amended]

■ 17. Section 460.72 is amended by revising paragraph (a)(3) to read as follows:

§ 460.72 Physical environment.

(a) * * *

(3) Equipment maintenance.

(i) A PACE organization must establish, implement, and maintain a written plan to ensure that all equipment is maintained in accordance with the manufacturer's recommendations.

(ii) A PACE organization must perform the manufacturer's recommended maintenance on all equipment as indicated in the organization's written plan.

* * * * *

■ 18. Section 460.78 is amended by revising paragraph (a)(1) introductory text to read as follows:

§ 460.78 Dietary services.

(a) *Meal requirements.* (1) Except as specified in paragraphs (a)(2) or (a)(3) of this section, the PACE organization must ensure, through the assessment and care planning process, that each participant receives nourishing, palatable, well-balanced meals that meet the participant's daily nutritional and special dietary needs. Each meal must meet the following requirements:

* * * * *

Subpart F—PACE Services

■ 19. Section 460.92 is revised to read as follows:

§ 460.92 Required services.

The PACE benefit package for all participants, regardless of the source of payment, must include the following:

(a) All Medicare-covered items and services.

(b) All Medicaid-covered items and services, as specified in the State's approved Medicaid plan.

(c) Other services determined necessary by the interdisciplinary team to improve and maintain the participant's overall health status.

■ 20. Section 460.94 amended by revising paragraph (b)(5) to read as follows:

§ 460.94 Required services for Medicare participants.

* * * * *

(b) * * *

(5) Section 411.15(g) and § 411.15(k) of this chapter that may prevent payment for PACE program services that are provided to PACE participants.

■ 21. Section 460.96 is amended by revising paragraph (e)(1) to read as follows:

§ 460.96 Excluded services.

* * * * *

(e) * * *

(1) In accordance with § 424.122 and § 424.124 of this chapter.

* * * * *

■ 22. Section 460.98 is amended by revising paragraph (b)(3) to read as follows:

§ 460.98 Service delivery.

* * * * *

(b) * * *

(3) The PACE organization may not 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 source of payment.

* * * * *

■ 23. Section 460.100 is amended by:

■ A. Revising paragraph (d).

■ B. Republishing the introductory text to paragraph (e).

■ C. Adding paragraph (e)(3) containing definitions of ''Post stabilization care'' and ''Urgent care.''

The revisions read as follows:

§ 460.100 Emergency care.

* * * * *

(d) *Explanation to participant.* The organization must ensure that the participant or caregiver, or both, understand when and how to get access to emergency services and that no prior authorization is needed.

(e) *On-call providers.* The plan must provide for the following:

* * * * *

(3) *Definitions.* As used in this section, the following definitions apply:

(i) Post stabilization care means services provided subsequent to an emergency that a treating physician views as medically necessary after an emergency medical condition has been stabilized. They are not emergency services, which POs are obligated to cover. Rather, they are non-emergency services that the PO should approve before they are provided outside the service area.

(ii) Urgent care means the care provided to a PACE participant who is out of the PACE service area, and who believes their illness or injury is too severe to postpone treatment until they return to the service area, but their life or function is not in severe jeopardy.

■ 24. In § 460.102, paragraph (b)(3) is revised to read as follows:

§ 460.102 Interdisciplinary team.

* * * * *

(b) * * *

(3) Master's-level social worker.

* * * * *

§ 460.104 [Amended]

■ 25. Section 460.104 is amended by—

■ A. Revising paragraph (a)(2).

■ B. Revising paragraph (c)(1)(iii).

■ C. Revising paragraph (c)(2).

■ D. Redesignating paragraphs (d) and (e) as paragraphs (e) and (f), respectively.

■ E. Redesignating paragraph (c)(3) as new paragraph (d) and revising it.

The revisions read as follows:

§ 460.104 Participant assessment.

(a) * * *

(2) As part of the initial comprehensive assessment, each of the following members of the interdisciplinary team must evaluate the participant in person, at appropriate intervals, and develop a discipline-specific assessment of the participant's health and social status:

(i) Primary care physician.

(ii) Registered nurse.

(iii) Master's-level social worker.

(iv) Physical therapist.

(v) Occupational therapist.

(vi) Recreational therapist or activity coordinator.

(vii) Dietitian.

(viii) Home care coordinator.

* * * * *

(c) * * *

(1) * * *

(iii) Master's-level social worker.

* * * * *

(2) *Annual reassessment.* On at least an annual basis, the following members of the interdisciplinary team must conduct an in-person reassessment:

(i) Physical therapist.

(ii) Occupational therapist.

(iii) Dietitian.

(iv) Home care coordinator.

(d) *Unscheduled reassessments.* In addition to annual and semiannual reassessments, unscheduled reassessments may be required based on the following:

(1) *A change in participant status.* If the health or psychosocial status of a participant changes, the members of the interdisciplinary team, listed in paragraph (a)(2) of this section, must conduct an in-person reassessment.

(2) *At the request of the participant or designated representative.* If a participant (or his or her designated representative) believes that the participant needs to initiate, eliminate, or continue a particular service, the appropriate members of the interdisciplinary team, as identified by the interdisciplinary team, must conduct an in-person reassessment.

(i) The PACE organization must have explicit procedures for timely resolution of requests by a participant or his or her designated representative to initiate, eliminate, or continue a particular service.

(ii) Except as provided in paragraph (d)(2)(iii) of this section, the interdisciplinary team must notify the participant or designated representative of its decision to approve or deny the request from the participant or designated representative as expeditiously as the participant's condition requires, but no later than 72 hours after the date the interdisciplinary team receives the request for reassessment.

(iii) The interdisciplinary team may extend the 72-hour timeframe for notifying the participant or designated representative of its decision to approve or deny the request by no more than 5 additional days for either of the following reasons:

(A) The participant or designated representative requests the extension.

(B) The team documents its need for additional information and how the delay is in the interest of the participant.

(iv) The PACE organization must explain any denial of a request to the participant or the participant's designated representative orally and in writing. The PACE organization must provide the specific reasons for the denial in understandable language. The PACE organization is responsible for the following:

(A) Informing the participant or designated representative of his or her right to appeal the decision as specified in § 460.122.

(B) Describing both the standard and expedited appeals processes, including the right to, and conditions for, obtaining expedited consideration of an appeal of a denial of services as specified in § 460.122.

(C) Describing the right to, and conditions for, continuation of appealed services through the period of an appeal as specified in § 460.122(e).

(v) If the interdisciplinary team fails to provide the participant with timely notice of the resolution of the request or does not furnish the services required by the revised plan of care, this failure constitutes an adverse decision, and the participant's request must be automatically processed by the PACE organization as an appeal in accordance with § 460.122.

* * * * *

■ 26. Section 460.112 is amended by—

■ A. Revising the introductory text of paragraph (a).

■ B. Revising paragraph (b)(1)(iii).

The revisions read as follows:

§ 460.112 Specific rights to which a participant is entitled.

(a) *Respect and nondiscrimination.* Each participant has the right to considerate, respectful care from all PACE employees and contractors at all times and under all circumstances. Each participant has the right not to be discriminated against in the delivery of required PACE services based on race, ethnicity, national origin, religion, sex, age, sexual orientation, mental or physical disability, or source of payment. Specifically, each participant has the right to the following:

* * * * *

(b) * * *

(1) * * *

(iii) At the time a participant's needs necessitate the disclosure and delivery of such information in order to allow the participant to make an informed choice.

* * * * *

■ 27. Section 460.122 is amended by—

■ A. Revising the introductory text to the section.

■ B. Revising paragraph (f)(1).

The revisions read as follows:

§ 460.122 PACE organization's appeals process.

For purposes of this section, an appeal is a participant's action taken with respect to the PACE organization's noncoverage of, or nonpayment for, a

service including denials, reductions, or termination of services.

* * * * *

(f) *Expedited appeals process.* (1) A PACE organization must have an expedited appeals process for situations in which the participant believes that his or her life, health, or ability to regain or maintain maximum function could be seriously jeopardized, absent provision of the service in dispute.

* * * * *

Subpart I—Participant Enrollment and Disenrollment

■ 28. Section 460.152 is amended by adding paragraph (a)(1)(vi) to read as follows:

§ 460.152 Enrollment process.

(a) * * *

(1) * * *

(vi) Post-eligibility treatment of income.

* * * * *

■ 29. Section 460.154 is amended by—

■ A. Revising paragraph (h).

■ B. Revising paragraph (t).

The revisions read as follows:

§ 460.154 Enrollment agreement.

* * * * *

(h) Notification that a Medicare participant may not enroll or disenroll at a Social Security office.

* * * * *

(t) The signature of the applicant or his or her designated representative and the date.

■ 30. Section 460.160 is amended by revising paragraph (b)(3) to read as follows:

§ 460.160 Continuation of enrollment.

* * * * *

(b) * * *

(3) *Continued eligibility criteria.* (i) The State administering agency, must establish criteria to use in making the determination of ''deemed continued eligibility.'' The State administering agency, in consultation with the PACE organization, makes a determination of deemed continued eligibility based on a review of the participant's medical record and plan of care. These criteria must be applied in reviewing the participant's medical record and plan of care.

(ii) The criteria used to make the determination of continued eligibility must be specified in the program agreement.

Subpart J—Payment

■ 31. Section 460.180 is amended by—

■ A. Revising paragraph (a).

■ B. Revising paragraphs (b)(1) through (b)(4).

The revisions read as follows:

§ 460.180 Medicare payment to PACE organizations.

(a) *Principle of payment.* Under a PACE program agreement, CMS makes a prospective monthly payment to the PACE organization of a capitation amount for each Medicare participant in a payment area based on the rate it pays to a Medicare Advantage organization.

(b) *Determination of rate.* (1) The PACE program agreement specifies the methodology used to calculate the monthly capitation amount applicable to a PACE organization.

(2) Except as specified in paragraph (b)(4) of this section, the monthly capitation amount is based on the Part A and Part B payment rates established for purposes of payment to Medicare Advantage organizations. As used in this section, ''Medicare Advantage rates'' means the Part A and Part B rates calculated by CMS for making payment to Medicare Advantage organizations under section 1853(c) of the Act.

(3) CMS will adjust the monthly capitation payment amount derived under paragraph (b)(2) of this section based on a risk adjustment that reflects the individual's health status. CMS will ensure that payments take into account the comparative frailty of PACE enrollees relative to the general Medicare population.

(4) For Medicare participants who require ESRD services, the monthly capitation amount is based on the Medicare Advantage ESRD risk adjustment model.

* * * * *

Subpart L—Data Collection, Record Maintenance, and Reporting

§ 460.210 [Amended]

■ 32. Section 460.210 is amended by removing paragraph (b)(13).

(Catalog of Federal Domestic Assistance Program No. 93.778, Medical Assistance Program)

(Catalog of Federal Domestic Assistance Program No. 93.773, Medicare—Hospital Insurance; and Program No. 93.774, Medicare—Supplementary Medical Insurance Program)

Dated: September 26, 2006.

Mark B. McClellan,

Administrator, Centers for Medicare & Medicaid Services.

Approved: November 14, 2006.

Michael O. Leavitt,

Secretary.

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