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Part II

Department of Health and Human Services

Health Care Financing Administration

**42 CFR Part 460, et al.
Medicare and Medicaid Programs;
Programs of All-Inclusive Care for the
Elderly (PACE); Final Rule**

DEPARTMENT OF HEALTH AND HUMAN SERVICES**Health Care Financing Administration****42 CFR Parts 460, 462, 466, 473, and 476****[HCFA-1903-IFC]****RIN 0938-AJ63****Medicare and Medicaid Programs; Programs of All-Inclusive Care for the Elderly (PACE)****AGENCY:** Health Care Financing Administration (HCFA), HHS.**ACTION:** Interim final rule with comment period.

SUMMARY: This rule establishes requirements for Programs of All-inclusive Care for the Elderly (PACE) under Medicare and Medicaid. These are pre-paid, capitated programs for beneficiaries who meet special eligibility requirements and who elect to enroll. Programs must apply for approval and are evaluated in terms of specific criteria. Only a limited number of programs can be approved. Priority consideration will be given to applicants that have been operating under ongoing PACE demonstration projects.

DATES: Effective date: These regulations are effective on November 24, 1999. The incorporation by reference of the publication listed in the rule was approved by the Director of the Federal Register as of November 24, 1999.

Comment date: Comments will be considered if we receive them at the appropriate address, as provided below, no later than 5 p.m. on January 24, 2000.

ADDRESSES: Mail an original and 3 copies of written comments to the following address: Health Care Financing Administration, Department of Health and Human Services, Attention: HCFA-1903-IFC, P.O. Box 8016, Baltimore, MD 21244-8016.

If you prefer, you may deliver an original and 3 copies of your written comments to one of the following addresses: Room 309-G, Hubert H. Humphrey Building, 200 Independence Avenue, SW., Washington, D.C. 20201, or Room C5-09-26, 7500 Security Boulevard, Baltimore, Maryland 21244-1850.

Comments may also be submitted electronically to the following e-mail address: HCFA1903IFC@hcfa.gov. For e-mail comment procedures, see the beginning of **SUPPLEMENTARY INFORMATION**. For further information on ordering copies of the **Federal Register** contained in this document, see the

beginning of **SUPPLEMENTARY INFORMATION**.

FOR FURTHER INFORMATION CONTACT: Janet Samen, (410) 786-4533; or Terry Pratt, for State technical assistance, (410) 786-5831.

SUPPLEMENTARY INFORMATION:**E-mail, Comments, Procedures, and Availability of Copies**

E-mail comments must include the full name and address of the sender, and must be submitted to the referenced address in order to be considered. All comments must be incorporated in the e-mail message because we may not be able to access attachments.

Electronically submitted comments will be available for public inspection at the Independence Avenue address, below. Because of staffing and resource limitations, we cannot accept comments by facsimile (FAX) transmission. In commenting, please refer to file code HCFA-1903-IFC. Comments received timely will be available for public inspection as they are received, generally beginning approximately 3 weeks after publication of a document, in Room 309-G of the Department's offices at 200 Independence Avenue, SW., Washington, D.C., on Monday through Friday of each week from 8:30 a.m. to 5 p.m. (phone: (202) 690-7890).

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by using local WAIS client software, or by telnet to swais.access.gpo.gov, then login as guest (no password required). Dial-in users should use communications software and modem to call 202-512-1661; type swais, then login as guest (no password required).

I. Background*A. Legislative History*

Section 4801 of Pub. Law 105-33, the Balanced Budget Act of 1997 (BBA), authorized coverage of PACE under the Medicare program. It amended title XVIII of the Social Security Act (the Act) by adding section 1894, which addresses Medicare payments to, and coverage of benefits under, PACE. Section 4802 of 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 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 project waiver status.

B. Demonstration Project History

Section 603(c) of the Social Security Amendments of 1983 (Pub. Law 98-21), as extended by section 9220 of the Consolidated Omnibus Budget Reconciliation Act (COBRA) of 1985 (Pub. Law 99-272) authorized the original demonstration waiver for On Lok Senior Health Services in San Francisco. Section 9412(b) of Pub. Law 99-509, the Omnibus Budget Reconciliation Act (OBRA) of 1986, authorized HCFA to conduct a PACE demonstration project 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 OBRA 1990 authorized an increase to 15 demonstration sites.) The PACE demonstration replicated a unique model of managed care service delivery for a small number of very frail community-dwelling elderly, most of whom were dually eligible for Medicare and Medicaid coverage and all of whom were assessed as being eligible for nursing home placement according to the standards established by their respective States. The model of care included as core services the provision of adult day health care and multidisciplinary team case management, through which access to and allocation of all health services was controlled. Physician, therapeutic,

ancillary and social support services were furnished in the participant's residence or on-site at the adult day health center, unless those locations were not feasible. Hospital, nursing home, home health, and other specialized services were furnished under contract. Financing of this model was accomplished through prospective capitation of both Medicare and Medicaid payments. Demonstration sites had been permitted by section 4118(g) of Pub. Law 100-203 (OBRA of 1987) to assume full financial risk progressively over the initial three years, but that authority was removed by section 4803(b)(1)(B) of the BBA. There are currently 25 approved PACE demonstration sites.

C. Use of the PACE Protocol

Throughout this document, when we refer to "the Protocol" we mean the Protocol for the Program of All-inclusive Care for the Elderly (PACE), as published by On Lok, Inc., as of April 14, 1995, or any successor protocol that may be agreed upon between HCFA and On Lok, Inc. A copy of the Protocol is included at Addendum A.

We are directed by sections 1894(f)(2) and 1934(f)(2) of the Act to incorporate the requirements applied to PACE demonstration waiver programs under the Protocol, to the extent consistent with the provisions of sections 1894 and 1934 of the Act. We also are authorized to modify or waive provisions of the Protocol if the 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.

D. Consultation With States

Sections 4801 and 4802 of Public Law 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 Welfare Association (APWA) as the conduit to solicit States for volunteers to consult with HCFA 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, HCFA staff arranged a series of conference calls to discuss a wide range of issues pertaining to PACE organization requirements, the application process, enrollment, and payment and related financial data collection. Each subject

area discussion included HCFA staff and two to three State representatives. The feedback obtained during these meetings has been an invaluable source of information in understanding State operational concerns, in constructing the regulation and in the development of operational guidelines that will be released at a later date. We believe that this approach will minimize operational barriers that are frequently inherent when new programs are initiated.

E. Consultations With State Agency on Aging

Under the Older Americans Act, State Agencies on Aging are charged with the responsibility of promoting comprehensive and coordinated service systems for older persons in their States. Consistent with this responsibility, the State Agencies on Aging oversee important programs for home and community-based services funded through Title III of the Older Americans Act, State revenues, and the Medicaid home and community-based waiver program. (Two thirds of the State agencies are involved in administering home and community-based programs.)

The State agencies also implement and oversee important planning, information and referral, case management, and quality assurance functions as well as 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. Home care quality is monitored in an increasing number of States.

The State agency which administers the PACE program should regularly consult with the State Agency on Aging in overseeing the operation of the PACE program in order to avoid service duplication in the PACE service areas and to assure the delivery and quality of services to PACE participants. We are 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. Additional information on this topic is presented in the section on "participant rights".

F. State Medicaid Plan Requirement

The State Medicaid plan is the contract between the States and the Federal government whereby States agree to administer the Medicaid program in accordance with Federal law and policy. The State plan preprint sets forth the scope of the Medicaid program, including groups covered, services furnished, and payment policy. When a State completes a new State

plan preprint page due to changes in its Medicaid program (called a "State plan amendment"), the preprint page must be approved by HCFA 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 BBA, provides authority for States to elect PACE as an optional Medicaid benefit. The State plan electing the optional PACE program must be approved before we can approve an application for a PACE organization in that State.

We developed an interim State plan preprint for PACE. A State Medicaid letter dated March 23, 1998, provides information and guidance to State Medicaid agencies on how to satisfy the State plan amendment requirement. Additional directions for completing the State plan amendment will be provided in a State Medicaid Director letter that will be issued at or soon after publication of this regulation.

G. Interaction With Medicare+Choice

The BBA also established a new Medicare+Choice program that expanded the health care options available to Medicare beneficiaries. Under the Medicare+Choice program, beneficiaries may elect to receive Medicare benefits through enrollment in one of an array of private health plan choices beyond the original (fee-for-service) Medicare program or the plans previously available through managed care organizations under section 1876 of the Act. The BBA set forth the requirements for Medicare+Choice organizations in a new part C of title XVIII of the Act. Interim final regulations to implement the Medicare+Choice program were published June 26, 1998 (63 FR 34968). Final regulations addressing some of the comments were published February 17, 1999 (64 FR 7968).

Although the PACE program has certain fundamental similarities to Medicare+Choice and managed care organizations, PACE is not a Medicare+Choice plan. The BBA established distinct requirements for the PACE program. PACE is similar to some Medicare+Choice 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 Medicare+Choice plan in other ways such as: it is not available nationwide (only in a limited number of sites); it includes statutory waivers that expand the scope of Medicare covered services; it is not available to all beneficiaries (only to a defined subset of frail elderly); and it is a joint Medicare/Medicaid program. However, the BBA did direct us to

consider some of the requirements established for Medicare+Choice as we develop regulations for PACE organizations in certain areas common to both programs, e.g., beneficiary protections, payment rates, and sanctions.

II. Provisions of the Interim Final Rule

General Approach

As part of the President's and Vice President's regulatory reform initiative, we have been committed to changing current regulations to focus on outcome of care and to eliminate unnecessary procedural requirements. We remain committed to this regulatory reform initiative. However, in the development of the regulations for the PACE program, several factors have contributed to the use of a more procedural rather than outcome-oriented approach.

As set forth in sections 4801 and 4802 of the BBA, the PACE program includes medical as well as non-medical services for the care of the frail elderly; this is both a new and a unique model of service delivery. Moreover, as previously noted, sections 1894(f)(2) and 1934(f)(2) of the Act establish as the foundation for this regulation the PACE Protocol. By imposing such a requirement, Congress assured the use of the procedural elements contained in the PACE Protocol as a minimum to ensure beneficiary protections and safeguards. As Congress mandated, we are adopting the requirements of the PACE Protocol to the extent they are consistent with the statutory provisions. We have clarified and expanded upon certain provisions contained in the Protocol to more clearly define the requirements and make them more quantifiable for purposes of enforcement. We will identify and discuss all substantive modifications made to the requirements contained in the Protocol.

After reviewing the public comments that we receive and after we gain some experience applying the provisions of this interim final rule to PACE programs, we will reevaluate the provisions to determine where we can make modifications to adopt an approach more consistent with the regulatory reform initiative.

This interim final rule contains the first published regulations applicable to the PACE program. To accommodate the new regulations, we are establishing a new subchapter E (PROGRAMS OF ALL-INCLUSIVE CARE FOR THE ELDERLY (PACE)) and a new part 460 (PROGRAMS OF ALL-INCLUSIVE CARE FOR THE ELDERLY (PACE)). We are also redesignating subchapter D as

subchapter F (PEER REVIEW ORGANIZATIONS); we are redesignating parts 462, 466, 473, and 476 as parts 475, 476, 478, and 480, respectively; and are revising the section numbers to conform to the new part numbers. We are reserving the former subchapter D. In addition, we are redesignating subchapter E as subchapter G (STANDARDS AND CERTIFICATION) with no changes in part designations.

Subpart A—Basis, Scope and Definitions

Basis (§ 460.2)

We state that the regulations set forth in Subchapter E, part 460, are based on sections 1894, 1905(a), and 1934 of the Act, which authorize Medicare payments to, and coverage of benefits under, PACE and authorize the establishment of PACE as a State option under Medicaid to provide for Medicaid payments to, and coverage of benefits under, PACE.

Scope and Purpose (§ 460.4)

We state that the purpose of this regulation is to set forth the requirements that an entity must meet in order to be approved as a PACE organization that operates a PACE program under Medicare and Medicaid. This part also sets forth how individuals may qualify to enroll in a PACE program, 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 terminations. We state that 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.

Definitions (§ 460.6)

We provide several definitions based on those in sections 1894(a) and 1934(a) of the Act and add definitions of several other terms.

Sections 1894(a)(3) and 1934(a)(3) of the Act define a "PACE provider." We have changed that term to "PACE organization" in this regulation for clarity. The term "PACE provider" would be confusing because both Medicare (at 42 CFR 400.202) and Medicaid (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 "PACE organization" since "organization" is the 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 do 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 narrow Medicare definition in 400.202. We define a PACE organization as an entity that has in effect a PACE program agreement.

Based on sections 1894(a)(4) and 1934(a)(4) of the Act, we define a PACE program agreement as an agreement between a PACE organization, HCFA, and the State administering agency for the operation of a PACE program.

In accordance with sections 1894(a)(8) and 1934(a)(8) of the Act, we define the State administering agency as the State agency responsible for administering the PACE program agreement.

In accordance with sections 1894(a)(9) and 1934(a)(9) of the Act, we define a trial period as the first three contract years in which a PACE organization operates under a PACE program agreement, including any contract year during which the entity operated under a PACE demonstration waiver program.

We have added a definition of a contract year as the term of a PACE program agreement, which is a calendar year except that a PACE organization's initial (start-up) contract year may be from 12 to 23 months as determined by HCFA. This will 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.

We define a Medicare beneficiary as an individual who is entitled to Medicare Part A benefits and/or enrolled under Medicare Part B. This term includes dually-eligible individuals who are also Medicaid recipients.

We have defined a participant as an individual enrolled in a PACE program. A Medicare participant is a Medicare beneficiary who is enrolled in a PACE

program, and a Medicaid participant is a Medicaid recipient who is enrolled in a PACE program.

We clarify that the term "services" includes both items and services.

Subpart B—PACE Organization Application and Evaluation

Purpose (§ 460.10)

This subpart establishes application requirements for an entity that seeks approval from HCFA as a PACE organization.

PACE Under Both Medicare and Medicaid

We are requiring that each PACE organization must enter into a program agreement under both sections 1894 and 1934 of the Act, *i.e.*, that each organization participate in both Medicare and Medicaid. Most of the text of those sections is identical and our analysis indicates that key sections contemplate entities acting as PACE organizations under both programs.

Sections 1894(f)(2) and 1934(f)(2) of the Act require that we incorporate in regulations the requirements applied to PACE demonstration waiver programs under the PACE Protocol, to the extent consistent with the provisions of sections 1894 and 1934. Under the Protocol, PACE demonstration programs operated under both Medicare and Medicaid. We believe that the directive to incorporate the requirements in the Protocol reflects an expectation by Congress that all PACE organizations 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, 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 have 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.

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 PACE organization 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 PACE organization. While this would curtail the availability of PACE programs in such 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 State administering agency that is responsible for administering PACE program agreements in the State under sections 1894 and 1934 of the Act. The State administering agency closely cooperates with HCFA in establishing procedures for entering into, extending, and terminating PACE program agreements. The State administering agency cooperates with HCFA and the PACE organization in the development of participant health status and quality of life outcome measures. The State administering agency cooperates with HCFA 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 a State administering agency. We believe that a State which has not chosen PACE as an optional service would be ill-prepared or unable to perform this role.

Most of the text of section 1894 of the Act is identical to text in section 1934. Portions of that text reflect the concept of entities acting as PACE organizations 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 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 level of care covered under the State Medicaid plan.

Section 1894(e) of the Act provides that "the Secretary, in close cooperation with the State administering agency" will establish program agreements for "entities that meet the requirements for a PACE organization 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 PACE organization 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 may be accomplished by either "the Secretary or a State administering agency."

On the other hand, we acknowledge that there are some portions of the law which are inconsistent with this position. First, there is the fact that Congress enacted Medicare and Medicaid PACE benefits through two separate statutory sections. In addition, section 4803(c)(1) of BBA directs us, in determining "provider status," to "give priority in processing applications of entities to qualify as PACE programs under section 1894 or 1934 of the Social Security Act." Further, section 1894(a)(4) defines a PACE program agreement as "an agreement, consistent with this section, section 1934 (if applicable), and regulations promulgated to carry out such sections." See also section 1934(a)(4).

Nonetheless, it is highly unlikely that any entity could be a viable PACE organization 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 such significant premiums.

As the above citations illustrate, some provisions of the law are conflicting and thus ambiguous. We therefore must interpret them to give effect to as many of the provisions as possible and to the policy objectives that they advance. In

keeping with the Congressional intent that the PACE Protocol guide our implementation of the PACE program, we have determined that PACE organizations 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 PACE organization, we would not accept an application from that entity.

Application Requirements (§ 460.12)

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 PACE organization in that State.

We have established § 460.12 to set forth the application requirements for the PACE program. In order for HCFA to determine whether an entity qualifies as a PACE organization, 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, HCFA will review and take action to approve, deny or request additional information only on complete applications; *i.e.*, those applications that address all elements of the PACE program agreement. HCFA will send a letter to each applicant indicating whether or not the application is complete and specifying when the 90-day review period ends.

Except for entities that qualify for priority processing or special consideration as discussed below, we will accept and begin to review applications 90 days after the effective date of this interim final regulation. Entities interested in obtaining specific information for use in applying for PACE organization status should access the PACE homepage, available through both the Medicare and Medicaid HCFA websites (www.hcfa.gov/medicare (or [medicaid](http://www.hcfa.gov/medicaid)) /[PACE/pacehmpg.htm](http://www.hcfa.gov/pacehmpg.htm)).

States have played a significant role in the development of PACE demonstration projects as well as other community-based alternatives to institutionalization. Most States have implemented home and community based programs to 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 State administering agencies and the State Medicaid Agencies. With regard to applications, we 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 State's overall long-term care delivery system.

Therefore, we are requiring in § 460.12(b) that applications for PACE organization status be accompanied by an assurance from the State administering agency indicating that it considers the entity to be qualified to be a PACE organization 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 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, there is sufficient funding for program development and facilities, there is adequate demand for PACE services as shown by demographic analysis, and 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.

Entities that are interested in developing a PACE program agreement should contact their State administering agency to determine whether the State has submitted or plans to submit a State plan amendment to elect PACE as an optional benefit under its State Medicaid plan and if the State has established additional requirements for PACE organizations.

Priority Consideration (§ 460.14)

We have established section 460.14 to address priority applications. The statute requires that we give priority in processing applications through August 5, 2000, to entities that are operating under PACE demonstration waivers under the authority of section 603(c) of the Social Security Amendments of 1983, as extended by section 9220 of COBRA of 1985, or section 9412(b) of the OBRA of 1986. In addition, we are directed to give priority to entities that applied to operate under a PACE

demonstration waiver under section 9412(b) of the OBRA of 1986 as of May 1, 1997.

To give priority in processing applications from entities that meet the criteria, we will accept applications only from these entities beginning on the effective date of this interim final regulation and continuing for 45 days. Applications from other entities will not be accepted during this period. During the subsequent 45 days, extending to 90 days after the effective date of this regulation, we will continue to accept applications from entities that meet the priority processing criteria and we also will accept applications from entities that qualify for special consideration.

Special Consideration (§ 460.16)

In § 460.16, Special Consideration, we define the qualifications to receive special consideration of a PACE application.

The statute requires that we give special consideration in the processing of applications through August 5, 2000, to an entity that, as of May 1, 1997, indicated a specific intent to become a PACE organization through formal activities, such as entering into a contract to conduct a PACE feasibility study.

To give special consideration in processing applications from entities that meet the criteria, we will accept applications from these entities beginning 45 days after the effective date of this interim final regulation. During the 45-day period that extends from 45 days after the effective date to 90 days after the effective date, we will accept applications only from entities that meet the priority processing criteria or entities that qualify for special consideration. Applications from other entities will not be accepted during this period.

Applications from entities that believe they are entitled to special consideration must include information regarding the formal activities they engaged in towards becoming a PACE organization. If we agree that special consideration is appropriate for applications submitted after the special 45-day window, we will identify those applicants and factor in the entity's special status in the event that we have a greater number of applications under review than available capacity for PACE program agreements.

HCFA Evaluation of Applications (§ 460.18)

We will approve entities based upon a review of the materials submitted as part of the application, as well as information from the State

administering agency and information obtained through onsite visits.

Notice of HCFA Determination
(§ 460.20)

Sections 1894(e)(8) and 1934(e)(8) of the Act require us to approve or deny an application for PACE organization 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 PACE organization status in writing or request additional information within the 90-day timeframe. We clarify that, for purposes of the 90-day time limit described in this section, the date that an application is considered to be submitted to HCFA is the date on which the application is delivered to the address designated by HCFA.

These sections also provide that we may request in writing such additional information as may be required in order to make a final determination regarding the application and, after the date we receive such information, the application shall be deemed approved unless, within 90 days of such date, we deny such 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 State administering agency or the PACE organization respond to HCFA's request for additional information 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.

Priority and Special Consideration

Section 4803(c) of the BBA directs us to give priority in processing applications of entities to qualify as PACE organizations under section 1894 or 1934 of the Act first to PACE demonstration sites and then to entities which had applied to operate a PACE demonstration site as of May 1, 1997. In addition, section 4803(c)(3) of the BBA requires that we give special consideration in the processing of applications to any entity that, as of May 1, 1997, had indicated specific intent to become a PACE organization

through formal activities such as entering into contracts for feasibility studies.

Service Area Designation (§ 460.22)

In § 460.22, Service Area Designation, we specify that each application must designate the service area of the program. HCFA (in consultation with the State administering agency) may exclude from the proposed service area designation any area that is already covered under another PACE program agreement. This will avoid unnecessary duplication of services and impairing the financial and service viability of an existing PACE organization. This section implements the provisions of sections 1894(e)(2)(B) and 1934(e)(2)(B) of the Act.

Limit on Number of PACE Program Agreements (§ 460.24)

Sections 1894(e)(1)(B) and 1934(e)(1)(B) of the Act establish a limit on the number of PACE program agreements that may be in effect on August 5 of each year, i.e., the anniversary of the enactment of the PACE statute. Those sections state that the Secretary shall not permit the number of PACE organizations with which agreements are in effect under those sections or under section 9412(b) of the OBRA of 1986 to exceed—

- 40 as of August 5, 1997, the date of the enactment of the PACE statute, or
- As of each succeeding anniversary of such 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.

Subpart C—PACE Program Agreement
Program Agreement Requirement
(§ 460.30)

In accordance with sections 1894(a)(4) and 1934(a)(4) of the Act we have established § 460.30 to require that each PACE organization have an agreement with HCFA and the State administering agency 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 HCFA official and an authorized State official.

Content and Terms of PACE Program Agreement (§ 460.32)

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

We are requiring 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 will require advance approval by HCFA and the State administering agency. 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 PACE organization 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. This includes, but is not limited to, all requirements contained elsewhere in these regulations. 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 each agreement indicate the effective date and term of the agreement.

We are requiring that each PACE program agreement include information related to: organizational structure of the PACE organization; participant rights; process for grievances and appeals; eligibility, enrollment and disenrollment policies; service description; quality assessment and performance improvement; 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.

We will identify in each PACE program agreement the levels of performance that we require the organization to achieve on standard quality measures and the data and information on participant care that we 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) of this regulation.

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 such additional terms and conditions as the parties agree to, if such 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.

Duration of PACE Program Agreement
(§ 460.34)

In § 460.34, we specify that each 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 sections 1894(e)(2)(A)(iii) and 1934(e)(2)(A)(iii) of the Act.

Subpart D—Sanctions, Enforcement Actions, and Terminations

Violations for Which HCFA May Impose Sanctions (§ 460.40)

In § 460.40 we specify, based on paragraph (e)(6)(B) of sections 1894 and 1934 of the Act, that HCFA can impose, in addition to any other remedies authorized by law, any of three types of sanctions if HCFA determines that a PACE organization has committed any of nine listed violations. The following PACE organization 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 HCFA

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.

Sanctions That HCFA Can Impose
(§§ 460.42 and 460.46)

We describe the two types of sanctions in §§ 460.42 (suspension of enrollment or payment by HCFA) 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, HCFA may suspend enrollment of Medicare beneficiaries after the date HCFA notifies the organization of the violation. Suspending enrollment of Medicaid recipients is an action taken by the State rather than HCFA. With respect to suspension of payment, HCFA may suspend Medicare payment to the PACE organization and deny payment to the State for medical assistance for services furnished under the PACE program agreement.

In addition, HCFA may impose civil money penalties of \$100,000 plus \$15,000 for each individual not enrolled as a result of the PACE organization'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 PACE organization; \$100,000 for each misrepresentation or falsification of information; and \$25,000 for any violation specified in § 460.40.

Additional Actions by HCFA or the State (§ 460.48)

In § 460.48 we specify, based on paragraph (e)(6)(A) of sections 1894 and

1934 of the Act, that if HCFA, after consultation with the State administering agency, determines that a PACE organization is not in substantial compliance with requirements in these regulations, HCFA or the State administering agency 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.

Termination of PACE Program Agreement (§ 460.50)

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

- Either there are significant deficiencies in the quality of care furnished to participants, or the PACE organization has failed to comply substantially with conditions under these regulations or with the terms of its PACE program agreement; and
- The PACE organization 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 provide for termination if HCFA or the State administering agency determines that the organization cannot ensure the health and safety of its participants. This determination may result from the identification of deficiencies which HCFA or the State administering agency determines cannot be corrected. Based on the Protocol, Part IX, section A.2, we also require that if the organization terminates the agreement, a minimum of 90 days notice must be given to HCFA and the State administering agency regarding the organization's intent and that participants must be given a minimum of 60 days notice.

Transitional Care During Termination
(§ 460.52)

Based on the Protocol, Part IX, section B, we require that the PACE organization develop a detailed written plan for phase-down in the event of termination which includes the following: the process for informing participants, the community, HCFA and the State administering agency 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. Also, in accordance with paragraphs (a)(2)(C) and (e)(5)(C) of sections 1894 and 1934 of the Act, we specify 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.

Termination Procedures (§ 460.54)

In § 460.54 we specify 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 Medicare+Choice 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:

- We provide the organization with the reasonable opportunity to develop and implement a corrective action plan to correct the deficiencies that were the basis of our determination that cause exists for termination; and
- We provide 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, resulting from compliance with these procedures before termination, would pose an imminent and serious risk to the health of participants enrolled with the organization.

Subpart E—PACE Administrative Requirements

PACE Organizational Structure
(§ 460.60)

We have established § 460.60 to specify the structural requirements for a PACE organization. We believe that these requirements are essential to the PACE organization'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 have based the organizational structure requirements on Part I of the Protocol.

We require that the PACE organization have a current organizational chart showing officials in the PACE organization and relationships to any other organizational entities. The chart for a corporate entity must indicate the PACE organization's relationship to the corporate board and to any parent, affiliate, or subsidiary corporate entities. A PACE organization that is planning a change in organizational structure must notify HCFA, the State administering agency, and participants, in writing, at least 60 days before the change would take effect. Changes in organizational structure must be approved by HCFA and the State administering agency. In the event of a change that would constitute a change of ownership, HCFA would apply the general provisions described in 42 CFR 422.550. Changes in organizational structure approved by HCFA and the State administering agency must be forwarded to the consumer advisory committee (described later in the preamble in the section on governing body) for dissemination to participants as appropriate. We specifically invite comment on the extent to which changes in organizational structure are important to participants, information on the types of changes that have been communicated to participants, the timing of disclosure, and the effect on participants.

The Protocol requires that a PACE organization have a project director. We have included this requirement, but have changed the term to program director. We have renamed this position and further defined the role of the individual. The PACE organization must have a program director who is responsible for the oversight and administration of the entity. She or he would be responsible for the effective planning, organization, administration, and evaluation of the organization's operations. The program director would 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 PACE organization is part of a larger health system, the program director would clearly define and inform staff (employees and contractors) of the relationship.

We have also maintained the Protocol's requirement for a medical director, but we have further defined the responsibilities of this position. The PACE organization must have a medical director who is responsible for the delivery of participant care, clinical outcomes, and the implementation and oversight of the quality assessment and performance improvement program. Thus, the medical director is responsible for achieving the best clinical outcomes possible for all participants. Under this requirement, we would expect the medical director to use data comparing the program with other PACE organizations, where data are available, and to use the organization's data to demonstrate internal improvements in outcomes over time.

Governing Body (§ 460.62)

This section focuses on the ability of the organization's governing body to provide effective administration in an outcome-oriented environment. The governing body guides operations and promotes and protects participant health and safety. The governing body is legally and fiscally responsible for the administration of the PACE organization. However, the specific approach to administration of the organization is left to the discretion of the governing body. This reflects 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 PACE organization's network. These provisions would be intended to avoid disruptions in care and permit orderly transition of responsibilities.

We have added a requirement that the governing body be responsible for the quality assessment and performance improvement program. The purpose of this requirement is to link the development, implementation, and coordination of the ongoing quality assessment and performance improvement 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 practices available for all participants. As discussed in the section on the quality assessment and performance improvement program, the PACE organization has the flexibility to design its own quality improvement program.

Consistent with the Protocol, we have included a requirement that the PACE organization must ensure community representation on issues related to participant care. This may be achieved by having a community representative on the governing body.

We have added a requirement that a PACE organization must establish a consumer advisory committee to provide advice to the governing body on matters of concern to participants. Consumer participation through advisory committees is a well accepted community organization vehicle to maximize the involvement of consumers in a program designed to serve them. With the use of such a committee the governing body will have the benefit of consumer advice, including advice on quality of care. Consumers also are likely to feel a greater stake in the operation of the program. In order to assure appropriate representation, participants and representatives of participants must constitute a majority of the membership of this committee. One specific duty of the consumer advisory committee is to receive information regarding changes in the PACE organization's structure to determine those about which information should be disseminated to participants.

Personnel Qualifications (§ 460.64)

Although the Protocol does not specify personnel requirements for the various staff employed by or under

contract with the PACE organization, 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 have established § 460.64.

Our approach to personnel qualifications follows principles described in a **Federal Register** publication proposing changes to the conditions of participation for home health agencies, 62 FR 11022-23 (March 10, 1997). This is a flexible approach that relies on State requirements as much as possible. We require that personnel meet applicable State licensure, certification, or registration requirements. 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 since not all States have licensure, certification, or registration requirements.

The first category consists of personnel for whom the Act contains qualifications. Section 1861(r) of the Act generally defines a physician as a doctor of medicine or osteopathy, legally authorized to practice medicine and surgery by the State in which such function or action is performed, or certain other practitioners for limited purposes. This definition is reflected in regulations at 42 CFR 410.20, and we have adopted this definition for a physician providing services for a PACE organization. In addition, to reflect the key role of the primary care physician in the PACE model, we are requiring the primary care physician to have a minimum of 1 year's experience in working with a frail or elderly population.

In the second category of personnel qualifications, we defer to State law. We specify that all staff (employee or contractor) of the PACE organization 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.

The third category of personnel qualifications includes certain professions for which not all States currently have licensure, certification, or registration requirements. If a State does have licensure, certification, or registration requirements for a professional listed in this section, then the State qualifications would apply.

We reviewed the personnel requirements of other Medicare and Medicaid providers that serve populations similar to PACE participants (e.g., home health agencies, nursing facilities, intermediate care facilities), and we have established personnel requirements for PACE organizations that are as consistent as possible with those applicable to other providers. If a State does not have licensure, certification, or registration requirements applicable to the following professions, then the qualifications specified below apply.

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

We are requiring 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 one year's experience working with a frail or elderly population.

We are requiring 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; and (2) have a minimum of one year's experience working with a frail or elderly population.

We are requiring 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 such 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 one year's experience working with a frail or elderly population.

We are requiring 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 are requiring 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 one year's experience working with a frail or elderly population.

We are requiring 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 believe that each of these persons should have experience working with the frail or elderly population in order to better recognize issues specific to this population.

We have not defined personnel requirements for the PACE center manager or the home care coordinator. We are giving PACE organizations the flexibility to determine who is best suited to fill these positions since each PACE center may have different needs. Since the home care coordinator is responsible for acting as the liaison between the multidisciplinary team 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 and evaluate the home care needs of participants. Therefore, we believe that a registered nurse or social worker would be a good candidate to fill this position.

We have not imposed personnel requirements for personal care attendants since these individuals will primarily be providing "non-skilled", personal care services (e.g., bathing, toileting, transferring). We are soliciting comments on whether to include specific personnel requirements for personal care attendants. It is important that personal care attendants possess certain basic skills necessary to provide quality care to PACE participants. Thus, we are requiring PACE organizations to implement a training program for each personal care attendant to ensure that they exhibit competency in basic skills in personal care services. 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 personal care attendant must include other elements consistent with their assigned duties for specific participants.

We recognize that personal care attendants in the home environment may furnish not only personal care services, but also home care services. When the participant needs home care services, the PACE organization must ensure that it has qualified staff (either employees or contractors) that meet the requirements for home health aides to furnish these services.

Training (§ 460.66)

In § 460.66, we have required that the PACE organization 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 PACE organization to ensure patient safety and to achieve patient-specific performance measures requires competent staff. We believe there is a direct relationship between the quality of the organization's staff and patient well-being. The training requirement is intended to ensure that all staff are able to adapt to new or additional job demands. The PACE organization is only responsible for ensuring that the individual is educated and trained for her or his specific job. The individual would continue to be responsible for her or his 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 have included a specific training requirement for personal care attendants as described above.

Program Integrity (§ 460.68)

We have established § 460.68 to guard against potential conflicts of interest or other program integrity problems for PACE organizations, based on Part I, section E of the Protocol. An organization must not have any staff (employees or contractors) who have been convicted of criminal offenses related to their involvement in Medicaid, Medicare, other health insurance or health care programs, or social service programs under Title XX of the Act. We expanded this provision from the Protocol to prohibit an organization from having any staff who have been excluded from participation in Medicare or Medicaid, or having staff in any capacity where an individual's

contact with participants would pose a potential risk because the individual has been convicted of physical, sexual, drug, or alcohol abuse. Members of the PACE organization's governing body, and their family members, are prohibited from having a direct or indirect interest in contracts with the organization. (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 and to prevent fraud under Medicare and Medicaid.

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 PACE organization. HCFA and the State administering agency may grant a waiver of the conflict of interest requirement for PACE organizations to allow individuals who have a direct or indirect interest in a contract or the provision of services to the PACE organization to recuse themselves from decisions directly or indirectly affecting those interests, rather than barring them entirely from serving on the PACE organization's policy making board or as directors, officers, partners, employees, or consultants of the PACE organization. Such a waiver may be granted if HCFA and the State administering agency determine that there are not enough people who could meet the requirement in the PACE organization's service area and the proposed alternative does not adversely affect the availability of care or the quality of care that is provided to participants.

We have also added the requirement that the PACE organization must have a process to gather information on program integrity issues and respond to any request from HCFA within a reasonable amount of time.

Contracted Services (§ 460.70)

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

A PACE organization can only contract with entities that meet all applicable Federal and State

requirements. We have provided some examples of the types of requirements that contractors would be expected to meet. The contractor must be accessible, *i.e.*, located within or near the PACE organization's service area.

To avoid breakdowns in communication or in the provision of care, we require a PACE organization to 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 PACE organization policies, changes in participants' plans of care, information from team meetings, and quality improvement activities and goals. Contractor staff would inform the PACE organization, 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 PACE organization, 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.

The PACE center is required to maintain a current list of contractors and provide a copy to anyone upon request. Copies of signed contracts for inpatient care must be furnished to HCFA and the State administering agency.

Under the specific contract content requirements, 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 multidisciplinary team; accept payment from the PACE organization as payment in full and not to bill participants, HCFA, the State Medicaid agency or private insurers; hold harmless HCFA, the State and PACE participants in the event that the PACE organization cannot or will not pay for services performed by the contractor pursuant to the contract; not assign or

delegate duties under the contract unless prior written approval is obtained from the PACE organization; and submit reports as required by the PACE organization.

We have not established a specific notice requirement for termination of contracts. We believe that PACE organizations will contract with individuals and entities that understand and embrace the organization's mission and commitment to participants. As discussed previously, the governing body is required to 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. We specifically request public comment on whether we should add a requirement for notice before a contractor could terminate its contract.

Physical Environment (§ 460.72)

To ensure that the center and home are free of hazards that may cause harm to the participants, staff, or visitors, we have established § 460.72. Because issues of adequate space, infection control, fire prevention, dietary services, and the safety of transportation services are important to ensure quality care, we have added requirements for each in this condition.

We have maintained the following requirements from the PACE Protocol with a few clarifications:

- 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 PACE organization should furnish primary care services in the center, but this provision allows flexibility to avoid duplicating an entire primary care clinic if that is not necessary.)

The PACE organization 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.

The Life Safety Code (LSC) is a set of fire protection requirements designed to provide a reasonable level of safety from fire. 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.

The 1997 edition of the LSC is 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 eligibles, so we have chosen 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 (*i.e.*, 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) notifications—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 its building. 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 (*i.e.*, nursing facilities, hospitals, 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 HCFA 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 (e.g., hospitals or office buildings), which must be considered in requiring adherence to the LSC. We also recognize that some 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 even be impractical or impossible to provide a specific feature due to the construction of the building. Therefore, we have specified that HCFA 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 have established four requirements that we believe are fundamental for a PACE organization to effectively prepare for emergency situations. The PACE organization 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 state 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.

PACE organizations must train each staff member (employee and contractors) 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 on what to do, where to go, and whom to contact if a center emergency occurs. The PACE center

must also provide periodic orientation to staff and participants.

Appropriate medical practice dictates that the organization must have trained personnel, drugs, and emergency equipment immediately available at every center at all times to adequately support participants until an Emergency Medical System (EMS) responds to the center. We have 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 center must have a documented plan to obtain EMS services from sources outside the center when needed.

At least annually, a PACE organization must actually test, evaluate, and document the effectiveness of its emergency and disaster plans to ensure 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.

Infection Control (§ 460.74)

Infection control is vital to the health and safety of participants, so we are requiring in § 460.74 that the PACE organization adhere to accepted policies and standard procedures, including at least 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 PACE organization must establish, implement, and maintain a documented infection control plan that will assure 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 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.

Transportation Services (§ 460.76)

Transportation services are a critical component of PACE service delivery, so

it is crucial that the PACE organization take appropriate steps to ensure that participants can be safely transported from their homes to the center and to appointments. We have established § 460.76 to require that the PACE organization'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) Maintenance 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 multidisciplinary team process, communicating relevant changes in the participants' care plans to transportation personnel.

Dietary Services (§ 460.78)

It is important that each PACE center provide each participant with a nourishing, palatable, well-balanced meal that meets the daily nutritional and special dietary needs of each participant. Each meal must be: prepared by methods that conserve nutritive value, flavor, and appearance; prepared in a form designed to meet individual needs; and prepared and served at the proper temperature. The 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 PACE organization must provide nutrition 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 are requiring the PACE organization 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.

Fiscal Soundness (§ 460.80)

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

Each PACE organization 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 HCFA and the State administering agency 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 PACE organization.

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

Marketing (§ 460.82)

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

All marketing material must be approved by HCFA and the State administering agency. 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 HCFA and the State administering agency. We will complete our review within 45 days after we receive the information from the organization or the material will be deemed approved. We have added the requirement for review and approval of revised marketing materials since 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 HCFA for review of changes to Medicare+Choice organization marketing materials.

Printed marketing materials must meet participants' special language requirements. Marketing materials must 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 PACE organization and that participants may be fully and personally liable for the costs of unauthorized or out-of-PACE program agreement services.

PACE organizations 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 PACE organization, HCFA, or the State administering agency; 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 PACE organization must establish, implement, and maintain a documented marketing plan with measurable enrollment objectives and a system for tracking its effectiveness.

Subpart F—PACE Services

PACE Benefits Under Medicare and Medicaid (§ 460.90)

Pursuant to sections 1894(a)(2)(B) and (b)(1) and 1934(a)(2)(B) and (b)(1) of the Act, we have 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 do not apply to PACE benefits. In addition, we have 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 PACE organization.

Required Services (§ 460.92)

Based on the provisions of sections 1894(b)(1)(A) and 1934(b)(1)(A) of the Act, we are requiring in § 460.92 that each PACE benefit package include for all participants, regardless of source of payment, all Medicaid covered services

as specified in the State's approved Medicaid plan, a variety of services specified in the Protocol, and other services determined necessary by the multidisciplinary team to meet the participant's needs (e.g., respite care). As specified in Part IV, section A.3 of the Protocol, at a minimum the PACE organization must provide the following benefit package:

- Multidisciplinary assessment and treatment planning;
- Primary care services including physician and nursing services;
- Social work services;
- Restorative therapies, including physical therapy, occupational therapy and speech-language pathology;
- Personal care and supportive services;
- Nutritional counseling;
- Recreational therapy;
- Transportation;
- Meals;
- Medical specialty services including, but not limited to: anesthesiology, audiology, cardiology, dentistry, dermatology, gastroenterology, gynecology, internal medicine, nephrology, neurosurgery, oncology, ophthalmology, oral surgery, orthopedic surgery, otorhinolaryngology, plastic surgery, pharmacy consulting services, podiatry, psychiatry, pulmonary disease, radiology, rheumatology, surgery, thoracic and vascular surgery, and urology;
- Laboratory tests, x-rays and other diagnostic procedures;
- Drugs and biologicals;
- Prosthetics and durable medical equipment, corrective vision devices such as eyeglasses and lenses, hearing aids, dentures, and repairs and maintenance for these items;
- Acute inpatient care: ambulance; emergency room care and treatment room services; semi-private room and board; general medical and nursing services; medical surgical/intensive care/coronary care unit, as necessary; laboratory tests, x-rays and other diagnostic procedures; drugs and biologicals; blood and blood derivatives; surgical care, including the use of anesthesia; use of oxygen; physical, occupational, and respiratory therapies; speech-language pathology; and social services.
- Nursing facility care: semi-private room and board; physician and skilled nursing services; custodial care; personal care and assistance; drugs and biologicals; physical, occupational, and recreational therapies and speech-language pathology, if necessary; social services; and medical supplies and appliances.

Required Services for Medicare Participants (§ 460.94)

In accordance with paragraph (b)(1)(A)(i) of sections 1894 and 1934 of the Act, we specify 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.

This provision is based on explicit statutory wording that requires the inclusion of Medicare covered services only for individuals enrolled under section 1894 of the Act. Those individuals include Medicare-only participants and dually-eligible Medicare/Medicaid participants. The PACE organization may choose to include coverage of these services for other participants, but is not required to do so.

In accordance with section 1894(g) of the Act, we specify that the following requirements of title XVIII of the Act (and regulations relating to such requirements) 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.

Excluded Services (§ 460.96)

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 multidisciplinary team, 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 multidisciplinary team as part of a participant's plan of care.

- Cosmetic surgery, which 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 rendered 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.)

Service Delivery (§ 460.98)

We are requiring in § 460.98 that the PACE organization must establish and implement a written plan to provide care that meets the needs of its participants across all care settings on a 24 hour basis, each day of the year. The PACE organization must furnish comprehensive medical, health, and social services that integrate acute and long-term care. These services must be furnished at least in the PACE center, the participant's home, and inpatient facilities. The PACE organization must not discriminate against any participant in the delivery of required PACE services based on race, ethnicity, national origin, religion, sex, age, mental or physical disability, 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 PACE organization 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 PACE organization 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 PACE organization must ensure accessible and adequate services to meet the needs of all its participants. When necessary, the organization must increase the number of centers, staff, and other PACE services.
- The frequency of a participant's attendance at the center is determined by the multidisciplinary team based on the needs and desires of each participant.

We added the requirement that, if there is more than one center, each center must offer the full range of services and have sufficient staff to meet the needs of participants.

Emergency Care (§ 460.100)

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.

We require a PACE organization to establish and maintain a written plan for handling emergency health care needs. The organization must ensure that the participants and caregivers know when and how to access emergency services and ensure that HCFA, the State, and PACE participants are held harmless if the PACE organization does not pay for emergency services.

Emergency care is appropriate when services are needed immediately because of an injury or sudden illness and the time required to reach the PACE organization or a network provider would cause 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 PACE organization or one of its contract providers) either in or out of the PACE organization'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 PACE organization. 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 (discussed in detail in the section on participant rights). The same standard is used in the Medicare+Choice 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.

Other services a participant may need while temporarily absent from the PACE organization'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 PACE organization 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 Medicare+Choice organizations, where prior authorization for urgently needed services is not required. We believe that the differences in the population served by PACE organizations warrant 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 coordination of care by the multidisciplinary team justifies contact with and authorization by the PACE organization prior to receipt of non-emergency care outside the PACE network.

The emergency services plan must 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 obtaining care when they are away from the PACE center, when they are away from the PACE organization'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 PACE organizations are organized to be responsive to all participant care needs, including the need for urgently needed or post-stabilization services. However, in order to ensure that unforeseen circumstances do not result in delays in needed care, we have clarified that the PACE organization 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.

Multidisciplinary Team (§ 460.102)

This section is based on provisions in Part IV, section B of the Protocol. The Protocol requires that the PACE organization assign each participant to a multidisciplinary team based at the PACE center where the participant attends. We have included a requirement that the PACE organization must establish a multidisciplinary team at each center to comprehensively assess and meet the individual needs of each participant. We believe that a well-functioning multidisciplinary team 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 multidisciplinary team should be knowledgeable about the overall needs of the patient, not just the needs which 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, we are requiring that the multidisciplinary team be composed of at least the following members:

a. Primary Care Physician—We considered expanding this to include nurse practitioners but decided to retain the requirement in the Protocol. While it would be acceptable for a PACE organization to include a nurse practitioner on the multidisciplinary team, we believe that this should be in addition to rather than instead of the primary care physician. The physician is an integral part of the team serving as a gatekeeper for the participant's medical care, and we feel it is important to retain this standard in order to ensure quality care.

b. Registered Nurse—The Protocol requires the inclusion of a "nurse." We are specifying that this team member be a registered nurse. The nurse represented on the multidisciplinary team must exhibit leadership and management skills that are more consistent with the training received by registered nurses, as opposed to licensed practical nurses. In addition, we believe that a registered nurse would be better able to determine and respond to the health care needs of the frail population, particularly for home care services. We welcome comments on this issue.

c. Social Worker;
d. Physical Therapist;
e. Occupational Therapist;
f. Recreational Therapist or Activity Coordinator;
g. Dietitian;
h. PACE Center Manager—We have changed the Protocol terminology from "PACE Center Supervisor" to "PACE Center Manager". The 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. She or he could be the leader of the multidisciplinary team, but we are not requiring this. We are giving the PACE organization and the multidisciplinary team 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 PACE organization has contractors providing the home care services. The PACE organization 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 are changing the Protocol's term "home care liaison" to "home care coordinator", because "home care liaison" has another meaning in Medicare and we want to avoid confusion.

j. Personal care attendants or their representatives—We have changed the Protocol term "health care worker/aide" to "personal care attendant", as we believe this term more accurately describes this type of worker. 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 PACE participants, a geriatrician could be a valuable member of the multidisciplinary team. As one option, the primary care physician 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 we welcome comments about whether such a requirement would be desirable and, if so, whether the geriatrician should be employed by the PACE organization and should primarily serve PACE participants.

Consistent with the Protocol, we are requiring that primary medical care for all participants be furnished by the PACE primary care physician(s). The primary care physician 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 multidisciplinary team. Ultimate responsibility for management of medical situations must rest with the PACE primary care physician.

The multidisciplinary team 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 multidisciplinary team is the degree to which team members share information and communicate with one another. The Protocol requires the physician to keep the multidisciplinary team informed of the medical condition of each participant and to remain alert to pertinent input from other team members. We feel 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. We are modifying the requirement to reflect this; *i.e.*, each member of the team must regularly inform the multidisciplinary team 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 (*e.g.*, CARDEX systems, informal updates during shift changes and as different personnel report to work) should be encouraged as well. It is critical that personal care attendants be involved in the

communication process. Since they often have the first contact with the participant, it is important that they regularly share information on the participant's mood, activities, daily habits, etc. Each team member must document changes in the participant's condition in the participant's medical record.

We are retaining the Protocol requirement that members of the multidisciplinary team must serve primarily PACE participants, unless a waiver is granted. After considering this issue, we concluded that for 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 patients, but this must not interfere with the provision of services for PACE participants. HCFA and the State administering agency may grant a waiver of this requirement if they determine that—

- There are not enough individuals available in the PACE organization's service area who meet the requirement; and
- The proposed alternative does not adversely affect the availability of care or the quality of care that is provided to participants.

If an applicant seeking approval as a PACE organization believes a waiver is warranted, it must include a request for the waiver in its application and describe in detail the circumstances supporting the request. For example, in a rural, Tribal, or urban Indian community the number of PACE participants, or the availability of appropriate multidisciplinary team members in some categories, may be insufficient for some team members to primarily serve PACE participants. Such an applicant would need to demonstrate that the alternative it proposes will maintain the continuity of care and assure sufficient availability of services so that participants receive prompt, effective care.

We are requiring that the PACE organization establish, implement and maintain documented internal procedures governing the exchange of information between team members, contractors, and participants and their caregivers consistent with the requirements for confidentiality in § 460.200(e). It is important for the organization to develop these procedures to avoid breakdowns in communication which would be

detrimental to the success of the PACE program. We also want to emphasize the importance of regular communication from family members and other caregivers and health care workers in the home. It is critical that these individuals routinely report changes in participant status to the multidisciplinary team.

Consistent with the Protocol, we are requiring that the following members of the team be employees of the PACE organization: primary care physician (unless an exception is granted), registered nurse, social worker, recreational therapist or activity coordinator, PACE center manager, home care coordinator, and PACE center personal care attendants. It is important to note that "personal care attendants" in this context refers to individuals who work in the PACE center to provide assistance to participants while they are at the center (*e.g.*, assist medical staff, escort participants, bathe and toilet participants) and does not refer to personal care attendants who provide care to participants outside of the PACE center. Personal care attendants who work in the home are not required to be employees of the PACE organization.

HCFA and the State administering agency may grant a waiver of the requirement that the primary care physician be employed by the PACE organization if they determine that—

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

If an applicant seeking approval as a PACE organization believes a waiver is warranted, it must include a request for the waiver in its application and describe in detail the circumstances supporting the request. For example, in a rural, Tribal, or urban Indian community the number of PACE participants, or the availability of primary care physicians, may be insufficient to make employment by the organization a feasible option. As another example, some State licensing laws prohibit the corporate practice of medicine, making it inappropriate for the organization to employ physicians. Such applicants would need to demonstrate that their contracts with physicians will maintain the continuity of care and assure sufficient availability of services so that participants receive prompt, effective care. We invite

comments on whether this waiver provision is too broadly defined.

Participant Assessment (§ 460.104)

The information obtained through the participant assessment is the basis for the treatment plan developed by the multidisciplinary team. As such, it is important that the assessment be as comprehensive as possible, in order to capture all of the information necessary for the multidisciplinary team 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 PACE organization evaluates whether a potential participant can be cared for appropriately in the program. Often, current PACE demonstration programs 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 has been 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, to perform an assessment that identifies the services necessary to address the participant's needs and care preferences.

As part of the initial comprehensive assessment, each of the following members of the multidisciplinary team 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.

These individuals represent the most vital components of the participant's

treatment and psychosocial development. These disciplines are the core needed to determine the specific needs of the participant. At the recommendation of individual team members, other professional disciplines (e.g., speech-language pathology, dentistry, or audiology) may participate in the initial comprehensive assessment if the participant's needs warrant their inclusion.

HCFA is currently in the preliminary stages of developing a standardized core assessment instrument to be used by PACE organizations for continuous quality improvement. Until such time as this instrument is completed, we are requiring that the participant's assessment 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 believe that this information will provide a basic framework from which a comprehensive plan of care can be developed. This assessment is appropriate for every participant, and ensures that the plan of care focuses on the participant's medical, psychosocial, and functional needs. However, this list represents the minimum information to be included in the comprehensive assessment, and the PACE organization is encouraged to include other assessment items as necessary. HCFA may impose additional or more specific assessment requirements upon development of the standardized core assessment instrument.

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 multidisciplinary team. We are clarifying this requirement 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 multidisciplinary team is also required 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 be in compliance with the Consumer's Bill of Rights and Responsibilities (discussed in more detail later in this preamble in the section on participant rights). This requirement is intended to ensure that female participants are able to select providers who specialize in women's health for routine and preventive care.

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 are requiring the following members of the multidisciplinary team to 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 provide assessments at least semi-annually 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. If the participant is not receiving these other services (e.g., home care, physical therapy, occupational therapy, dietitian services), these members of the team would not be required to conduct a semi-annual assessment.

Consistent with the Protocol, we are requiring the following members of the multidisciplinary team 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 multidisciplinary team 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 at least all members of the multidisciplinary team that are required to perform the initial comprehensive assessment should reassess the participant. If fewer members participate in this reassessment, a critical component of a participant's care might be overlooked.

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 for the participant, the appropriate multidisciplinary team 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 subsequent development of the 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 any care or services will be furnished.

The PACE organization is required to have explicit procedures for timely resolution of requests from participants (or designated representatives) to initiate, continue, or terminate a particular service. Unless an extension is granted, the multidisciplinary team 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 multidisciplinary team receives the request. We considered establishing both a standard process and an expedited process for responding to a participant request; 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 multidisciplinary team may extend the 72-hour timeframe by no more than 5 additional days if the participant or designated representative requests the extension, or the team documents its need for additional information and how the delay is in the interest of the participant. An extension could be warranted because not all the appropriate members of the multidisciplinary team may always be able to meet with the participant, conduct a discipline-specific reassessment, discuss the results of the reassessment with the entire multidisciplinary team, and develop a response to the request within 72 hours. The PACE organization 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 multidisciplinary team decides to deny the participant's request, the denial must be explained to the participant (or designated representative) orally and in writing. The PACE organization 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 PACE organization 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 multidisciplinary team 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 PACE organization 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 multidisciplinary team 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 (*e.g.*, installing a wheelchair ramp at the participant's home) may require more time to accomplish, we have chosen not to specify a timeframe for delivering services. However, we are soliciting comment 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.

Plan of Care (§ 460.106)

Based on Part IV, section B of the Protocol, we developed requirements for the participant's plan of care. We are requiring that the multidisciplinary team promptly develop a comprehensive plan of care that specifies the care needed to meet the participant's medical, physical, emotional, and social needs, as identified in the initial comprehensive assessment. The plan of care must identify measurable outcomes to be achieved and must be developed in collaboration with the participant and her or his 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.

We are requiring the team to implement, coordinate, and monitor the plan of care by providing services directly and 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 through the provision of services, informal observation, input from participants and caregivers, and communications among

members of the multidisciplinary team and other providers.

We are requiring that, on at least a semiannual basis, the multidisciplinary team reevaluate the participant 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 if the participant's level of health has changed thus dictating a change in the level of services or even the setting in which care must be provided.

We are requiring 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 are giving PACE organizations the flexibility to determine how often care plans should be reviewed with the participant. We welcome comments on the issue of whether or not to impose a timeframe for this activity.

The participant's plan of care and any changes in the plan must be documented in the participant's medical record.

Subpart G—Participant Rights

(Sections 460.110–460.118)

Introduction

In accordance with sections 1894(b)(2)(B) and 1934(b)(2)(B) of the Act, the PACE program agreement requires the PACE organization 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 give us the discretion to apply such requirements of part C of title XVIII and sections 1903(m) and 1932 of the Act relating to protection of beneficiaries and program integrity as would apply to Medicare+Choice organizations under part C and to Medicaid managed care organizations under prepaid capitation agreements under section 1903(m). Moreover, sections 1894(f)(2) and 1934(f)(2) of the Act require us to incorporate the requirements in the PACE protocol which includes a patient bill of rights.

We also have made every effort to assure that the rights and protections established in the PACE agreement are

in substantial compliance with the Presidential Advisory Commission's (The Commission) Consumer Bill of Rights and Responsibilities (CBRR), which appears as an addendum to The Commission's Final Report to the President, entitled *Quality First: Better Health Care for All Americans* (March 1998). (A copy of the Final Report can be obtained by calling the Agency for Health Care Policy and Research, Department of Health and Human Services at 1-800-358-9295.) The President issued an Executive Memorandum to the Secretary of the Department of Health and Human Services dated February 20, 1998, which requires 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.

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, Medicare+Choice, 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 PACE organization, 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, PACE organizations 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 PACE organization 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, PACE organizations 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 PACE Protocol, the PACE organization 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. We have relied on the PACE Protocol and incorporated the basic rights that it identifies. However, we are also guided by the Medicare+Choice regulations and by the CBRR.

We also recognize that the statute directs us to consider State law. We have interpreted this to mean that a PACE organization'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 this regulation. Regardless, it is up to the PACE organization to establish appropriate policies and procedures for assuring that the participant bill of rights is fully operational throughout the PACE organization.

Consistent with the Protocol and the CBRR, we have retained the concept that participants can 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.

We are requiring, as did the Protocol, the PACE organization to provide encouragement and assistance to participants in understanding and exercising their rights and in recommending changes in PACE policies and services. In addition, it is likely that many of the frail elderly or their chosen representatives will need guidance in navigating the pre-enrollment, enrollment, and post-enrollment processes of PACE. In the previous discussion on consultations with the State Administration on Aging, 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. We are specifically requesting 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 are also interested in receiving public input as to whether an ombudsman could provide one-on-one consumer assistance to PACE participants and their designated representatives to exercise their rights and work effectively with the multidisciplinary team.

In § 460.110, we require a PACE organization 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 addition, the organization must protect participants' rights and provide for the exercise of those rights.

Finally, there are numerous references throughout the regulations to the PACE organization furnishing various kinds of information to participants in writing. In order for this information to be understandable and useful, it must be presented in a legible format. The frail elderly PACE population would be expected to have vision problems that make the use of sufficiently large, clear type particularly important in written communications. While we are not mandating the use of a particular typeface or font size, we expect PACE organizations to ensure that documents are legible for their intended audience.

Specific Participant Rights

- **Right #1—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, 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. Within this context, it is essential that PACE participants are assured of the following rights:

(1) To receive comprehensive health care in a safe and clean environment and in an accessible manner.

(2) To be treated with dignity and respect, be afforded privacy and confidentiality in all aspects of care, and be provided humane care.

(3) Not to be required to perform services for the PACE organization.

(4) To have reasonable access to a telephone.

(5) To be free from harm, including physical or mental abuse, neglect, corporeal punishment, involuntary seclusion, excessive medication, and any physical or chemical restraint imposed for purposes of discipline or convenience and not required to treat the participant's medical symptoms.

(6) To be encouraged and assisted to exercise rights as a participant, including the Medicare and Medicaid appeals processes as well as civil and other legal rights.

(7) To be encouraged and assisted to recommend changes in policies and services to PACE staff.

The following discussion provides the rationale for inclusion of these rights. 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 have expanded this requirement to state that the participant has a right to receive comprehensive health care. The PACE organization must offer and manage all health, medical, and social services needed to restore or preserve the participant's independence. The PACE multidisciplinary team must arrange for preventive, rehabilitative, curative, and supportive services in adult day health centers, participant homes, hospitals, and nursing homes. The revised language addresses the complete range of services in each setting that a participant is entitled to, once enrolled in the PACE organization.

The Protocol stipulates that the participant has the right to have dignity, privacy, and humane care. For purposes of clarification, we require the PACE organization 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 PACE organization 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 are not advocating 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 have adopted from the Protocol the right to be free from harm, including physical or mental abuse, neglect, corporeal punishment, involuntary seclusion, excessive medication, and inappropriate use of physical or chemical restraints. We have revised the wording used in the Protocol regarding the use of restraints. We do not view this as a policy change from the protocol, but felt the rewording was necessary to emphasize that the use of restraints must be limited to those situations with adequate, appropriate clinical justification. 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 restraints are established in § 460.114.

We are in the midst of examining our seclusion and restraint policy for all HCFA-covered providers. We call your attention to the discussion of the use of seclusion and restraints in the HCFA interim final rule with comment concerning the conditions of participation for hospitals (HCFA-3018-IFC, published July 2, 1999, 64 FR 36070). In that regulation, we have established very 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 have 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 for the hospital conditions of participation, we indicate our intent to examine the

applicability of the hospital restraint and seclusion standards to other providers. Therefore, we formally ask for comments about how best to extend the protections proposed for hospital patients to participants in the PACE program.

We have also 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 and we have maintained the right to telephone access. On the other hand, we have altered the right not to be required to perform services for the organization unless the services are included for therapeutic purposes in the plan of care. Upon reflection, it is our belief that a therapeutic program should not be tied to performing services for the PACE organization.

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. PACE organizations 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, PACE organizations 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 home eligibility standard but can be cared for in the community. Meeting required certification standards within the PACE context is not deemed a violation of antidiscrimination laws. Still, in order to ensure that the qualification decision is free from other, illegal forms of discrimination, we are requiring PACE organizations to retain information on individuals who are assessed but, for whatever reason, are not enrolled.

• **Right #2—Information disclosure.** Each PACE participant has the right to receive accurate, easily understood information and to receive assistance in making informed health care decisions. Specifically, each participant has the right:

(1) To be fully informed in writing of the services available from the PACE organization, including identification of all services that are delivered through contracts, rather than furnished directly by the PACE organization—

- (A) Before enrollment;
- (B) At enrollment; and
- (C) When there is a change in services.

(2) To have the enrollment agreement, described in § 460.154, fully explained in a manner understood by the participant.

(3) To examine, or upon reasonable request, to be assisted to examine the results of the most recent review of the PACE organization conducted by HCFA or the State administering agency and any plan of correction in effect.

In order for consumers, independently or in concert with their designated representatives, to make rational decisions, they need accurate, reliable information that will allow them to 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 have linked the right to information disclosure to the information that is included in the enrollment agreement. The PACE organization must explain the enrollment agreement in a manner understood by the participant to ensure that all participants fully comprehend their rights and responsibilities from the beginning of their relationship with the PACE organization. Among the items in the enrollment agreement are: an acknowledgment that the participant understands that the PACE organization is the participant's sole service provider; a description of PACE services available and how services are obtained from the PACE organization; 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. We are requiring that the PACE organization inform participants whenever changes occur in the services available from the PACE organization.

The enrollment agreement also indicates that the PACE organization

has a program agreement with HCFA and the State administering agency that is subject to renewal on a periodic basis. In order to provide participants with information on the status of their organization's agreement, PACE participants have the right to examine the results of the most recent review of the PACE organization conducted by HCFA and the State administering agency and any plan of correction in effect.

We are also requiring in § 460.60(d), that changes in the organizational structure of the PACE provider be approved in advance by HCFA and the State administering agency. Once approved, information about changes in organizational structure will be forwarded to the consumer advisory committee for dissemination to participants as appropriate. In this way, participants will be kept informed about the organizational structure of the PACE provider and may determine if any organizational changes made by the PACE organization affect their continued enrollment in PACE.

• **Right #3—Choice of providers.** Each participant has the right to a choice of health care providers, within the PACE organization's network, that is 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 and specialists from 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 care planning in conjunction with a multidisciplinary team 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, use of the multidisciplinary team approach may not be waived. Development of a participant's plan of care begins with a comprehensive assessment. Participant preferences for care are identified components of the assessment. Once the plan of care is developed, the team is required to continuously monitor the effectiveness of the plan in collaboration with participants.

Moreover, the team is required to develop, review, and reevaluate the plan of care in collaboration with the participant to ensure there is agreement

with the plan of care and that participant concerns are addressed. These provisions complement the participant rights to participate in treatment decisions, to be fully informed of his or her functional status by the multidisciplinary team, 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 the decisions.

It is in this context that the determination with regard to the need for specialty care is made by the multidisciplinary team and the participant. If there is disagreement, then the participant has the right to engage the dispute resolution process. Regardless, the multidisciplinary team 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. To further emphasize access to a woman's health care specialist within the context of the PACE model, we have identified such a request as one of the participant preferences that must be considered in developing the plan of care.

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, with its reliance on an all-inclusive plan of care that is derived by a multidisciplinary team in collaboration with the participant, 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.

With regard to having a choice of primary care physician and specialists, the PACE organization is required to maintain sufficient staff and contractors to meet the needs of its participants.

Given the participant census of PACE organizations, it is most likely that choice will be limited. PACE organizations likely will start out with one of each type of specialist and perhaps only one primary care physician. Although CBRR includes the right to choose among physicians in the provider's network, it was aimed at managed care organizations with thousands of patients and numerous providers. Such is not the case with the PACE model. Potential participants must weigh the limited network of PACE organizations with the benefits of a comprehensive, all-inclusive delivery system in choosing to enroll.

CBRR provides a right to transitional care for patients who are undergoing an extensive course of treatment for a chronic or disabling condition. As we discuss in greater detail in the section on the enrollment process, potential participants must be advised that the PACE organization is the participant's sole source provider and that the organization guarantees access to services, but not to a specific provider. As a result, PACE employees and specialists under contract are expected to provide as much advance notice as possible of their decision to terminate their relationship with the PACE organization in order to provide sufficient time for the organization to secure a replacement. In addition, the PACE organization and its contractors are expected to provide as much advance notice as possible of a decision to terminate a contract in order to provide for an orderly transition for participants. We are requesting public input on the propriety of establishing a contract requirement to ensure a minimum transition period.

- **Right #4—Access to emergency services.** Each participant has the right to access emergency health care services when and where the need arises without prior authorization by the PACE multidisciplinary team.

In addition to establishing a participant right to emergency services without prior authorization, we have described emergency care, emergency medical condition, urgently needed services and post-stabilization care services previously in the preamble in the section regarding emergency care and in § 460.100, consistent with the CBRR.

- **Right #5—Participation in treatment decisions.** 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 PACE organization 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 multidisciplinary team.

- (4) To participate in the development and implementation of the plan of care.

- (5) To request a reassessment by the multidisciplinary team.

- (6) To be given reasonable advance notice, in writing, of any transfer to another treatment setting and the justification for the transfer (*i.e.*, 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.

As noted previously, active involvement by participants and their designated representatives in care planning is fundamental to the PACE model of care. As a result, we have retained the rights in the Protocol related to participant involvement in the development and implementation of the plan of care. We retained the participant's right to be fully informed by the multidisciplinary team of his or her health and functional status. In support of this right, the PACE 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 PACE organization 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. The Protocol also states that PACE participants can 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 the right to refuse treatment

is a type of health care decision. We have maintained the participant's right to make advance directives but have clarified that within this right the PACE organization is required to fully explain advance directives (in accordance with §§ 489.100 and 489.102 of this chapter) to participants.

We have maintained the requirement that PACE organizations provide reasonable advance notice in writing of any transfer to another part of the program. However, we are soliciting comment on the necessity of specifying a timeframe for participant notification. Given the frailty of the PACE population, some participants may require additional time to prepare for the transition to other parts of the program, while others may require the transfer without delay. We welcome comments on the feasibility of including a specific timeframe that would apply to all participants.

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 and input from participant and caregivers is used by the multidisciplinary team 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 for a specific sanction if we determine that the PACE organization 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)).

• **Right #6—Confidentiality of health information.** 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 Medicare+Choice and Medicaid managed care organization requirements, participants have the right to communicate with any member of the multidisciplinary team 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 (see § 460.200) specifically addresses confidentiality and the safeguarding of health, financial, and other information. It requires PACE organizations to establish written policies and implement procedures to safeguard the privacy of participant information and ensure appropriate use and release of participant information. When the HHS privacy standards required by the Health Insurance Portability & Accountability Act of 1996, Public Law 104–191, are finalized, most plans and providers (including HCFA components and most PACE organizations) will be required to comply with the requirements of that regulation as well.

• **Right #7—Complaints and appeals.** Each participant has the right to a fair and efficient process for resolving differences with the PACE organization, 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 PACE organization, its employees, or contractors through the process described in § 460.122.

We have adopted the concepts expressed in the CBRR for both the internal and external appeals processes as described in detail in the following section.

§ 460.116 requires the PACE organization to have written policies and implement procedures to ensure that the staff, the participant, and his or her representative understand these rights. The regulations also require that, at the time of enrollment, staff review the bill of rights with the participant and representative, if any, in a manner which they understand. The PACE organization 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 have 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, center staff, and other concerned persons to review the participant's 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.

§ 460.118 requires the PACE organization to have and implement documented, established procedures to respond to and rectify a violation of a participant's right. This is intended to ensure that the PACE organization will address all violations of participants' rights and not allow problems to continue.

Grievances and Appeals

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.

Grievance Process (§ 460.120)

A grievance is defined as a complaint, either written or oral, expressing dissatisfaction with service delivery or the quality of care furnished.

The PACE organization 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 have 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 PACE organization.

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 PACE organization's internal procedures should assure that every grievance is handled in a uniform manner and that there is communication between different individuals who are responsible for reviewing or resolving grievances. In addition, the PACE organization must also have appropriate documentation, so the information can be utilized both in the organization's internal quality improvement activities and in HCFA's quality assessment projects. Requiring that grievances be responded to and resolved in a timely manner provides a protection to the participants. It is intended to ensure that the PACE organization 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 may also prevent reprisal against the participant.

It is critical that the PACE organization continue to provide care to the participant during the grievance process because under the law participants must receive care solely through the PACE organization. Continuing care also encourages

participants to continue to voice concerns about service delivery without fear of any reprisal.

The PACE organization must discuss the step, 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 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.

The PACE organization must maintain, aggregate, and analyze information on grievance proceedings. This requirement is an integral part of fostering an environment of continuous improvement, and it complements the requirement on internal quality assessment and performance improvement. We expect that, once an organization has a quality improvement system in place, participant grievances will be analyzed evaluated since grievances may be the first clue that a problem exists. By analyzing the number and types of grievances, a PACE organization will be able to develop activities to monitor and improve the grievance resolution process, as well as identify and make improvements or modifications in area of care. This also applies to the appeals process.

PACE Organization's Appeals Process (§ 460.122)

An appeal is defined as participant's action taken with respect to a PACE organization's noncoverage of or nonpayment for a service. The PACE organization must have a formal written appeals process, with specified timeframes for response. We have retained 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 multidisciplinary team denies a request for services or payment. The appeals process, at a minimum, must include 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 that was not in the original action and that 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 it receives an appeal; and
- (6) maintaining confidentiality of the participant's appeals.

The appeals process is very similar to the grievance process. However, we have included the requirement that an objective third party be appointed to review all appeals, so information is reviewed by an individual or group that has no stake or involvement in the decision. This helps to prevent bias in the decision. In addition, we have specified that the PACE organization must respond to participant appeals within 30 days of receipt of an appeal and established a shorter timeframe for expedited appeals. We have not included a provision for a 14-day extension of this 30-day timeframe (as allowed under the Medicare+Choice regulations at 42 CFR 422.590(a)) in recognition of the frailty of the PACE population. We are soliciting comments on both the appropriateness of this timeframe and on the necessity of requiring a specific timeframe.

We have adopted the Protocol requirement that the PACE organization 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 PACE organization continue to furnish care to the participant during the appeal process because under the law participants must receive care solely through the PACE organization. In addition, we have incorporated the Medicaid continuation of benefits provision for all Medicaid participants. Under the continuation of benefits provision, the PACE organization 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 he or she 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 PACE organization must have an expedited appeals process for situations in which the participant believes that if the service is not furnished her or his life, health, or ability to regain

maximum function would be jeopardized. This provides for prompt consideration of requests for services if the participant's health might be adversely affected if she or he had to wait for the standard appeals process. As noted above, the goal of the 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 have added a requirement that the PACE organization 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 organization justifies to the State administering agency the need for additional information and how the delay is in the interest of the participant. These timeframes for responding to expedited appeals are consistent with the requirements for Medicare+Choice plans in 42 CFR 422.590(d), published June 26, 1998 (63 FR 35110-35111). We recognize that the outcome of pending litigation may compel modification of this requirement. We will amend the requirement if resolution of the litigation makes changes necessary.

The PACE organization must take appropriate action 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 PACE organization 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 care not be delayed and that the participant continue to receive comprehensive care that maintains her or his functional status.

We have maintained the Protocol requirement that all determinations that are wholly or partially adverse to the participant must be forwarded to HCFA and the State administering agency. We have required that the PACE organization notify HCFA, the State administering agency, and the participant of its actions at the time the decision is made.

Additional Appeal Rights Under Medicare or Medicaid (§ 460.124)

The PACE organization must also inform participants in writing of their additional appeal rights under Medicaid or Medicare managed care (§ 460.124), 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 appropriate appeals process would apply.

Subpart H—Quality Assessment and Performance Improvement

We have adopted quality assessment and performance improvement requirements that are consistent with the provisions from Part V of the Protocol. We have also added requirements to prepare PACE organizations for the outcome-based continuous quality improvement (OBCQI) system that is being developed under a HCFA contract by the Center for Health Services and Policy Research (CHSPR) at the University of Colorado.

Sections 1894(e)(3) and 1934(e)(3) of the Act state that under a PACE program agreement, the PACE organization, the Secretary, and the State administering agency shall jointly cooperate in the development and implementation of health status and quality of life outcome measures with respect to PACE participants.

The CHSPR is developing a core data set that will provide the foundation for OBCQI in PACE. In developing the data set for PACE, CHSPR is examining existing HCFA data instruments such as the Minimum Data Set (a part of the nursing home Resident Assessment Instrument), the Outcome and Assessment Information Set (OASIS, a part of the Medicare home health agency conditions of participation, DataPACE (developed by On Lok, Inc. and used currently by PACE demonstration sites), and the Functional Independence Measure (FIM) items (an assessment data set used in rehabilitation hospitals), for data items which may be pertinent for PACE. This project supports the development of an OBCQI system for PACE and consists of five tracks of activities: (1) Outcome indicator development; (2) outcome measure development; (3) data item and instrument assessment and specification; (4) feasibility and pilot testing of the measures, the data items, and the system; and (5) construction and finalization of a practical OBCQI program for PACE. The data items to be specified will need to be collected at defined time points. In order to have comparable data across the PACE centers, all PACE providers will be required to collect all items in this data set for each of their PACE centers exactly as specified.

In spring of 1999, CHSPR began feasibility testing of the proposed data items and the time point for data collection. Pilot testing activities are scheduled March 2000 and continue through November 2000. Draft final recommendations for the core data items, outcome measures, data collection time points, risk-adjustment methods for the organization-level outcome reports, and the OBCQI implementation plan will be available early in 2001 with the final report completed in the spring of 2001.

The OBCQI system for PACE will be used to assess and improve (where needed) the quality of care provided to PACE participants. In order to have comparable data across the PACE centers, all PACE organizations will be required to collect the items in this data set for each of their PACE centers as specified. If new PACE organizations are investing in data systems, these systems must be flexible enough to incorporate the data items specified as a result of the OBCQI project. HCFA's expectation is that the OBCQI approach resulting from this project will be carefully integrated into, not simply added to or superimposed on, current clinical and administrative practices at the PACE sites. The unique nature of PACE and the health status attributes of PACE participants are being considered in developing the OBCQI system.

HCFA has begun to specify a preliminary classification scheme or framework of outcomes relevant to the PACE program. This taxonomy will be refined over the course of the project to develop an OBCQI system. The initial classification of outcomes includes: functional status, physiologic status and symptom management, cognitive functioning, emotional and mental health status, participant quality of life, caregiver quality of life, satisfaction with care, knowledge and compliance, end of life, and utilization.

The general framework for the PACE OBCQI system consists of two stages. The first stage is outcome analysis which includes data collection, analysis, and outcome reporting. The second stage is outcome enhancement and entails selecting specific outcomes for review, after which plans of action are documented to change or reinforce care behaviors. A key characteristic of OBCQI is the use of outcomes to help focus efforts in individual PACE sites to improve care behaviors. For the purposes of this project an outcome is defined as a participant or caregiver change in health, knowledge, ability, quality of life, outlook, or motivation that occurs over a period of time. Outcomes can be global ones that

pertain to all PACE participants or can be more focused and pertain to specific types of participants such as those diagnosed with dementia. There are both end-result and instrumental outcomes. An end-result outcome is a change in participant or caregiver status in an area that care is or should be intended to directly impact. Attainment of one or more end-result outcomes is the primary purpose of care (e.g., an improvement in skin breakdown when care has or should have been furnished to maintain or enhance skin integrity). An instrumental outcome is a "facilitating" outcome that may be important in attaining an end-result outcome, although it is not the primary purpose of care (e.g., participant adherence to a medication regimen). Outcome indicators are constructs or attributes of change in health status that reflect a participant outcome, but are not concerned with the quantification of the outcome. When the outcome indicator is precisely quantified, it results in an outcome measure.

PACE organizations and reviewers will be able to use organization-level outcome reports to compare one PACE organization and its PACE centers to all other PACE organizations and their PACE centers relative to risk-adjusted outcomes. Additionally, a PACE organization or reviewers will be able to track a given organization's outcomes and evaluate/monitor how the outcomes have changed relative to an earlier time period.

PACE organizations and States have opportunities to give input into the development of the outcome measures and the OBCQI system. These opportunities include membership in the project Advisory Committee, participation in the clinical and research technical expert panels, and involvement in piloting the data collection instruments, time points for data collection, and the outcome measures. Additionally, feedback and input from State Medicaid representatives and PACE organizations is sought at the annual PACE policy forum sponsored by the National PACE Association (NPA) in the spring of each year.

General Rule (§ 460.130)

We are requiring the PACE organization to develop, implement, maintain, and evaluate an effective data-driven quality assessment and performance improvement program. It is important that the quality assessment and performance improvement 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 PACE organization must take actions that result in improvements in its performance across the spectrum of care.

Quality Assessment and Performance Improvement Plan (§ 460.132)

The PACE organization must have a written quality assessment and performance improvement plan. Consistent with the protocol, we are requiring PACE organizations to have their quality assessment and performance improvement plan annually reviewed by the PACE governing body and, if necessary, revised. Further, in this section we set forth the minimum requirements for a written plan that specifies how the PACE organization 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 quality assessment and improvement activities to the PACE staff and subcontractors.

Minimum Requirements for Quality Assessment and Performance Improvement Program (§ 460.134)

The requirement contained in § 460.134 is consistent with the PACE Protocol, but it provides more explicit information about what types of outcomes must be used to monitor quality. The PACE organization's quality assessment and performance improvement program must include, but need not be limited to, the use of objective measures to demonstrate improved performance with regard to:

(1) Service utilization. PACE demonstration programs currently collect utilization data such as inpatient hospitalizations and emergency room visits. This information can be used to evaluate fiscal well-being, as well as evaluate quality of care. A PACE organization can use its own utilization data for its PACE centers to compare with other PACE organizations and their centers across the nation. By comparing utilization data across PACE centers, the PACE organizations, HCFA and State administering agencies can identify PACE centers who appear to have unusually high or low utilization of a particular service. Reviewers will be able 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 PACE organization's quality

assessment and performance improvement program is to help the PACE organization 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 PACE organization can identify areas for improvement.

(2) Caregiver and participant satisfaction. Caregiver and participant satisfaction with services is an important element of a quality assessment and performance improvement program. A PACE organization 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. HCFA expects the PACE organization to use this information to identify opportunities to improve services and caregiver and participant satisfaction. HCFA does not intend, at this point, to prescribe the specific tools for measuring participant and family satisfaction. Since the OBCQI project has not finalized the indicators to measure these issues, it would be unreasonable to request specific data collection for these items at this time. It is the responsibility of the PACE organization to survey the participants and family but HCFA is not specifying the survey tool they must use. The PACE organization will be expected to demonstrate its satisfaction measurement system and how it is used as part of the overall internal quality assessment and performance improvement system. Upon completion of the CHSPR OBCQI project, PACE organizations may be required to collect data on a limited number of specific caregiver and participant satisfaction measures. In developing the measures, we will examine the Consumer Assessments of Health Plans Study Surveys that HCFA is currently using for Medicare managed care plans.

(3) 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. At the completion of the PACE OBCQI project, the types of measures will be specified in these areas. In the meantime, PACE organizations should begin to use similar measures in these areas as part of their internal quality improvement programs. For example, PACE organizations should begin to focus their own 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 PACE organization 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 PACE organization 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 PACE organization's internal quality assessment and performance improvement 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 PACE organization finds a high rate of grievances not resolved, the PACE organization might target its activities to improve the grievance process.

We expect PACE organizations 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 HCFA is not imposing any specific standards of practice, this requirement establishes the expectation that the PACE organization will utilize the current standards as a routine part of its daily operations.

We have added a requirement that the PACE organization must meet minimum levels of performance on standardized quality measures that will be established by HCFA and the State administering agency which are specified in the PACE program agreement. For example, HCFA might require all PACE organizations to achieve a 95 percent flu immunization rate for their PACE participants. If a PACE organization fails substantially to meet these specified requirements, the continuation of the PACE program agreement may be conditional on the execution of a corrective action plan, 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 based on analysis of available data sets that are applicable to PACE participants.

We have added a requirement that the PACE organization take actions to ensure the accuracy and completeness of all data used for outcome monitoring. A data-driven quality assessment and performance improvement program must be based on accurate data. The regulations require that PACE organizations set up mechanisms to check for the accuracy, timely collection, and completeness of all data.

Internal Quality Assessment and Performance Improvement Activities (§ 460.136)

In § 460.136, we require that the PACE organization 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 PACE organization also must incorporate any actions resulting 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 PACE organization must use its own experience from its performance improvement program to change care behaviors and to ensure that these behaviors are sustained.

Unlike the Protocol, we are requiring the PACE organization 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 are requiring the PACE organization to designate an individual to coordinate and oversee implementation of quality assessment and performance improvement activities. The purpose of this requirement is to ensure that the PACE organization designates responsibility for a quality assessment and performance improvement 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 assessment and performance improvement activities.

We have added a requirement that the PACE organization ensure that all team members, PACE staff, and contract providers are involved in the development and implementation of the quality assessment and performance improvement 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 multidisciplinary teams are 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 PACE organization to make full use of the multidisciplinary team and other staff in contributing to the internal quality improvement program.

Consistent with the Protocol, we are requiring the PACE organization to involve PACE participants and caregivers in the quality assessment and performance improvement 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.

Committees With Community Input
(§ 460.138)

Similar to the Protocol, we are requiring that the PACE organization 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 quality assessment and performance improvement 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 PACE organization will be able to receive guidance regarding its quality assessment and performance improvement program and the ethical issues faced by PACE organizations.

Additional Quality Assessment Activities
(§ 460.140)

As the final requirement under Quality Assessment and Performance Improvement as set forth in this section, we require that PACE organizations participate in periodic, external quality improvement reporting requirements as may be specified by the HCFA or the State administering agency. Examples of participation in a quality assessment and performance improvement activity include the reporting of data items for outcome measurement purposes, participation in the survey process, and participation in a HCFA-directed national quality improvement project.

Subpart I—Participant Enrollment and Disenrollment

Eligibility To Enroll in a PACE Program
(§ 460.150)

In accordance with sections 1894(a)(5) and (c)(1) and 1934(a)(5) and (c)(1) of the Act, we have established § 460.150, to specify the requirements for eligibility to enroll in the PACE program. According to the Protocol, in order to be eligible for enrollment in PACE, an individual must be:

- a. At least fifty-five years of age;
- b. A resident in the PACE organization's service area;
- c. Assessed by the multidisciplinary team; and
- d. Certified by the State Medicaid Agency as eligible for nursing home level of care.

With the exception of the requirement to be assessed by the multidisciplinary team, these requirements are also included in the statute.

Sections 1894(c)(2) and 1934(c)(2) of the Act provide that a PACE program

eligible must have a health status comparable to the health status of individuals who have participated in the PACE demonstration waiver 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 and 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 a uniform minimum data set collected by PACE organizations on potential PACE program eligible individuals. This provision means that PACE organizations will continue to serve patients who are as frail as those served under the demonstration; this will prevent PACE organizations from selecting enrollees who need less care and whose care is therefore less costly.

We examined some informational 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 sites as of December 31, 1995. Activities of daily living (ADL) 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 measures dependencies in 8 instrumental activities of daily living (IADL), which are 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 the PACE demonstration sites is individuals who meet the nursing facility level of care,

the specific criteria used to determine if an individual needs this level of care vary 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 have 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 nursing facility 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 nursing facility level of care. Under the demonstration program, the need for a nursing facility level of care was a one-time certification. Thus, under the demonstration, PACE organizations could continue to serve individuals who had a short-term need for a nursing facility level of care but whose condition had shown significant improvement. The law's annual recertification requirement ensures that participants will continue to need a nursing facility level of care.

Additionally, we are implementing a requirement that PACE organizations must notify HCFA and the State administering agency of enrollment denials. HCFA and State administering agencies may analyze this information to detect selective enrollment. Finally, the quality assurance requirements included in these regulations will allow the monitoring of case-mix profiles across sites. While it might be very difficult to identify situations where organizations engage in selective enrollment on an individual participant basis, the improved quality assurance mechanisms will allow the identification and correction of routine instances through the review of organization-level case-mix profiles.

After weighing both the need to maintain State and organization flexibility to develop programs suitable to the communities in which the PACE organizations will operate and the implementation of other safeguards against selective enrollment, we believe

having a health status comparable to the PACE demonstrations is inherently equivalent to needing a nursing facility level of care. We are satisfied that applying the nursing facility level of care requirement in conjunction with the other safeguards discussed will minimize selective enrollment while preserving program flexibility; however, we invite 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. Although we are aware that under the demonstration some PACE sites have set their minimum age limits higher than 55, we believe the provision of the law allowing site-specific eligibility requirements allows for additional requirements not the modification of the three requirements specified in the law.

We also caution 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, and HCFA 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 to be easier to care for.

The eligibility requirement specified in § 450.150(c) incorporates 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 setting involves assessing the individual's care support network as well as the individual's health condition. As specified in § 460.152(a)(4), this determination is made by the PACE organization when assessing whether the potential participant can be cared for appropriately in this program. Consequently, we have not included the Protocol requirement regarding assessment by the multidisciplinary team in the eligibility criteria. We believe that the intent of this Protocol requirement is preserved through the intake process requirements in § 460.152.

We have reflected in the regulations the statutory provision 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.

Enrollment Process (§ 460.152)

We have established § 460.152 to specify the PACE organization's responsibility during the intake process and actions required in the event a potential PACE participant is denied enrollment because his or her health or safety would be jeopardized by living in a community setting.

Although we recognize that the intake process must be flexible, we have specified certain steps that must, at a minimum, be included. 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 PACE organization 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 pre-enrollment 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 PACE organization. Once that disclosure is made and understood by the potential participant, other key disclosures relate 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. Other information that should be disclosed upon request includes the process that the PACE organization uses to decide that drugs, devices, and procedures are experimental and whether the PACE organization uses a drug formulary.

The uniqueness of the PACE model depends upon the partnership formed between the participant and the multidisciplinary team. Therefore, a potential participant should 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 multidisciplinary team, to contractors

who furnish specialty services, to health care facilities such as hospitals and nursing homes, and to home health care. Also, participants may request information regarding whether there are financial incentives to providers. Finally, to the extent that board certification and other credentials, clinical protocols and medical practice guidelines, consumer satisfaction survey results, or the results of the organization's most recent Federal or State review are of particular interest to participants, these must be disclosed upon request.

With regard to specific intake tasks, we have deleted the Protocol requirement for a complete assessment by the multidisciplinary team 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 multidisciplinary team assessment and that this is consistent with actual practice under the PACE demonstration program. As an additional protection against selective enrollment, we have added a requirement that HCFA and the State administering agency must be notified when potential participants are denied enrollment because the PACE organization has determined that their health or safety would be jeopardized in a community setting. Additional wording and organization changes have been made in this section; however, except where otherwise specifically noted, our intent is 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 are requiring the PACE organization to inform the individual in writing of the reason for the denial; as appropriate, refer the individual to alternative services; retain supporting documentation of the reason for the determination; and notify HCFA and the State administering agency as well as make the documentation available for review.

Enrollment Agreement (§ 460.154)

While the program agreement will contain the specific enrollment and disenrollment procedures to be followed by the PACE organization, in § 460.154 we are specifying general requirements which must be met by all PACE organizations. The statute is silent as to any general enrollment requirements; however, it provides that the regulations should incorporate, to the extent possible, the requirements applied to the PACE demonstration waiver programs under the PACE Protocol.

Thus, we are adopting the Protocol enrollment and disenrollment provisions with the exceptions noted below.

We have removed the reference to the Member Handbook because we found the distinction between the Member Handbook and the Enrollment Agreement to be confusing. We have defined the minimum information which must be included in the Enrollment Agreement to incorporate those materials which would generally be expected to be included in a Member Handbook. Although PACE organizations may actually utilize 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.

Although this is not a change from current practice, we would like to emphasize that an individual who accepts PACE as his/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 PACE organization since the PACE model of care is designed to furnish services which meet health care needs along a continuum.

We have added a requirement for the Enrollment Agreement to 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 added 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 is 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 prepayment plan.

We have added a requirement that any changes to the information contained in the Enrollment Agreement must be provided to the participant in writing and be fully discussed with the participant and his or her representative or caregiver. We feel it is essential that all participants be aware of any changes

in this information in order to protect and exercise their rights.

Other Enrollment Procedures (§ 460.156)

We have established this section to specify the documentation that must be provided to a PACE participant who signs the 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 identifying the individual as a PACE participant which includes the phone number of the PACE organization, 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 PACE organization.

In addition, the PACE organization must submit participant information to HCFA and the State administering agency in accordance with established procedures.

We have 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 PACE organization must provide to the participant an updated copy of the information to the participant at least 60 days before any change, and explain the changes to the participant and his or her representative or caregiver in a manner they understand.

Effective Date of Enrollment (§ 460.158)

Consistent with the Protocol, we have established this section to specify that a PACE participant's enrollment in the program is effective the first day of the calendar month following the date the PACE organization receives the signed enrollment agreement.

Continuation of Enrollment (§ 460.160)

In this section we have specified 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 have incorporated the statutory requirement contained in sections 1894(c)(3) and 1934(c)(3) of the Act for an annual recertification of the need for a nursing facility level of care. We believe that the law contemplated that reevaluations would be conducted by the State administering agency for all participants, whether Medicaid eligible or not.

The statute provides that this annual reevaluation may be waived for those individuals for whom the State administering agency determines there is no reasonable expectation of improvement or significant change in condition. As a waiver could 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 feel it is unlikely, especially in view of the age and frailty of PACE participants as a whole, that a person who has not shown significant improvement in the past year would show significant enough improvement in the future to no longer need a nursing facility level of care. The law permits a waiver "during a period in accordance with regulations" in those cases where the State administering agency determines no reasonable expectation of improvement. Therefore, we are providing in regulations that such a waiver should be for the life of the participant; the reasons for the waiver must be explicitly documented in the medical record. We recognize that this regulation as drafted does not provide a mechanism for reinitiating the recertification process once a waiver has been granted, and we invite comments on this issue.

Finally, sections 1894(c)(4) and 1934(c)(4) of the Act allow for the continuing, or deemed, eligibility of those individuals who are determined through the annual recertification process to no longer meet the nursing facility level of care requirement if, in the absence of continued coverage under PACE, the individual would reasonably be expected to again meet the nursing facility level of care within the next 6 months. We feel this determination should be made by the State administering agency, which may solicit input from the PACE organization and that the deemed eligibility should continue until the next annual recertification. While it is the State's responsibility to determine the need for nursing facility level of care, the PACE organization has a detailed knowledge of the day-to-day care and service requirements of the individual participants and would, therefore, be better able to predict a participant's reaction to the loss of PACE services. We invite comments on whether this responsibility should be shared or carried out solely by either the State administering agency or the PACE organization. We also invite comments on whether this deemed eligibility should continue for 12 months (until

the next annual recertification is due) or for a shorter period.

Voluntary Disenrollment (§ 460.162)

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.

Involuntary Disenrollment (§ 460.164)

In accordance with sections 1894(c)(5)(B) and 1934(c)(5)(B) of the Act, we have established this section to specify the conditions under which a PACE participant can be involuntarily disenrolled from the 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 (if applicable) on a timely basis or for engaging in disruptive or threatening behavior. We have incorporated the Protocol requirement that a participant may be involuntarily disenrolled if he/she fails to pay or to make satisfactory arrangements to pay any premium due the PACE organization after a 30-day grace period.

We have incorporated the following reasons for involuntary disenrollment from the Protocol:

a. The participant moves out of the PACE program service area or is out of the service area for more than 30 days unless the PACE organization agrees to a longer absence due to extenuating circumstances;

b. The PACE organization is unable to offer health care services due to the loss of State licenses or contracts with outside providers.

We have also added as a reason for involuntary disenrollment that the PACE organization agreement with HCFA and the State administering agency is not renewed or is terminated. In all of these situations the disenrollment is not a subjective determination made by the PACE organization but is necessary due to outside causes. We also incorporated as a reason for involuntary disenrollment the statutory provision regarding the annual recertification of nursing facility level of care.

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. We also did not incorporate, as a reason for disenrollment, a breakdown in the physician and/or team and participant relationship. Since this relationship and the functioning of the multidisciplinary team are critical to the success of the PACE model, we expect that a breakdown in team function would signal a severe problem that needed attention from HCFA and the State administering agency far surpassing a review of an involuntary disenrollment decision.

In revising the Protocol provisions to incorporate the statutory provision regarding disruptive or threatening behavior, we felt the need to balance two concerns: first, to protect participants who are exhibiting difficult behaviors from being "dumped" by the PACE organization but secondly to provide a safeguard which allows the organization 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 State agencies, we have defined a person who engages in disruptive or threatening behavior as:

a. A person whose behavior is jeopardizing his/her health or safety or that of others, or

b. A person with decision-making capacity who consistently refuses to comply with his/her individual plan of care or the terms of the Enrollment Agreement.

However, a PACE organization 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/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 certainly 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 specify that proposed involuntary disenrollments are subject to a timely review and final determination prior to the proposed disenrollment becoming effective. This provision further protects the participant from "dumping" by the organization and provides for the continuation of services until a final determination is made. The State administering agencies would review all proposed involuntary disenrollments. We also invite comments on whether the regulations should specify a time frame in which the review must be conducted and, if so, what an appropriate timeframe is.

Effective Date of Disenrollment (§ 460.166)

We are requiring that the PACE organization must use the most expedient process allowed for by Medicare and Medicaid procedures as specified in the program agreement while ensuring 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. We are further requiring that, until such time the enrollment is terminated, PACE participants must continue to use PACE organization services and remain liable for any premiums, and the PACE organization must continue to furnish all needed services.

Reinstatement in Other Medicare and Medicaid Programs (§ 460.168)

We have established this section to prescribe the PACE organization's responsibility to facilitate a PACE participant's reinstatement in other Medicare and Medicaid programs after disenrollment. We are requiring that the PACE organization make appropriate referrals and ensure medical records are made available to new providers in a timely manner. In addition, we are requiring that the PACE organization work with the State administering agency and HCFA to reinstate the participant in other Medicare and Medicaid programs for which the individual is eligible.

Reinstatement in PACE (§ 460.170)

Section 460.170 provides that a previously disenrolled participant may be reinstated in the PACE program. We did not adopt the protocol provision limiting a participant to a one-time-only

reinstatement following a voluntary disenrollment because we believe that frail elderly individuals may experience living arrangement changes that take them in and out of a PACE organization's service area and result in unavoidable disenrollments. We have retained the Protocol provision that a PACE participant can be reinstated in the PACE program with no break in coverage if the reason for the disenrollment was failure to pay the premiums and the PACE participant pays the premium before the effective date of the disenrollment.

Documentation of Disenrollments (§ 460.172)

We have established § 460.172 to specify that a PACE organization must have a procedure in place to document the reasons for all voluntary and involuntary disenrollments; make the documentation available for review by HCFA and the State administering agency; and use the information on voluntary disenrollments in the PACE organization's internal quality assessment and performance improvement program.

Subpart J—Payment

Sections 1894(d) and 1934(d) of the Act require that payment to a PACE organization be based on a capitation amount. The Medicare capitation amount will be based upon the Medicare+Choice payment rates established under section 1853 of the Act. The Medicaid capitation amount is negotiated between the State and the PACE organization.

The following basic principles distinguish the PACE financing model from traditional Medicare and Medicaid reimbursement:

- Obligation for payments is shared by Medicare, Medicaid, and individuals.
- 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 nursing-facility-eligible population not enrolled under the PACE program.

- The PACE organization accepts the capitation payment amounts described in this section as payment in full from Medicare and Medicaid.

Medicare Payment to PACE Organizations (§ 460.180)

Section 1894(d) of the Act requires us to make prospective monthly payments of a capitation amount for each PACE program eligible individual enrolled in

the same manner and from the same sources as payments are made to a Medicare+Choice organization under section 1853 of the Act. Payments 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 risk-based HMOs, PACE organizations will receive monthly payments based on an interim per capita rate per participant. Under that methodology, separate rates are established for Part A and Part B. The PACE organization receives payments based on each participant's entitlement to Medicare Part A and B. Therefore, if the participant is entitled to Part A benefits, but is not enrolled under Part B, the PACE organization receives 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, PACE organizations should verify at the time of enrollment whether the participant is dually eligible for Medicare and Medicaid and whether the participant has Medicare Part A and Part B. Payment for a participant will begin with 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 end-stage renal disease (ESRD) will be applied to the appropriate payment rate.

Frailty Factor

Under the PACE demonstration, the Medicare capitation rate for each PACE organization was calculated using HCFA's standard Adjusted Average Per Capita Cost (AAPCC) 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 is one frailty adjuster of 2.39 for all PACE participants except those diagnosed with ESRD. As of January 1, 1998,

instead of using the AAPCC, the Medicare capitation rate paid to PACE demonstration projects is calculated using the Medicare+Choice rates with the frailty adjuster of 2.39.

This frailty factor was developed for the PACE demonstration sites using information gathered from the "pre-Channeling" demonstrations serving the nursing-facility-eligible population and information from the cost experience at On Lok, which began receiving Medicare and Medicaid payments in 1983. (The pre-Channeling demonstration targeted the frail elderly and provided case management and community-based services in order to decrease the use of institutional care.) Studies have been done to examine the accuracy of the 2.39 factor. Researchers at the Bigel Institute for Health Policy did a study in 1990 to estimate the per capita costs of the nursing-facility-eligible population in the period 1984–1985. They linked data from the 1984 National Long-Term Care Survey (which collected health and functional status information on Medicare beneficiaries) to Medicare claims. Their cost estimates suggest that the per capita Medicare costs for the nursing-facility-eligible population averaged 2.42 times the average Medicare costs for the overall elderly population.

In 1998, the University of Wisconsin assessed the adequacy of this factor in relation to the Medicare costs experienced by nursing-facility-eligible populations. The authors found significant variation among States in the manner in which nursing-facility-eligibility is determined. The application of these various definitions of nursing-facility-eligible to available survey data indicates that there is a natural clustering of results, despite the apparent difference among definition formats. Marginal cost differences between nursing-facility-eligible and non-nursing-facility-eligible individuals can be explained in part by key variables: age, sex, functional impairment, and the level of recent health service utilization. With no prior risk adjustment, the data suggest that an average frailty factor of about 200 percent is appropriate. However, this factor should be adjusted for the profile of participants at each site. These studies relate to populations that are nursing-facility-eligible and not specifically to PACE. Consequently, we believe that the 2.39 factor used in the demonstration is an appropriate interim payment measure. As discussed later in this section, we are working to develop a risk adjustment methodology that will account for the relative frailty of the PACE population.

End Stage Renal Disease (ESRD) Adjustment

Under the PACE demonstration, PACE programs have been paid in two ways for Medicare ESRD participants. Each month for each ESRD participant, the PACE program is paid the AAPCC Part A and Part B ESRD rate. The rate is not adjusted by the 2.39 frailty factor. Instead, PACE programs receive additional payment each month for the actual cost of services in excess of the AAPCC ESRD payment rate. However, section 1894(d) of the Act does not contemplate payment of actual cost.

An analysis of 1994 Medicare claims data for ESRD patients shows that Medicare expenditures for ESRD patients who are 75 or older are significantly higher than expenditures for all ESRD patients. This finding has been fairly constant over time. The group of ESRD patients who are 75 or over tend to be very frail and in most cases would be considered nursing-facility-eligible. This group of elderly ESRD patients can be used as a proxy for ESRD patients who are nursing-facility-eligible. ESRD patients who are 75 or over have 46 percent higher Part A expenditures relative to all ESRD patients, while their Part B expenditures are 36 percent higher. We have applied this information to calculate adjusters for ESRD patients enrolled in PACE. Thus, the Part A ESRD adjuster will be 1.46 and the Part B ESRD adjuster will be 1.36. We welcome comments on these adjustment factors. As discussed in more detail below, these adjustment factors are established as an interim measure pending development of a risk adjustment methodology.

Risk Adjustment

Section 1853(a)(3) of the Act requires that payment rates to Medicare+Choice plans be risk-adjusted starting January 1, 2000. At the present time HCFA is developing the risk adjustment methodology and evaluating how to apply the methodology to PACE and other HCFA demonstration projects. The Announcement of Calendar Year 2000 Medicare+Choice Payment Rates, published January 15, 1999 on the HCFA website, displays the risk adjuster rates and methodology that will be effective for Medicare+Choice plans starting January 1, 2000. The demographic rate methodology will be phased out, while a risk methodology using health status will be phased in. By 2003, 80 percent of the capitated payments will be based on health status risk adjusters, while 20 percent will be based on the existing AAPCC rate structure. Specific HCFA

demonstrations programs and PACE will not implement the new risk adjuster methodology on January 1, 2000, but will have a one-year deferral. This extension is needed to study the applicability and impact of risk adjustment on capitated payments for the frail.

We anticipate using the encounter data and other types of information collected from Medicare+Choice organizations and PACE organizations to conduct research to evaluate risk adjustment payment options for special populations such as PACE participants and examine the possibility of using a hybrid methodology.

We will require initially that each PACE organization submit inpatient hospital encounter data using the UB-92 to HCFA through a fiscal intermediary (FI), similar to the requirements for Medicare+Choice plans. The PACE organizations will need to establish electronic linkages with the designated FIs and may need to modify their contracts with hospitals to ensure that a completed UB-92 for each hospital discharge of a PACE participant is provided by the hospital to the PACE organization. We will subsequently require PACE organizations to submit additional encounter data consistent with the encounter data requirements for Medicare+Choice plans set forth in 42 CFR 422.257, published in the **Federal Register** on June 26, 1998 (63 FR 35092).

In order to develop a frailty adjuster for payment to PACE organizations, we may also collect and analyze data on functional status of PACE participants to profile participants at each PACE site. PACE demonstration projects are participating in the Health Outcomes Survey. PACE organizations may be required to collect this or similar functional data in order to adjust the Medicare+Choice payment rates. Until we develop a specific risk adjustment methodology for PACE, we will continue to adjust PACE rates using the frailty and ESRD adjusters described above. We welcome comments on this issue.

Medicare Secondary Payer (MSP)

We specify the application of MSP provisions because HCFA cannot pay for PACE services to the extent that Medicare is not the primary payer under section 1862(b) of the Act and 42 CFR part 411. We require the PACE organization to identify payers that are primary to Medicare, determine the amounts payable by those payers, and coordinate its benefits to Medicare participants with the benefits of the primary payers.

Under MSP provisions, the PACE organization may charge other individuals or entities for PACE services covered under Medicare for which Medicare is not the primary payer, as follows:

- If a Medicare participant receives from a PACE organization covered services that are also covered under State or Federal workers' compensation, any no-fault insurance, or any liability insurance policy or plan, including a self-insured plan, the PACE organization may charge—
 - + The insurance carrier, the employer, or any other entity that is liable for payment for the services under section 1862(b) of the Act and 42 CFR part 411; and
 - + The Medicare participant, to the extent that he or she has been paid by the carrier, employer, or entity.
- If Medicare payment is precluded by section 1862(b) of the Act for services that a PACE organization furnished to a Medicare participant who is covered under a group health plan (GHP) or large group health plan (LGHP), the organization may charge the GHP or LGHP for those services and may charge the Medicare participant to the extent that he or she has been paid by the GHP or LGHP for those services.

Medicaid Payment (§ 460.182)

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 which elects PACE as a Medicaid State plan option will 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 PACE organization and the State administering agency and can be renegotiated on an annual basis.

As these statutory requirements do not differ from the Protocol requirements regarding Medicaid payments under the PACE demonstration, the regulations mirror the Protocol requirements.

Post-Eligibility Treatment of Income
(§ 460.184)

Section 1934(b)(1)(A)(i) of the Act indicates that a PACE organization 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 PACE organization by the amount remaining after specified deductions are made from the income of the PACE participant. The income remaining 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) 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) is not cost sharing prohibited by section 1934(b)(1)(A)(I).

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 and/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).

We interpret section 1934(b)(1)(A)(I) 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) merely surplusage which could not be given meaning. Therefore, to give meaning to each of the sections of the Act at issue here, we are providing in section 460.184, which implements section 1934(i), references to 42 CFR 435.726 and 435.735 which lay out the post-eligibility treatment of income and resource requirements which may be applied here in the same manner as applied to individuals receiving home and community-based services.

Conforming Amendments

The BBA also 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) 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 section 1934 or 1894. 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 at section 1902(a)(10)(A)(ii)(IV) of the Act.

PACE Premiums (§ 460.186)

Neither section 1894 nor section 1934 of the Act addresses the premiums a PACE organization can charge a PACE participant. In accordance with sections 1894(f)(2) and 1934(f)(2) of the Act, we have adopted most of the PACE premium requirements from Part VI, section D, of the Protocol into the regulations.

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 is more narrow 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. PACE organizations can 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 both 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.

Subpart K—Federal/State Monitoring

Monitoring During Trial Period
(§ 460.190)

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 PACE organization's first 3 contract years (see sections 1894(a)(9) and 1934(a)(9) of the Act). We have established § 460.190 to address the law's requirements for review during the trial period. During the trial period, HCFA in cooperation with the State administering agency will conduct comprehensive annual reviews of a PACE organization.

In accordance with the law, the review will include an on-site visit to the PACE organization, 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 and these regulations, and any other elements that HCFA or the State administering agency find necessary.

We anticipate that on-site reviews would be conducted by a survey team that includes an individual who is experienced in providing care to the frail elderly and is knowledgeable about the PACE service delivery system.

Ongoing Monitoring After Trial Period
(§ 460.192)

In accordance with paragraph (e)(4)(B) of sections 1894 and 1934 of the Act, we specify that at the conclusion of the trial period, HCFA, in cooperation with the State administering agency, continues to conduct reviews of a PACE program, as appropriate. These reviews will take into account the performance level of the PACE organization with respect to the quality of care provided and compliance of the organization in meeting the PACE program requirements. Such reviews will include an on-site visit at least every two years.

Corrective Action (§ 460.194)

We require the PACE organization to take action to correct deficiencies identified during the reviews. HCFA or the State administering agency will monitor the effectiveness of corrective actions. Failure to correct deficiencies can result in sanctions or terminations in accordance with subpart D.

Disclosure of Review Results (§ 460.196)

In accordance with paragraph (e)(4)(C) of sections 1894 and 1934 of the Act, we specify requirements for disclosing the results of oversight reviews. HCFA and the State administering agency promptly report the results of reviews under §§ 460.190 and 460.192 to the PACE organization, along with any recommendations for changes to the organization's program. The results are made available to the public upon request. In addition, we are requiring that the PACE organization post a notice of the availability of the results of the most recent review and any plans of correction or responses related to the most recent review. The PACE organization must also make the results available for examination in a place readily accessible to participants.

Subpart L—Data Collection, Record Maintenance and Reporting*Maintenance of Records and Reporting of Data* (§ 460.200)

In accordance with sections 1894(e)(3)(A) and 1934(e)(3)(A) of the Act, we are requiring PACE organizations 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 HCFA and the State administering agency upon request and be stored in a manner consistent with the PACE organization's written policies that protects them from

loss, destruction, unauthorized use or inappropriate alteration.

We have established several requirements intended to safeguard the privacy of any information that identifies a particular participant. The PACE organization 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. A participant's written consent must be obtained before the release of identifiable information to persons not otherwise authorized to receive it. A participant's 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 PACE organization 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 does not specify a minimum record retention timeframe. In order to enable adequate oversight and to be consistent with the requirements established for Medicare+Choice plans, we require PACE organizations 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 shall be retained until completion of the litigation, or until claims or audit findings involving the records have been resolved and final action taken.

Participant Health Outcomes Data
(§ 460.202)

We have modified the requirement in Part VII, section B of the Protocol for data collection and reporting. We are requiring that PACE organizations maintain a health information system that collects, analyzes, integrates, and reports data necessary to measure their performance and to develop their quality assessment and performance improvement programs. After development of HCFA's collection and reporting strategy, PACE organizations will be expected to collect specific data at specified time intervals. We envision that this information system can be used

by HCFA, the State administering agency, PACE organizations, participants and their caregivers, researchers, policy makers, and other professionals furnishing care to PACE participants. This system also will provide information to help PACE organizations, participants, and caregivers make better choices about care and help identify organizations' opportunities for continuous improvement in all participant care processes.

Each PACE organization will collect, evaluate, and report the data as part of managing its quality assessment and performance improvement program. These data will assist the PACE organization in its efforts to identify opportunities to improve participant care and outcomes, to evaluate the results of its performance improvement activities, and to share those results with other PACE organizations.

The data set will focus on items such as functional status, health status, cognitive ability, mental health, medication use, nutritional status, health care utilization, participant and caregiver quality of life, and any other measures of participant care that the PACE organization community believes to be useful both for tracking participant care and for identifying opportunities for improvement. The items in the data set will be essential to the PACE organization for purposes of continuous care planning, for the effective and efficient operation of the organization, and for assisting participants and their caregivers in making informed decisions about their care. Thus, accurate and precise data collected at uniform time points (*i.e.*, from a baseline point such as enrollment, return from hospital, etc.) will be essential. Aggregating the data to a level that makes it useful to PACE organizations for internal quality improvement programs is an important benefit of having a central data system that feeds data back to PACE organizations for comparative purposes on a continuous basis. An aggregated data set is also useful in establishing national improvement efforts.

Given that the core data set is still under development and will not be ready for implementation until sometime in the summer of 2000, PACE organizations should be collecting information on their own to feed into their quality assessment and performance improvement activities. PACE organizations may want to collect the items on DataPACE, which was developed by On Lok and contains information on participant demographics, health and functional status, service utilization, and informal

support. This will allow for the continued collection of data elements collected in the demonstration project for comparison between demonstration sites and permanent PACE organizations. However, if PACE organizations are developing computerized information systems, the systems should be flexible enough to be able to replace, in the future, items now in the system with similar items that are developed as a result of the CHSPR project.

Additionally, we have added a requirement that the PACE organization must furnish data and information in the manner and at the time intervals specified by HCFA and the State administering agency, pertaining to its participant care activities. These data will be used to monitor the quality of care provided to PACE participants, including participant outcomes. The items to be collected will be specified in the PACE program agreement and will be subject to the confidentiality requirements specified in § 460.200. Once the core data set is completed, PACE organizations will be required to submit these data to HCFA and/or the State administering agency. Since this data set is under development, HCFA will require PACE organizations, in the meantime, to submit to HCFA and/or the State administering agency a limited amount of information in order to monitor the quality of care furnished to PACE participants. This information will be specified in the PACE program agreement. The required information will include the number of grievances and appeals; rates and reasons for disenrollment; utilization of the adult day health center, home health, acute hospital, nursing home, transitional housing, rehabilitation unit/facility, mental health services, and outpatient drugs; vaccination rates for flu and pneumonia; percent of participants receiving retinal eye exams and dental exams; and the number of participants with a fracture or decubitus during the reporting period.

We also will require each PACE organization to conduct an annual satisfaction survey of its participants and caregivers. The findings will be reported to HCFA and/or the State administering agency and should be used by the PACE organization to identify opportunities for improvement. Finally, as discussed previously, we will require reporting of inpatient and outpatient encounter data and may require reporting of functional data in order to develop a risk adjustment methodology for PACE.

Financial Record Keeping and Reporting Requirements (§ 460.204)

In § 460.204, Financial Record Keeping and Reporting Requirements, we require that a PACE organization must provide HCFA and the State administering agency with accurate financial reports that are prepared using an accrual basis of accounting and verifiable by auditors.

In addition, we are requiring that the PACE organization maintain an accrual accounting record-keeping 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 as set forth in 42 CFR 413, a PACE organization must follow standardized definitions and accounting, statistical, and reporting practices that are widely accepted in the health care industry.

We are also requiring that a PACE organization must permit HCFA and the State administering agency 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.

Under the PACE demonstration, HCFA and the PACE organization had a risk-sharing agreement in which HCFA shared in a portion of the organization's losses during the first 3 years of operations. To monitor each organization's costs and the amount of HCFA's liability, HCFA required the organization to submit monthly budgeted versus actual financial reports during the first year and quarterly reports during subsequent years unless the organization's performance indicated a need for more frequent reporting. In addition, organizations were required to submit quarterly cumulative cost reports for risk-sharing determinations. Annually, organizations were required to submit independently certified cost reports for final risk sharing determinations.

The statute does not provide for risk-sharing arrangements between HCFA and PACE organizations. It places the organization at full financial risk for all services. Since risk sharing is no longer a condition of the agreement, the cost and financial reports described above are no longer needed for this purpose.

Financial Statements (§ 460.208)

HCFA, in cooperation with the State administering agency, has the responsibility of assessing fiscal soundness as described in § 460.80.

The financial information required to assess the fiscal soundness of a PACE organization is information from basic financial statements, the balance sheet, statement of revenues and expenses, and sources and uses of funds statement. An organization that has completed its trial period will be required to submit these basic financial statements, annually. An organization that is in the trial period will be 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 of Nashville, Tennessee (615-254-6291) for reporting by HMOs.

Sections 1894(e)(3) and (4) and 1934(e)(3) and (4) of the Act require the Secretary and the State administering agency to work in consultation to determine what data and cost and financial reports the PACE organization must submit so these agencies can monitor the cost and effectiveness of a PACE organization and perform necessary reviews.

In § 460.208, we are requiring that, not later than 180 days after the end of the organization's fiscal year, the PACE organization submit a certified 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 entire duration of the trial period, we are requiring that not later than 45 days after the end of each quarter of the organization's fiscal year, a PACE organization must submit a quarterly financial statement, which is not required to be certified by an independent certified public accountant.

At the conclusion of the trial period, HCFA or the State administering agency may require a PACE organization to submit monthly or quarterly financial statements, or both, if HCFA or the State administering agency 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.

We consulted with representatives from various State organizations that currently service PACE programs under demonstrations. Initial observations indicate that data collection and

financial reporting requirements vary among the State organizations at the present time. It appears that the data collection and financial reports we require in this interim final regulation can also assist the State administering agency in the monitoring and oversight requirements. Of course, States will still have the authority to request any data and reports that they consider to be necessary in implementing PACE. HCFA will continue to consult with State organizations to develop consistency in reporting requirements in order to minimize the reporting burden for PACE organizations. We welcome comments on this issue.

Medical Records (§ 460.210)

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 multidisciplinary team; (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 this population will be provided by a variety of sources (*i.e.*, 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, we have 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 are requiring in § 460.210 that the PACE organization maintain a single comprehensive medical record for each participant at the PACE center he or she attends. Participant medical records should be complete, accurately documented, easily retrievable, systematically organized, and available to all staff. We recognize that a PACE organization may have more than one site. However, participant medical records must be located at the site the participant receives services so that staff have access to pertinent information. This requirement also should prevent time lost in obtaining records and facilitate timely review and documentation of the medical record. We have added appropriate language to address this issue.

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 the last phrase to ensure that any services furnished to the participant outside the scope of the center's direct care is documented in the medical record. It is critical to the continuity of care that the center staff be informed of all outside services furnished to the participant. Once the participant returns to the 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 is intended to ensure that anyone who furnishes services to the participant, as either an employee of the PACE organization or under contract, shares the information with the center staff for documentation in the medical record. Again, this requirement is intended to facilitate communication between providers.);
- Multidisciplinary assessments, reassessments, plans of care, and treatment and progress notes that are signed and dated;
 - Laboratory, radiological and other test reports (This change 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 (*e.g.*, care giver, 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 PACE organization cannot implement an advance directive as a matter of conscience that fact also should be prominently displayed.);
 - A signed release permitting disclosure of personal information; and
 - Accident and incident reports. (Accident and incident reports are included because 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 center or its staff.)

We also require the PACE organization to provide for the prompt transfer of copies of appropriate medical record information through 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, such things as 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 are soliciting comments on whether a specific timeframe for the transfer of participant medical record information should be required.

We have added 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.

III. Response to Comments

Because of the large number of items of correspondence we normally receive on **Federal Register** documents published for comment, we are not able to acknowledge or respond to them individually. We will consider all comments we receive by the date and time specified in the **DATES** section of this preamble, and, when we proceed with a subsequent document, we will respond to the comments in the preamble to that document.

IV. Waiver of Proposed Rulemaking and Delayed Effective Date

We ordinarily publish a notice of proposed rulemaking in the **Federal Register** and invite public comment on the proposed rule. The notice of proposed rulemaking includes a reference to the legal authority under which the rule is proposed and the terms and substance of the proposed rule or a description of the subjects and issues involved. This procedure can be waived, however, if an agency finds good cause that a notice-and-comment procedure is impracticable, unnecessary, or contrary to the public interest and incorporates a statement of

the finding and its reasons in the rule issued.

Section 4803(a) of BBA directed us to promulgate these regulations in a timely manner, so that entities may establish and operate ongoing PACE programs under Medicare and Medicaid for periods beginning not later than August 5, 1998. Section 1894(f)(1) of the Act, as added by section 4801 of BBA, and section 1934(f)(1) of the Act, as added by section 4802 of BBA, authorize the issuance of interim final regulations for this purpose. Thus, the BBA expressly provides that we may implement the PACE program without publication of a notice of proposed rulemaking and a period for public comment.

For these reasons, we find notice-and-comment rulemaking procedures both unnecessary and impracticable. Therefore, we find good cause to waive the notice of proposed rulemaking and to issue this final rule on an interim basis. We are providing a 60-day period for public comment.

Generally, we provide a 30-day delay before effectuation of a final rule unless we find good cause to dispense with that delay (5 U.S.C. section 553(d)). For the same reasons applicable to waiver of proposed rulemaking and in order to allow the current PACE demonstration projects the opportunity to apply for PACE organization status as soon as possible after publication of this interim final rule, we find that the 30-day delay is impracticable and not in the public interest. Therefore, we find good cause to waive the 30-day delay in the effective date of the regulation.

V. Collection of Information Requirements

Under the Paperwork Reduction Act of 1995 (PRA), we are required to provide 60-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 the information collection requirements (ICRs) summarized and discussed below.

A. *The following ICRs and Associated Burden Are Subject to the PRA.*

Section 460.12 Application Requirements

Section 460.12(a)(1) states that in order for HCFA to determine whether an entity qualifies as a PACE organization, an individual authorized to act for the entity must submit to HCFA a complete application that describes how the entity meets all requirements in this part.

The burden associated with this requirement is the time and effort to compile and submit application information to HCFA. We estimate that 25 entities will apply per year and that each entity will take 151 hours to complete the requirements of this section for a total annual burden of 3,775 hours.

In summary, section 460.12(a)(2) provides that HCFA will only evaluate applications from entities located in States with approved State plan amendments electing PACE as an optional Medicaid benefit. In addition, 460.12(b) states that an application must be accompanied by an assurance from the State administering agency of the State in which the program is located indicating that the State considers the entity to be qualified to be a PACE organization and is willing to enter into a PACE program agreement with the entity.

The burden associated with these requirements is the time and effort for a State to develop its State plan amendment to elect PACE as an optional Medicaid benefit and to write an assurance to HCFA indicating that the State considers the entity to be qualified to be a PACE organization and that the State is willing to enter into a PACE program agreement with the entity. We estimate that 25 States will each take 20 hours to complete these requirements for a total annual burden of 500 hours.

Section 460.30 Program Agreement Requirement

In summary, § 460.30(a) and (b) state that a PACE organization must have an agreement with HCFA and the State administering agency to operate a PACE program under Medicare and Medicaid. Furthermore, the program agreement must be signed by an authorized official of the organization, HCFA, and the State administering agency.

Since HCFA prepares the program agreement, the burden associated with

this requirement is the time and effort of officials to review and sign the agreement. We estimate that organization and State officials will take 2 hours per agreement to complete this requirement. There will be approximately 54 agreements for a total annual burden of 108 hours.

Section 460.70 Contracted Services

In summary, § 460.70(b)(1) requires that a PACE organization contract only with entities that meet all applicable Federal and State requirements.

The burden associated with this requirement to demonstrate that a PACE organization has contracted only with appropriate entities is captured by the initial contracts in section 460.12, application requirements. The remaining burden associated with this section is the ongoing time associated with the PACE organizations' verification, and maintenance of the verification documentation, that any new contractors are qualified entities. We estimate that each organization will spend 5 hours verifying the qualifications of new contractors. There will be approximately 54 PACE organizations for a total annual burden of 270 hours.

Section 460.70(d) states that the PACE organization must furnish a copy of each signed contract for inpatient care to HCFA and the State administering agency.

While the requirement to furnish a copy of each signed contract for inpatient care is subject to the PRA, the initial burden associated with this requirement is captured in § 460.12, application requirements. The remaining burden associated with this requirement is the time and effort associated with furnishing a copy of each new or revised contract for inpatient care to HCFA and the State administering agency. We estimate that each PACE organization will take 30 minutes to complete this requirement. There will be approximately 54 PACE organizations for a total annual burden of 27 hours.

Section 460.72 Physical Environment

Section 460.72(a)(3) states that 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.

The burden associated with this requirement is the time and effort to establish and maintain a written plan to ensure that all equipment is maintained in accordance with the manufacturer's recommendations. While the requirement to "establish" a written

plan is subject to the PRA, the burden associated with that requirement is captured in § 460.12, application requirements. We estimate that each PACE organization will take 1 hour to “maintain” a written plan. There will be approximately 54 PACE organizations for a total annual burden of 54 hours.

Section 460.72(c)(5) states that at least annually, a PACE organization must actually test, evaluate, and document the effectiveness of its emergency and disaster plans.

The burden associated with this requirement is the time and effort for a PACE organization to document the effectiveness of its emergency and disaster plans. We estimate that each PACE organization will take 30 minutes to complete this requirement. There will be approximately 54 PACE organizations for a total annual burden of 27 hours.

Section 460.82 Marketing

Section 460.82(c) states that a PACE organization must furnish printed marketing materials to prospective and current participants in English and in any other principal languages of the community, and in braille if necessary.

While the requirement to “furnish” these materials is subject to the PRA, the burden associated with that requirement is captured in § 460.82(a), which is discussed below under paragraph F. The remaining burden associated with this requirement is the time and effort for the PACE organization to prepare printed marketing materials to meet special language requirements. We estimate that 54 PACE organizations will each take 2 hours to prepare and update the material on an annual basis for a total of 108 burden hours.

Section 460.82(f) states that a PACE organization must establish, implement, and maintain a documented marketing plan with measurable enrollment objectives and a system for tracking its effectiveness.

While the requirement to “establish” a documented plan and a tracking system is subject to the PRA, the burden associated with that requirement is captured in § 460.12, application requirements. The remaining burden associated with this requirement is the time and effort for a PACE organization to update and maintain a marketing plan and a tracking system. We estimate that each PACE organization will take 16 hours on an annual basis to comply with this requirement. There will be approximately 54 PACE organizations for a total annual burden of 864 hours.

Section 460.102 Multidisciplinary Team

Section 460.102(e) states that the PACE organization must establish, implement, and maintain documented internal procedures governing the exchange of information between team members, contractors, and participants and their caregivers.

While the requirement to “establish” the documented procedures is subject to the PRA, the burden associated with that requirement is captured in section 460.12, application requirements. The remaining burden associated with this requirement is the time and effort for the PACE organization to update and maintain documented internal procedures governing the exchange of information. We estimate that each PACE organization will take 1 hour on an annual basis to complete this requirement. There will be approximately 54 PACE organizations for a total annual burden of 54 hours.

Section 460.104 Participant Assessment

Section 460.104(c)(3)(ii) specifies a timeframe for the multidisciplinary team to perform a reassessment and respond to a participant’s (or the participant’s designated representative) request for a change in services. The team may extend the timeframe in accordance with § 460.104(c)(3)(iii) if they document its need for information and how the delay is in the interest of the participant.

The burden associated with this requirement is the time and effort for the PACE organization to document the reasons for an extension. We estimate that on average there will be approximately 8 participants per organization who request a reassessment and the team determines they need additional time to respond. Therefore, the burden associated with this requirement is $(8 \text{ participants} \times 10 \text{ minutes}) \times 54 \text{ PACE organizations} = 72 \text{ annual hours of burden}$.

Section 460.116 Explanation of Rights

Section 460.116(c) states that the PACE organization must write the participant rights in English and in any other principal language of the community and display the rights in a prominent place in the PACE center.

The burden associated with this requirement is the time and effort for the PACE organization to (1) write the participant rights in English and in any other principal language of the community; and (2) display the rights in a prominent place in the PACE center. While the ICRs listed above are subject

to the PRA, we believe that the burden associated with writing the participant rights in English and in any other principal language of the community 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. However, we do believe the remaining burden associated with updating and displaying these rights is subject to the PRA. We estimate that, on average, each PACE organization will take 8 hours on an annual basis to comply with these requirements. There will be approximately 54 PACE organizations for a total annual burden of 432 hours.

Section 460.120 Grievance Process

Section 460.120(b) states that upon enrollment, and at least annually thereafter, the organization must give a participant written information on the grievance process.

The burden associated with this requirement is the time and effort for the PACE organization to give a participant written information on the grievance process. We estimate that, on average, there will be 160 participants per organization receiving written information on the grievance process. Therefore, the burden associated with the disclosure of the grievance materials is $(160 \text{ participants} \times 5 \text{ minutes}) \times 54 \text{ PACE organizations} = 720 \text{ annual hours of burden}$.

Section 460.120(e) states that the PACE organization must discuss with, and provide to the participant in writing the specific steps, including timeframes for response, that will be taken to resolve the participant’s grievance.

The burden associated with this requirement is the time and effort for the PACE organization to discuss with, and provide to the participant in writing the specific steps, including timeframes for response, that will be taken to resolve the participant’s grievance. We estimate that, on average, there will be 8 participants per organization receiving the additional written information on the grievance process. Therefore, the burden associated with the disclosure of the additional grievance materials is $(8 \text{ participants} \times 10 \text{ minutes}) \times 54 \text{ PACE organizations} = 72 \text{ annual hours of burden}$.

Section 460.122 PACE Organization’s Appeals Process

Section 460.122(b) states that upon enrollment, and at least annually thereafter, and whenever the multidisciplinary team denies a request

for service or payment, the organization must give a participant written information on the appeals process.

The burden associated with this requirement is the time and effort for a PACE organization to give a participant written information on the appeals process upon enrollment and at least annually thereafter. We estimate that, on average, there will be 160 participants per organization receiving written information on the appeals process. Therefore, the burden associated with the disclosure of the material outlining the appeals process is $(160 \text{ participants} \times 5 \text{ minutes}) \times 54 \text{ PACE organizations} = 720 \text{ annual hours of burden}$.

Section 460.122(h) states that for a determination that is wholly or partially adverse to a participant, at the same time the decision is made, the PACE organization must notify HCFA, the State administering agency, and the participant.

The burden associated with this requirement is the time and effort for a PACE organization to notify HCFA, the State administering agency, and the participant that the PACE organization has made an adverse decision. We estimate that, on average, each organization will be required to notify 4 participants in writing of an adverse decision. Therefore, the burden associated with these disclosure requirements is 1 hour per plan, $(4 \text{ participant notifications} \times 5 \text{ minutes}) + (4 \text{ HCFA notifications} \times 5 \text{ minutes}) + (4 \text{ State notifications} \times 5 \text{ minutes}) \times 54 \text{ organizations} = 54 \text{ annual hours of burden for all organizations}$.

Section 460.124 Additional Appeal Rights Under Medicare or Medicaid

Section 460.124 states that a PACE organization must inform a participant in writing of his or her appeal rights under Medicare or Medicaid managed care, or both, assist the participant in choosing which to pursue if both are applicable, and forward the appeal to the appropriate external entity.

The burden associated with this requirement is the time and effort for a PACE organization to provide information to a participant in writing of his or her appeal rights under Medicare or Medicaid, or both, to assist the participant in filing Medicare and Medicaid appeals. We estimate that, on average, there will be two participants per organization receiving written information and assistance related to their appeal rights. Therefore, the burden associated with the disclosure of the material outlining appeals rights and assistance is $(2 \text{ participants} \times 1 \text{ hour}) \times 54 \text{ organizations} = 108 \text{ annual hours of burden}$.

Section 460.132 Quality Assessment and Performance Improvement Plan

Section 460.132(b) states that the PACE governing body must review the plan annually and revise it, if necessary.

The burden associated with this requirement is the time and effort for a PACE organization to document that the annual review was conducted and to revise the quality assessment and performance improvement plan if necessary. We estimate that each PACE organization will take 8 hours to complete this requirement. There will be approximately 54 PACE organizations for a total annual burden of 432 hours.

Section 460.152 Enrollment Process

Section 460.152(a)(3) states that the State administering agency must assess the potential participant, including any individual who is not eligible for Medicaid, to ensure that he or she needs the level of care required under the State Medicaid plan for coverage of nursing facility services.

The burden associated with this requirement is the time and effort necessary for each State administering agency to maintain documentation of each potential participant assessment. We estimate that each State administering agency will take 100 hours to complete this requirement. There are approximately 25 State agencies that will be affected by this requirement for a total annual burden of 2,500 hours.

Section 460.152(b)(4) 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 HCFA and the State administering agency and make the documentation available for review.

The burden associated with this requirement is the time and effort for the PACE organization to notify HCFA and the State administering agency of the action. We estimate that on average 25 applicants per organization will be denied on an annual basis. The burden associated with notifying HCFA and the State agency is estimated to be 5 minutes each, for a total of $(25 \text{ applicants} \times 10 \text{ minutes}) \times 54 \text{ organizations} = 225 \text{ total annual hours}$.

Section 460.156 Other Enrollment Procedures

Section 460.156(a) states that after the participant signs the Enrollment Agreement, the PACE organization must give the participant the following: (1) A copy of the enrollment agreement; (2) a PACE membership card; (3) emergency

information to be posted in his or her home identifying the individual as a PACE participant and explaining how to access emergency services; and (4) stickers for the participant's Medicare and Medicaid cards, when applicable, which indicate that he or she is a PACE participant and include the phone number of the PACE organization.

While the ICRs listed above are subject to the PRA, we believe that the burden associated with items 1, 2, and 3 (above) 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.

The burden associated with item 4 (above) is the time and effort for a PACE organization to give stickers for the participant's Medicare and Medicaid cards, when applicable, which indicate that he or she is a PACE participant and include the phone number of the PACE organization. We estimate each PACE organization will take 1 minute per new enrollee to complete this requirement. There will be approximately 54 organizations that each will spend 1 hour a year for a total annual burden of 54 hours.

Section 460.156(b) states that the PACE organization must submit monthly participant information to HCFA and the State administering agency, in accordance with established procedures.

The burden associated with this requirement is the time and effort for the PACE organization to submit monthly participant information to HCFA and the State administering agency. We estimate that each PACE organization will take 12 hours (1 hour per month) to complete this requirement. There will be approximately 54 PACE organizations for a total annual burden of 648 hours.

Section 460.160 Continuation of Enrollment

In summary, § 460.160(b) states that at least annually, the State administering agency must reevaluate whether a participant needs the level of care required under the State Medicaid plan for coverage of nursing facility services.

The burden associated with this requirement is the time and effort for the State administering agency to document the annual reevaluation. We estimate that each State agency will take 170 hours to complete this requirement. There are approximately 25 State agencies for a total annual burden of 4,250 hours.

Section 460.164 Involuntary Disenrollment

Section 460.164(e) states that before an involuntary disenrollment is effective, the State administering agency must review the documentation and determine in a timely manner that the PACE organization has adequately documented acceptable grounds for disenrollment.

The burden associated with this requirement is the time and effort for the State administering agency to review and determine that the PACE organization has adequately documented acceptable grounds for disenrollment. We estimate that each State agency will be required to review 17 case files on an annual basis, at 1 hour each, for a total of 17 hours. There are approximately 25 State agencies for a total annual burden of 425 hours.

Section 460.190 Monitoring During Trial Period

Section 460.190(a) states that during the trial period, HCFA, in cooperation with the State administering agency, will conduct comprehensive annual reviews of the operations of a PACE organization to ensure compliance with the requirements of these regulations. The burden associated with this requirement is the time and effort necessary to disclose all materials necessary to demonstrate compliance with the regulations. Given that PACE organizations are obligated under the program agreement and the requirements set forth in these regulations to maintain all information that would be requested as part of the comprehensive review, we estimate the burden to be 8 hours per organization to disclose necessary information to demonstrate compliance. Approximately 42 PACE organizations will be in the trial period. The total burden imposed by this section is 336 hours.

Section 460.196 Disclosure of Review Results

Section 460.196(c) states that the PACE organization must post a notice of the availability of the results of the most recent review and any plans of correction or responses related to the most recent review.

The burden associated with this requirement is the time and effort for a PACE organization to post a notice. We estimate that each PACE organization will take 5 minutes to complete this requirement. There will be approximately 54 PACE organizations for a total annual burden of 4.5 hours.

Section 460.202 Participant Health Outcomes Data

In summary, § 460.202(a) and (b) state that a PACE organization must establish and maintain a health information system that collects, analyzes, integrates, and reports data necessary to measure the organization's performance, including outcomes of care furnished to participants. Also, a PACE organization must furnish data and information pertaining to its provision of participant care in the manner, and at the time intervals, specified by HCFA and the State administering agency.

The burden associated with this requirement is the time and effort for a PACE organization to demonstrate the establishment of a health information system and to furnish data and information pertaining to its provision of participant care to HCFA and the State administering agency. While the requirement to demonstrate the "establishment" of a system is subject to the PRA, the burden associated with that requirement is captured in § 460.12, application requirements. Therefore, the remaining burden associated with this section is the requirement to furnish information specified by HCFA and the State administering agency. We estimate that each PACE organization will take 100 hours (50 hours for HCFA compliance + 50 Hours for State compliance) to complete this requirement. There will be approximately 54 PACE organizations for a total annual burden of 5,400 hours.

Section 460.208 Financial Statements

Section 460.208(a)(1) states that not later than 180 days after the organization's fiscal year ends, a PACE organization must submit a certified financial statement that includes appropriate footnotes.

The burden associated with this requirement is the time and effort for a PACE organization to submit a certified financial statement. We estimate that each PACE organization will take 4 hours to complete this requirement. There will be approximately 54 PACE organizations for a total annual burden of 216 hours.

Section 460.208(c)(1) states that not later than 45 days after the end of each quarter of the organization's fiscal year throughout the trial period, a PACE organization must submit a quarterly financial statement.

The burden associated with this requirement is the time and effort for a PACE organization to submit a quarterly financial statement. We estimate that each PACE organization will take 16 hours (4 hours per quarter) to complete

this requirement. There will be approximately 42 PACE organizations that are affected by this trial period requirement for a total annual burden of 672 hours.

B. The following ICRs Are Subject to the PRA. However, the Burden Associated With These Requirements Is Captured in the Application Requirements Described in § 460.12, Application Requirements (Paragraph A, Above)

Section 460.22 Service Area Designation

Section 460.22(a) states that each entity must state in its application the service area it proposes for its program.

Section 460.32 Content and Terms of PACE Program Agreement

Section 460.32 specifies various information that the PACE organization must furnish so that the information can be included in the PACE program agreement.

Section 460.52 Transitional Care During Termination

Section 460.52(a) states that the PACE organization must develop a detailed written plan for phase-down in the event of termination.

Section 460.60 PACE Organizational Structure

Section 460.60(d)(1) and (2) requires the PACE organization to have a current organizational chart showing officials in the organization and relationships to any other organizational entities; the chart for a corporate entity must indicate the organization's relationship to the corporate board and to any parent, affiliate, or subsidiary corporate entities.

Section 460.68 Program integrity.

Section 460.68(c)(2) states that if an applicant seeking approval as a PACE organization believes a waiver regarding direct or indirect interest is warranted, it must include a request for the waiver in its application.

Section 460.80 Fiscal Soundness

Section 460.80(b) states that the organization must have a documented plan in the event of insolvency, approved by HCFA and the State administering agency.

Section 460.80(c) states that a PACE organization must demonstrate that it has arrangements to cover expenses in the event it becomes insolvent.

Section 460.82 Marketing

Section 460.82(b)(2) states that HCFA reviews initial marketing information as

part of an entity's application for approval as a PACE organization, and approval of the application includes approval of marketing information.

Section 460.102 Multidisciplinary Team

Section 460.102(g)(2) states that if an applicant seeking approval as a PACE organization believes a waiver of restrictions on the multidisciplinary team is warranted, it must include a request for the waiver in its application and describe in detail the circumstances supporting the request.

Section 460.104 Participant Reassessment

Section 460.104(c)(3) states that the PACE organization must establish procedures for timely resolution of requests by a participant to initiate, eliminate, or continue a particular service. We will review the procedures as part of the application approval process.

Section 460.118 Violation of Rights

Section 460.118 states that the PACE organization must have established documented procedures to respond to and rectify a violation of a participant's rights.

Section 460.120 Grievance Process

Section 460.120(a) states that a PACE organization must have a formal written process to evaluate and resolve medical and non-medical grievances by participants, their family members, or representatives.

Section 460.122 PACE Organization's Appeals Process

Section 460.122(a) states that the PACE organization must have a formal written appeals process, with specified time frames for response, which may be used by a participant to address noncoverage or nonpayment of a service.

Section 460.132 Quality Assessment and Performance Improvement Plan

Section 460.132(a) requires a PACE organization to have a written quality assessment and performance improvement plan.

Section 460.200 Maintenance of Records and Reporting of Data

Section 460.200(d) states that a PACE organization must establish written policies and procedures to safeguard all data, books, and records against loss, destruction, unauthorized use, or inappropriate alteration.

C. The Following ICRs Are Subject to the PRA. However, the Burden

Associated With These Requirements Is Contained in § 460.132(b), Quality Assessment and Performance Improvement Plan (Paragraph A, Above)

Section 460.120 Grievance Process

Section 460.120(f) states that the PACE organization must maintain, aggregate, and analyze information on grievance proceedings. This information must be used in the internal quality assessment and performance improvement program.

Section 460.122 PACE Organization's Appeals Process

Section 460.122(i) states that a PACE organization must maintain, aggregate, and analyze information on appeal proceedings and use this information in the organization's internal quality assessment and performance improvement program.

D. The following ICRs Are Subject to the PRA. However, the Burden Associated With These Requirements Are Contained in §§ 460.202, Participant Health Outcomes Data, and Statistical Reports, and 460.208, Financial Statements (Paragraph A, Above)

Section 460.200 Maintenance of Records and Reporting of Data

Section 460.200(a) states that a PACE organization must collect data, maintain records, and submit reports as required by HCFA and the State administering agency.

Section 460.200(c) states that a PACE organization must submit to HCFA and the State administering agency all reports that HCFA and the State administering agency require to monitor the operation, cost, quality, and effectiveness of the program and establish payment rates.

E. The following ICRs Are Subject to the PRA. However, the Burden Associated With These Requirements Is Contained in § 460.208, Financial Statements (Paragraph A, Above).

Section 460.204 Financial Recordkeeping and Reporting Requirements

Section 460.204(a) states that a PACE organization must provide HCFA and the State administering agency with accurate financial reports.

F. 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. We Are Soliciting Comments on This Determination and Request Any Data on the Additional Burdens That May Be Imposed by These Requirements.

Section 460.52 Transitional Care During 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 participant'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 except for emergency services as described in section 460.100.

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 Environment

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, including primary care and specialist physician services (other than emergency 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 provide 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 Multidisciplinary Team

In summary, § 460.102(d) states that the multidisciplinary 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 multidisciplinary 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.

Section 460.104 Participant Assessment

In summary, § 460.104 states that the multidisciplinary 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)(3) states that a participant has the right to be fully informed of his or her health and functional status by the multidisciplinary team and to participate in the development and implementation of the plan of care.

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)(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; and any Medicaid spenddown obligations.

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

In summary, § 460.154 states that if the potential participant meets the eligibility requirements and wants to enroll, he or she 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.

§ 460.164 Involuntary Disenrollment

Section 460.164(c) states that if a PACE organization proposes to disenroll a participant who is disruptive or threatening, the organization must document in the participant's medical record the reasons for proposing to disenroll the participant; and all efforts to remedy the situation.

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 maintain 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; and obtain a participant's consent 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 a the 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.

G. We Believe the Following Requirements Are Not Subject to the PRA in Accordance With 5 CFR

1320.3(c)(4) Since They Do Not Require Information From Ten or More Entities on an Annual Basis. We Are Soliciting Comments on This Determination and Request Any Data on the Additional Burdens That May Be Imposed by These Requirements.

Section 460.20 Special Consideration

Section 460.20(b) states that an application from an entity seeking special consideration must include documentation of those formal activities.

Section 460.60 PACE Organizational Structure

Section 460.60(d)(3) states that A PACE organization planning a change in organizational structure must notify HCFA and the State administering agency, in writing, at least 60 days before the change takes effect.

Section 460.82 Marketing

Section 460.82(b)(3) states that once a PACE organization is under a PACE program agreement, any revisions to existing marketing information and new information are subject to the following: HCFA approves or disapproves marketing information within 45 days after receipt from the organization.

H. 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(d) 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 HCFA within a reasonable amount of time.

Section 460.172 Documentation of Disenrollment

Section 460.172(b) states that a PACE organization must make documentation available for review by HCFA 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, HCFA, in cooperation with the State administering agency, continues 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 compliance of the

organization 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 and Reporting of Data

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 HCFA 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; and/or determination of Medicare and Medicaid amounts payable.

Section 460.208 Financial Statements

Section 460.208(c)(2) states that if HCFA or the State administering agency determines that an organization's performance requires more frequent monitoring and oversight due to concerns about fiscal soundness, HCFA or the State administering agency may require a PACE organization to submit monthly or quarterly financial statements, or both.

We have submitted a copy of this interim final with comment rule to OMB for its review of the information collection requirements described above. These requirements are not effective until they have been approved by OMB.

If you comment on any of these information collection and record keeping requirements, please mail copies directly to the following: Health Care Financing Administration, Office of Information Services, Security and Standards Group, Division of HCFA Enterprise Standards, Room C2-26-17, 7500 Security Boulevard, Baltimore, MD 21244-1850, Attn: John Burke, HCFA-1903-IFC, and Office of Information and Regulatory Affairs, Office of Management and Budget, Room 10235, New Executive

Office Building, Washington, DC
20503, Attn: Allison Eydt, HCFA Desk
Officer.

VI. Regulatory Impact Statement

We have examined the impacts of this interim final rule as required by Executive Order 12866 and the Regulatory Flexibility Act (RFA) (Public Law 96-354). Executive Order 12866 directs agencies to assess all costs and benefits of available regulatory alternatives and, when regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety effects, distributive impacts, and equity). The RFA requires agencies to analyze options for regulatory relief of small businesses. For purposes of the RFA, small entities include small businesses, non-profit organizations and government agencies. Most hospitals and most other providers and suppliers are small entities, either by non-profit status or by having revenues of \$5 million or less annually. For purposes of the RFA, all PACE providers are considered to be small entities. Individuals and States are not included in the definition of a small entity.

Section 1102(b) of the Social Security Act, (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. Such an analysis must conform to the provisions of section 604 of the RFA. For purposes of section 1102(b) of the Act, we define a small rural hospital as a hospital that is located outside of a Metropolitan Statistical Area and has fewer than 50 beds. This rule will not affect a significant number of small rural hospitals.

This interim final rule will affect a very limited number of small non-profit entities that are operating, or seek to operate, a PACE program. We are authorized to approve no more than 40 such programs as of August 5, 1997, and the ceiling increases by an additional 20 each year as of each succeeding August 5th (e.g., we can approve no more than 60 by August 5, 1998 and no more than 80 by August 5, 1999). The rule will indirectly affect Medicare beneficiaries and Medicaid recipients who could qualify for a PACE program and who might wish to enroll in one in their geographic area, because it will affect the availability of those programs. A typical PACE program maintains an enrollment of about 200-300 individuals.

Non-profit entities that wish to receive Medicare and Medicaid

payment for their PACE services must comply with the requirements in this rule. Due to the all-inclusive nature of the services and the concomitant expense of providing such care, entities that do not qualify for Medicare and Medicaid funding are unlikely to be financially viable.

The requirements contained in this rule are largely similar to the requirements that have been applicable to the existing PACE demonstration project sites through the Protocol (described in section I.C of this document). 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 codify 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.

If this rule were not issued, PACE programs could not be approved as ongoing programs under Medicare or Medicaid. Sections 4801 and 4802 of BBA require us to promulgate regulations to carry out those sections and approve PACE programs. Section 4803(d) of BBA specifies that the PACE demonstration authority remains in effect until the effective date of these regulations, and a transition period from demonstration status to ongoing status begins on that date.

We are not preparing analyses for either the RFA or section 1102(b) of the Act because we have determined, and we certify, that this rule will not have a significant economic impact on a substantial number of small entities or a significant impact on the operations of a substantial number of small rural hospitals.

Federalism

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 HCFA, the States, and PACE organizations in order to implement the PACE program.

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 program. 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—1894(e)(1)(A) and 1934(e)(1)(A).
 2. Establishing procedures for excluding service areas already covered under other PACE provider agreements in order to avoid unnecessary duplication of services and also to avoid impairing the financial and service viability of the existing program—1894(e)(2)(B) and 1934(e)(2)(B).
 3. Establishing procedure for the PACE provider to make available PACE program data—1894(e)(3)(A)(i)(III) and 1934(e)(2)(A)(i)(III).
 4. In conjunction with the PACE provider, developing and implementing health status and quality of life outcome measures—1894(e)(3)(B) and 1934(e)(3)(B).
 5. The statute requires the Secretary and State to conduct a comprehensive annual review—1894(e)(4)(A) and 1934(e)(4)(A).
 6. Establishing the frequency of the on-sight review—1894(e)(4)(B) and 1934(e)(4)(B).
 7. Establishing a mechanism for communicating of the Secretary's findings and State action when a PACE provider is failing to comply with Federal requirements; i.e., enforcement authority—1894(e)(6)(A) and 1934(e)(6)(A).
 8. Establishing the entity responsible for the annual eligibility recertification—1894(c)(3) and 1934(c)(3); and continuation of eligibility requirements—1894(c)(4) and 1934(c)(4).
- For this reason, we obtained State input in the early stages of policy development through conference calls with State Medicaid Agency representatives. The BBA requires the States to designate the agency of the State responsible for the administration of the PACE program. Although the State may designate the State Medicaid Agency to administer the PACE program, another agency may be named. The 8 agencies that volunteered to participate in these discussions represented a balanced view of States;

some with PACE demonstration site experience and some who were not yet involved with PACE, 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 program, we have maintained ties with State representatives through monthly conference calls to obtain information on a variety of topics including the applications review and approval process, data collection needs, and enrollment/disenrollment issues.

We are committed to continuing this dialogue with States after publication of the regulation to ensure this cooperative atmosphere continues as we implement the PACE program and transition the current PACE demonstration sites to full provider status. We expect that States would take responsibility for site selection and participate in provider approval and ongoing monitoring activities. States may also determine how many sites to authorize and how many participants each site may serve. In recognition of the unique relationship between the Secretary and the States for the PACE program, we have directed potential PACE organizations to first contact their State administering agency to verify that the State has elected PACE as an optional benefit under its State Medicaid Plan, determine whether the State has established additional requirements for PACE organizations, and obtain technical assistance.

In accordance with the provisions of Executive Order 12866, this regulation was reviewed by the Office of Management and Budget.

List of Subjects

42 CFR Part 460

Aged, Health Incorporation by reference, Medicare, Medicaid, Reporting and recordkeeping requirements.

42 CFR Part 462

Grant programs-health, Health care, Health professions, Peer Review Organizations (PRO).

42 CFR Part 466

Grant programs-health, Health care, Health facilities, Health professions, Peer Review Organizations (PRO), Reporting and recordkeeping requirements.

42 CFR Part 473

Administrative practice and procedure, Health care, Health professions, Peer Review Organizations

(PRO), Reporting and recordkeeping requirements.

42 CFR Part 476

Health care, Health professional, Health record, Peer Review Organizations (PRO), Penalties, Privacy, Reporting and recordkeeping requirements.

For the reasons set forth in the preamble, 42 CFR Chapter IV is amended as follows:

SUBCHAPTER D [Redesignated]

1. Subchapter D is redesignated as subchapter F; a new subchapter D is added and reserved; and parts 462, 466, 473, and 476 are redesignated as parts 475, 476, 478 and 480, respectively.

SUBCHAPTER E [Redesignated]

2. Subchapter E is redesignated as Subchapter G.

3. A new subchapter E, consisting of part 460 is added to read as follows:

SUBCHAPTER E—PROGRAMS OF ALL-INCLUSIVE CARE FOR THE ELDERLY (PACE)

PART 460—PROGRAMS OF ALL-INCLUSIVE CARE FOR THE ELDERLY (PACE)

Subpart A—Basis, Scope, and Definitions

- Sec.
460.2 Basis.
460.4 Scope and purpose.
460.6 Definitions.

Subpart B—PACE Organization Application and Evaluation

- 460.10 Purpose.
460.12 Application requirements.
460.14 Priority consideration.
460.16 Special consideration.
460.18 HCFA evaluation of applications.
460.20 Notice of HCFA determination.
460.22 Service area designation.
460.24 Limit on number of PACE program agreements.

Subpart C—PACE Program Agreement

- 460.30 Program agreement requirement.
460.32 Content and terms of PACE program agreement.
460.34 Duration of PACE program agreement.

Subpart D—Sanctions, Enforcement Actions, and Termination

- 460.40 Violations for which HCFA may impose sanctions.
460.42 Suspension of enrollment or payment by HCFA.
460.46 Civil money penalties.
460.48 Additional actions by HCFA or the State.
§ 460.50 Termination of PACE program agreement.
460.52 Transitional care during termination.
460.54 Termination procedures.

Subpart E—PACE Administrative Requirements

- 460.60 PACE organizational structure.
460.62 Governing body.
460.64 Personnel qualifications.
460.66 Training.
460.68 Program integrity.
460.70 Contracted services.
460.72 Physical environment.
460.74 Infection control.
460.76 Transportation services.
460.78 Dietary services.
460.80 Fiscal soundness.
460.82 Marketing.

Subpart F—PACE Services

- 460.90 PACE benefits under Medicare and Medicaid.
460.92 Required services.
460.94 Required services for Medicare participants.
460.96 Excluded services.
460.98 Service delivery.
460.100 Emergency care.
460.102 Multidisciplinary team.
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Subpart G—Participant Rights

- 460.110 Bill of rights.
460.112 Specific rights to which a participant is entitled.
460.114 Restraints.
460.116 Explanation of rights.
460.118 Violation of rights.
460.120 Grievance process.
460.122 PACE organization's appeals process.
460.124 Additional appeal rights under Medicare or Medicaid.

Subpart H—Quality Assessment and Performance Improvement

- 460.130 General rule.
460.132 Quality assessment and performance improvement plan.
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460.136 Internal quality assessment and performance improvement activities.
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460.194 Corrective action.

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460.200 Maintenance of records and reporting of data.

460.202 Participant health outcomes data.

460.204 Financial recordkeeping and reporting requirements.

460.208 Financial statements.

460.210 Medical records.

Authority: Secs. 1102 and 1871 of the Social Security Act (42 U.S.C. 1302 and 1395).

Subpart A—Basis, Scope, and Definitions

§ 460.2 Basis

This part implements sections 1894, 1905(a), and 1934 of the Act, which authorize the following:

(a) Medicare payments to, and coverage of benefits under, PACE.

(b) The establishment of PACE as a State option under Medicaid to provide for Medicaid payments to, and coverage of benefits under, PACE.

§ 460.4 Scope and purpose.

(a) *General.* This part sets forth the following:

(1) The requirements that an entity must meet to be approved as a PACE organization that operates a PACE program under Medicare and Medicaid.

(2) How individuals may qualify to enroll in a PACE program.

(3) How Medicare and Medicaid payments will be made for PACE services.

(4) Provisions for Federal and State monitoring of PACE programs.

(5) Procedures for sanctions and terminations.

(b) *Program purpose.* PACE provides pre-paid, capitated, comprehensive health care services designed to meet the following objectives:

(1) Enhance the quality of life and autonomy for frail, older adults.

(2) Maximize dignity of, and respect for, older adults.

(3) Enable frail, older adults to live in the community as long as medically and socially feasible.

(4) Preserve and support the older adult's family unit.

§ 460.6 Definitions.

As used in this part, unless the context indicates otherwise, the following definitions apply:

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

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 PACE organization where primary care is furnished to participants.

PACE organization 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 PACE organization, HCFA, and the State administering agency for the operation of a PACE program.

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

Services includes 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 PACE organization operates under a PACE program agreement, including any contract year during which the entity operated under a PACE demonstration waiver program.

Subpart B—PACE Organization Application and Evaluation

§ 460.10 Purpose.

This subpart sets forth application requirements for an entity that seeks approval from HCFA as a PACE organization.

§ 460.12 Application requirements.

(a) *General.* (1) An individual authorized to act for the entity must submit to HCFA a complete application that describes how the entity meets all requirements in this part.

(2) HCFA evaluates only complete applications from entities located in States with approved State plan amendments electing PACE as an optional Medicaid benefit.

(3) HCFA accepts applications from entities that seek approval as PACE organizations beginning on February 22, 2000 except for the following:

(i) Beginning on November 24, 1999, HCFA accepts applications from entities that meet the requirements for priority consideration in processing of applications, as provided in § 460.14.

(ii) Beginning on January 10, 2000, HCFA accepts applications from entities that meet the requirements for special consideration in processing applications, as provided in § 460.16.

(b) *State assurance.* An entity's application must be accompanied by an assurance from the State administering agency of the State in which the program is located indicating that the State—

(1) Considers the entity to be qualified to be a PACE organization; and

(2) Is willing to enter into a PACE program agreement with the entity.

§ 460.14 Priority consideration.

Until August 5, 2000, HCFA gives priority consideration in processing applications for PACE organization status to an entity that meets either of the following criteria:

(a) Is operating under PACE demonstration waivers under one of the following authorities:

(1) Section 603(c) of the Social Security Amendments of 1983, as extended by section 9220 of the Consolidated Omnibus Budget Reconciliation Act of 1985.

(2) Section 9412(b) of the Omnibus Budget Reconciliation Act of 1986.

(b) Has applied to operate under a PACE demonstration under section 9412(b) of the Omnibus Budget Reconciliation Act of 1986 as of May 1, 1997.

§ 460.16 Special consideration.

Until August 5, 2000, HCFA gives special consideration in processing applications to an entity that meets the following conditions:

(a) Indicated, by May 1, 1997, a specific intent to become a PACE organization through formal activities.

(b) Includes documentation of its formal activities.

§ 460.18 HCFA evaluation of applications.

HCFA evaluates an application for approval as a PACE organization on the basis of the following information:

(a) Information contained in the application.

(b) Information obtained through onsite visits conducted by HCFA or the State administering agency.

(c) Information obtained by the State administering agency.

§ 460.20 Notice of HCFA determination.

(a) *Time limit for notification of determination.* Within 90 days after an

entity submits a complete application to HCFA, HCFA takes one of the following actions:

- (1) Approves the application.
- (2) Denies the application and notifies the entity in writing of the basis for the denial and the process for requesting reconsideration of the denial.
- (3) Requests additional information needed to make a final determination.

(b) *Additional information requested.* If HCFA requests from an entity additional information needed to make a final determination, within 90 days after HCFA receives all requested information from the entity, HCFA takes one of the following actions:

- (1) Approves the application.
- (2) Denies the application and notifies the entity in writing of the basis for the denial and the process for requesting reconsideration of the denial.

(c) *Deemed approval.* An application is deemed approved if HCFA fails to act on the application within 90 days after one of the following dates:

- (1) The date the application is submitted by the organization.
- (2) The date HCFA receives all requested additional information.

(d) *Date of submission.* For purposes of the 90-day time limit described in this section, the date that an application is submitted to HCFA is the date on which the application is delivered to the address designated by HCFA.

§ 460.22 Service area designation.

(a) An entity must state in its application the service area it proposes for its program.

(b) HCFA, in consultation with the State administering agency, may exclude from designation an area that is already covered under another PACE program agreement to avoid unnecessary duplication of services and avoid impairing the financial and service viability of an existing program.

§ 460.24 Limit on number of PACE program agreements.

(a) *Numerical limit.* Except as specified in paragraph (b) of this section, HCFA does not permit the number of PACE organizations with which agreements are in effect under this part or under section 9412(b) of the Omnibus Budget Reconciliation Act of 1986, to exceed the following:

- (1) As of August 5, 1997—40.
- (2) As of each succeeding August 5, the numerical limit for the preceding year plus 20, without regard to the actual number of agreements in effect on a previous anniversary date. (For example, the limit is 60 on August 5, 1998 and 80 on August 5, 1999.)

(b) *Exception.* The numerical limit does not apply to a private, for-profit

PACE organization that meets the following conditions:

(1) Is operating under a demonstration project waiver under section 1894(h) and 1934(h) of the Act.

(2) Was operating under a waiver and subsequently qualifies for PACE organization status in accordance with sections 1894(a)(3)(B)(ii) and 1934(a)(3)(B)(ii) of the Act.

Subpart C—PACE Program Agreement

§ 460.30 Program agreement requirement.

(a) A PACE organization must have an agreement with HCFA and the State administering agency for the operation of a PACE program by the PACE organization under Medicare and Medicaid.

(b) The agreement must be signed by an authorized official of the PACE organization.

§ 460.32 Content and terms of PACE program agreement.

(a) *Required content.* A PACE program agreement must include the following information:

(1) A designation of the service area of the organization's program. The area may be identified by county, zip code, street boundaries, census tract, block, or tribal jurisdictional area, as applicable. HCFA and the State administering agency must approve any change in the designated service area.

(2) The organization's commitment 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.

(3) The effective date and term of the agreement.

(4) A description of the organizational structure of the PACE organization and information on administrative contacts, including the following:

- (i) Name and phone number of the program director.
- (ii) Name of all governing body members.
- (iii) Name and phone number of a contact person for the governing body.

(5) A participant bill of rights approved by HCFA and an assurance that the rights and protections will be provided.

(6) A description of the process for handling participant grievances and appeals.

(7) A statement of the organization's policies on eligibility, enrollment, voluntary disenrollment, and involuntary disenrollment.

(8) A description of services available to participants.

(9) A description of the organization's quality assessment and performance improvement program.

(10) A statement of the levels of performance required by HCFA on standard quality measures.

(11) A statement of the data and information required by HCFA and the State administering agency to be collected on participant care.

(12) The capitation rates for Medicare and Medicaid.

(13) A description of procedures that the organization will follow if the PACE program agreement is terminated.

(b) *Optional content.* (1) An agreement may provide additional requirements for individuals to qualify as PACE program eligible individuals, in accordance with § 460.150(b)(4).

(2) An agreement may contain any additional terms and conditions agreed to by the parties if the terms and conditions are consistent with sections 1894 and 1934 of the Act and regulations in this part.

§ 460.34 Duration of PACE program agreement.

An agreement is effective for a contract year, but may be extended for additional contract years in the absence of a notice by a party to terminate.

Subpart D—Sanctions, Enforcement Actions, and Termination

§ 460.40 Violations for which HCFA may impose sanctions.

In addition to other remedies authorized by law, HCFA may impose any of the sanctions specified in §§ 460.42 and 460.46 if HCFA determines that a PACE organization commits any of the following violations:

(a) Fails substantially to provide 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.

(b) Involuntarily disenrolls a participant in violation of § 460.164.

(c) 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.

(d) 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.

(e) Imposes charges on participants enrolled under Medicare or Medicaid

for premiums in excess of the premiums permitted.

(f) Misrepresents or falsifies information that is furnished—

(1) To HCFA or the State under this part; or

(2) To an individual or any other entity under this part.

(g) 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.

(h) Operates a physician incentive plan that does not meet the requirements of section 1876(i)(8) of the Act.

(i) Employs or contracts with any individual who is excluded from participation in Medicare or Medicaid under section 1128 or section 1128A of the Act (or with any entity that employs or contracts with that individual) for the provision of health care, utilization review, medical social work, or administrative services.

§ 460.42 Suspension of enrollment or payment by HCFA.

(a) *Enrollment.* If a PACE organization commits one or more violations specified in § 460.40, HCFA may suspend enrollment of Medicare beneficiaries after the date HCFA notifies the organization of the violation.

(b) *Payment.* If a PACE organization commits one or more violations specified in § 460.40, for individuals enrolled after the date HCFA notifies the PACE organization of the violation, HCFA may take the following actions:

(1) Suspend Medicare payment to the PACE organization.

(2) Deny payment to the State for medical assistance for services furnished under the PACE program agreement.

(c) *Term of suspension.* A suspension or denial of payment remains in effect until HCFA is satisfied that the following conditions are met:

- (1) The PACE organization has corrected the cause of the violation.
- (2) The violation is not likely to recur.

§ 460.46 Civil money penalties.

(a) HCFA may impose civil money penalties up to the following maximum amounts:

(1) For each violation regarding enrollment or disenrollment specified in § 460.40 (c) or (d), \$100,000 plus

\$15,000 for each individual not enrolled as a result of the PACE organization's discrimination in enrollment or disenrollment or practice that would deny or discourage enrollment.

(2) For each violation regarding excessive premiums specified in § 460.40(e), \$25,000 plus double the excess amount above the permitted premium charged a participant by the PACE organization. (The excess amount charged is deducted from the penalty and returned to the participant).

(3) For each misrepresentation or falsification of information, specified in § 460.40(f)(1), \$100,000.

(4) For any other violation specified in § 460.40, \$25,000.

(b) The provisions of section 1128A of the Act (other than subsections (a) and (b)) apply to a civil money penalty under this section in the same manner as they apply to a civil money penalty or proceeding under section 1128A(a).

§ 460.48 Additional actions by HCFA or the State.

After consultation with the State administering agency, if HCFA determines that the PACE organization is not in substantial compliance with requirements in this part, HCFA or the State administering agency may take one or more of the following actions:

(a) Condition the continuation of the PACE program agreement upon timely execution of a corrective action plan.

(b) Withhold some or all payments under the PACE program agreement until the organization corrects the deficiency.

(c) Terminate the PACE program agreement.

§ 460.50 Termination of PACE program agreement.

(a) *Termination of agreement by HCFA or State.* HCFA or a State administering agency may terminate at any time a PACE program agreement for cause, including, but not limited to the circumstances in paragraphs (b) or (c) of this section.

(b) *Termination due to uncorrected deficiencies.* HCFA or the State administering agency may terminate a PACE program agreement if HCFA or the State administering agency determines that both of the following circumstances exist:

(1) Either—

(i) There are significant deficiencies in the quality of care furnished to participants; or

(ii) The PACE organization failed to comply substantially with conditions for a PACE program or PACE organization under this part, or with terms of its PACE program agreement.

(2) Within 30 days of the date of the receipt of written notice of a determination made under paragraph (b)(1) of this section, the PACE organization failed to develop and successfully initiate a plan to correct the deficiencies, or failed to continue implementation of the plan of correction.

(c) *Termination due to health and safety risk.* HCFA or a State administering agency may terminate a PACE program agreement if HCFA or the State administering agency determines that the PACE organization cannot ensure the health and safety of its participants. This determination may result from the identification of deficiencies that HCFA or the State administering agency determines cannot be corrected.

(d) *Termination of agreement by PACE organization.* A PACE organization may terminate an agreement after timely notice to HCFA, the State administering agency, and participants, as follows:

(1) To HCFA and the State administering agency, 90 days before termination.

(2) To participants, 60 days before termination.

§ 460.52 Transitional care during termination.

(a) The PACE organization must develop a detailed written plan for phase-down in the event of termination, which describes how the organization plans to take the following actions:

(1) Inform participants, the community, HCFA and the State administering agency in writing about termination and transition procedures.

(2) Assist participants to obtain reinstatement of conventional Medicare and Medicaid benefits.

(3) Transition participants' care to other providers.

(4) Terminate marketing and enrollment activities.

(b) 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.

§ 460.54 Termination procedures.

(a) Except as provided in paragraph (b) of this section, if HCFA terminates an agreement with a PACE organization, it furnishes the PACE organization with the following:

(1) A reasonable opportunity to develop and implement a corrective action plan to correct the deficiencies

that were the basis of HCFA's determination that cause exists for termination.

(2) Reasonable notice and opportunity for hearing (including the right to appeal an initial determination) before terminating the agreement.

(b) HCFA may terminate an agreement without invoking the procedures described in paragraph (a) of this section if HCFA 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.

Subpart E—PACE Administrative Requirements

§ 460.60 PACE organizational structure.

(a) A PACE organization must be, or be a distinct part of, one of the following:

(1) An entity of city, county, State, or Tribal government.

(2) A private not-for-profit entity organized for charitable purposes under section 501(c)(3) of the Internal Revenue Code of 1986. The entity may be a corporation, a subsidiary of a larger corporation, or a department of a corporation.

(b) *Program director.* The organization must employ a program director who is responsible for oversight and administration of the entity.

(c) *Medical director.* The organization must employ a medical director who is responsible for the delivery of participant care, for clinical outcomes, and for the implementation, as well as oversight, of the quality assessment and performance improvement program.

(d) *Organizational chart.* (1) The PACE organization must have a current organizational chart showing officials in the PACE organization and relationships to any other organizational entities.

(2) The chart for a corporate entity must indicate the PACE organization's relationship to the corporate board and to any parent, affiliate, or subsidiary corporate entities.

(3) A PACE organization planning a change in organizational structure must notify HCFA and the State administering agency, in writing, at least 60 days before the change takes effect.

(4) Changes in organizational structure must be approved in advance by HCFA and the State administering agency.

(5) Changes in organizational structure approved by HCFA and the State administering agency must be forwarded to the consumer advisory

committee described in § 460.62(c) of this part for dissemination to participants as appropriate.

§ 460.62 Governing body.

(a) *Governing body.* A PACE organization must be operating under the control of an identifiable governing body (for example, a board of directors) or a designated person functioning as a governing body with full legal authority and responsibility for the following:

(1) Governance and operation of the organization.

(2) Development of policies consistent with the mission.

(3) Management and provision of all services, including the management of contractors.

(4) Establishment of personnel policies that address adequate notice of termination by employees or contractors with direct patient care responsibilities.

(5) Fiscal operations.

(6) Development of policies on participant health and safety, including a comprehensive, systemic operational plan to ensure the health and safety of participants.

(7) Quality assessment and performance improvement program.

(b) *Community representation.* A PACE organization must ensure community representation on issues related to participant care. This may be achieved by having a community representative on the governing body.

(c) *Consumer advisory committee.* A PACE organization must establish a consumer 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.

§ 460.64 Personnel qualifications.

(a) *General qualification requirements.* Except as specified in paragraphs (b) and (c) of this section, each member of the staff (employee or contractor) of the PACE organization must meet the following conditions:

(1) Be legally authorized (currently licensed or, if applicable, certified or registered) to practice in the State in which he or she performs the function or actions.

(2) Only act within the scope of his or her authority to practice.

(b) *Federally-defined qualifications for physician.* (1) A physician must meet the qualifications and conditions in § 410.20 of this chapter.

(2) A primary care physician must have a minimum of 1 year's experience working with a frail or elderly population.

(c) *Qualifications when no State licensing laws, State certification, or*

registration requirements exist. If there are no State licensing laws, State certification, or registration applicable to the profession, the following requirements must be met:

(1) *Registered nurse.* A registered nurse must meet the following requirements:

(i) Be a graduate of a school of professional nursing.

(ii) Have a minimum of 1 year's experience working with a frail or elderly population.

(2) *Social worker.* A social worker must meet the following requirements:

(i) Have a master's degree in social work from an accredited school of social work.

(ii) Have a minimum of 1 year's experience working with a frail or elderly population.

(3) *Physical therapist.* A physical therapist must meet the following requirements:

(i) Be a graduate of a physical therapy curriculum approved by one of the following:

(A) The American Physical Therapy Association.

(B) The Committee on Allied Health Education and Accreditation of the American Medical Association.

(C) The Council on Medical Education of the American Medical Association and the American Physical Therapy Association.

(D) Other equivalent organizations approved by the Secretary.

(ii) Have a minimum of 1 year's experience working with a frail or elderly population.

(4) *Occupational therapist.* An occupational therapist must meet the following requirements:

(i) 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 or other equivalent organizations approved by the Secretary.

(ii) Be eligible for the National Registration Examination of the American Occupational Therapy Association.

(iii) 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 the 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.

(iv) Have a minimum of 1 year's experience working with a frail or elderly population.

(5) *Recreation therapist or activities coordinator.* A recreation therapist or activities coordinator must 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.

(6) *Dietitian.* A dietitian must meet the following requirements:

(i) Have a baccalaureate or advanced degree from an accredited college with major studies in food and nutrition or dietetics.

(ii) Have a minimum of 1 year's experience working with a frail or elderly population.

(7) *Drivers.* A PACE center driver must meet the following requirements:

(i) Have a valid driver's license to operate a van or bus in the State of operation.

(ii) Be capable of, and experienced in, transporting individuals with special mobility needs.

§ 460.66 Training.

(a) The PACE organization must provide training to maintain and improve the skills and knowledge of each staff member with respect to the individual's specific duties that results in his or her continued ability to demonstrate the skills necessary for the performance of the position.

(b) The PACE organization must develop a training program for each personal care attendant to establish the individual's competency in furnishing personal care services and specialized skills associated with specific care needs of individual participants.

§ 460.68 Program integrity.

(a) *Persons with criminal convictions.* A PACE organization must not employ individuals or contract with organizations or individuals—

(1) Who have been excluded from participation in the Medicare or Medicaid programs;

(2) Who have been convicted of criminal offenses related to their involvement in Medicaid, Medicare, other health insurance or health care programs, or social service programs under title XX of the Act; or

(3) In any capacity where an individual's contact with participants would pose a potential risk because the individual has been convicted of physical, sexual, drug, or alcohol abuse.

(b) *Direct or indirect interest in contracts.* Except as provided in paragraph (c) of this section, no member

of the PACE organization's governing body or any immediate family member may have a direct or indirect interest in any contract that supplies any administrative or care-related service or materials to the PACE organization.

(c) *Waiver.* (1) HCFA and the State administering agency may waive the requirement in paragraph (b) of this section for PACE organizations in the following communities:

- (i) Rural.
- (ii) Tribal.
- (iii) Urban Indian.

(2) If an applicant seeking approval as a PACE organization believes a waiver under this paragraph is warranted, it must include a request for the waiver in its application that meets the following requirements:

(i) Identifies the rural, tribal, or urban Indian community.

(ii) Establishes recusal restrictions for each member of the PACE organization governing body or immediate family member to which the exception would apply.

(iii) Establishes a process to record recusal actions on a case-by-case basis.

(iv) Establishes a process to make available to the public the general recusal restrictions and record of actions.

(3) HCFA and the State administering agency may grant a waiver if they determine the following:

(i) There is insufficient availability in the PACE organization's service area of individuals who could meet the requirement.

(ii) The proposed alternative does not adversely affect the availability of care or the quality of care that is provided to participants.

(d) *Disclosure requirements.* 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 HCFA within a reasonable amount of time.

§ 460.70 Contracted services.

(a) *General rule.* 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 except for emergency services as described in § 460.100.

(b) *Contract requirements.* A contract between a PACE organization and a contractor must meet the following requirements:

(1) The PACE organization must contract only with an entity that meets all applicable Federal and State requirements, including, but not limited to, the following:

(i) An organizational contractor, such as a hospital, must meet Medicare or Medicaid participation requirements.

(ii) A practitioner or supplier must meet Medicare or Medicaid requirements applicable to the services it furnishes.

(iii) A contractor must comply with the requirements of this part with respect to service delivery, participant rights, and quality assessment and performance improvement activities.

(2) A contractor must be accessible to participants, located either within or near the PACE organization's service area.

(3) A PACE organization must designate an official liaison to coordinate activities between contractors and the organization.

(c) *List of contractors.* A current list of contractors must be on file at the PACE center and a copy must be provided to anyone upon request.

(d) *Copies of signed contracts.* The PACE organization must furnish a copy of each signed contract for inpatient care to HCFA and the State administering agency.

(e) *Content of contract.* Each contract must be in writing and include the following information:

- (1) Name of contractor.
- (2) Services furnished.
- (3) Payment rate and method.

(4) Terms of the contract, including beginning and ending dates, methods of extension, renegotiation, and termination.

(5) Contractor agreement to do the following:

(i) Furnish only those services authorized by the PACE multidisciplinary team.

(ii) Accept payment from the PACE organization as payment in full, and not bill participants, HCFA, the State administering agency, or private insurers.

(iii) Hold harmless HCFA, the State, and PACE participants if the PACE organization does not pay for services performed by the contractor in accordance with the contract.

(iv) Not assign the contract or delegate duties under the contract unless it obtains prior written approval from the PACE organization.

(v) Submit reports required by the PACE organization.

§ 460.72 Physical environment.

(a) *Space and equipment—(1) Safe design.* A PACE center must meet the following requirements:

(i) Be designed, constructed, equipped, and maintained to provide for the physical safety of participants, personnel, and visitors.

(ii) Ensure a safe, sanitary, functional, accessible, and comfortable environment for the delivery of services that protects the dignity and privacy of the participant.

(2) *Primary care clinic.* 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.

(3) *Equipment maintenance.* 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.

(b) *Fire Safety.* (1) Except as provided in paragraph (b)(2) of this section, a PACE center must meet the occupancy provisions of the 1997 edition of the Life Safety Code of the National Fire Protection Association (which is incorporated by reference) that apply to the type of setting in which the center is located. Incorporation by reference of the Life Safety Code, 1997 edition, was approved by the Director of the **Federal Register** in accordance with 5 U.S.C. 552(a) and 1 CFR part 51. The Life Safety Code is available for inspection at the Office of the Federal Register, 800 North Capitol Street, N.W., Washington, D.C. Copies of the Life Safety Code may be obtained from the National Fire Protection Code (NFPA), 1 Batterymarch Park, P.O. Box 9101, Quincy, MA 02269-9101. If any changes in the Life Safety Code, 1997 edition, are also to be incorporated by reference, notice to that effect will be published in the **Federal Register**.

(2) *Exceptions.* (i) The Life Safety Code provisions do not apply in a State in which HCFA determines that a fire and safety code imposed by State law adequately protects participants and staff.

(ii) HCFA may waive specific provisions of the Life Safety Code that, if rigidly applied, would result in unreasonable hardship on the center, but only if the waiver does not adversely affect the health and safety of the participants and staff.

(c) *Emergency and disaster preparedness—(1) Procedures.* 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.

(2) *Emergencies defined.* Emergencies include, but are not limited to, the following:

(i) Fire.

(ii) Equipment, water, or power failure.

(iii) Care-related emergencies.

(iv) Natural disasters likely to occur in the organization's geographic area. (An organization is not required to develop emergency plans for natural disasters that typically do not affect its geographic location.)

(3) *Emergency training.* A PACE organization must provide appropriate training and periodic orientation to all staff (employees and contractors) and participants to ensure that staff demonstrate a knowledge of emergency procedures, including informing participants what to do, where to go, and whom to contact in case of an emergency.

(4) *Availability of emergency equipment.* Emergency equipment, including easily portable oxygen, airways, suction, and emergency drugs, along with staff who know how to use the equipment, must be on the premises of every center at all times and be immediately available. The organization must have a documented plan to obtain emergency medical assistance from sources outside the center when needed.

(5) *Annual test of emergency and disaster plan.* At least annually, a PACE organization must actually test, evaluate, and document the effectiveness of its emergency and disaster plans.

§ 460.74 Infection control.

(a) *Standard procedures.* The PACE organization must follow accepted policies and standard procedures with respect to infection control, including at least the standard precautions developed by the Centers for Disease Control and Prevention.

(b) *Infection control plan.* The PACE organization must establish, implement, and maintain a documented infection control plan that meets the following requirements:

(1) Ensures a safe and sanitary environment.

(2) Prevents and controls the transmission of disease and infection.

(c) *Contents of infection control plan.* The infection control plan must include, but is not limited to, the following:

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

(2) Procedures to record any incidents of infection.

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

§ 460.76 Transportation services.

(a) *Safety, accessibility, and equipment.* A PACE organization's transportation services must be safe, accessible, and equipped to meet the needs of the participant population.

(b) *Maintenance of vehicles.* (1) If the PACE organization owns, rents, or leases transportation vehicles, it must maintain these vehicles in accordance with the manufacturer's recommendations.

(2) If a contractor provides transportation services, the PACE organization must ensure that the vehicles are maintained in accordance with the manufacturer's recommendations.

(c) *Communication with PACE center.* The PACE organization must ensure that transportation vehicles are equipped to communicate with the PACE center.

(d) *Training.* The PACE organization must train all transportation personnel (employees and contractors) in the following:

(1) Managing the special needs of participants.

(2) Handling emergency situations.

(e) *Changes in care plan.* As part of the multidisciplinary team process, PACE organization staff (employees and contractors) must communicate relevant changes in a participant's care plan to transportation personnel.

§ 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 provide each participant with a nourishing, palatable, well-balanced meal that meets the daily nutritional and special dietary needs of each participant. Each meal must meet the following requirements:

(i) Be prepared by methods that conserve nutritive value, flavor, and appearance.

(ii) Be prepared in a form designed to meet individual needs.

(iii) Be prepared and served at the proper temperature.

(2) The PACE organization must provide substitute foods or nutritional supplements that meet the daily nutritional and special dietary needs of any participant who has any of the following problems:

(i) Refuses the food served.

(ii) Cannot tolerate the food served.

(iii) Does not eat adequately.

(3) The PACE organization must provide nutrition support to meet the daily nutritional needs of a participant, if indicated by his or her medical condition or diagnosis. Nutrition support consists of tube feedings, total parenteral nutrition, or peripheral parenteral nutrition.

(b) *Sanitary conditions.* The PACE organization must do the following:

(1) Procure foods (including nutritional supplements and nutrition support items) from sources approved, or considered satisfactory, by Federal, State, Tribal, or local authorities with jurisdiction over the service area of the organization.

(2) Store, prepare, distribute, and serve foods (including nutritional supplements and nutrition support items) under sanitary conditions.

(3) Dispose of garbage and refuse properly.

§ 460.80 Fiscal soundness.

(a) *Fiscally sound operation.* A PACE organization must have a fiscally sound operation, as demonstrated by the following:

(1) Total assets greater than total unsubordinated liabilities.

(2) Sufficient cash flow and adequate liquidity to meet obligations as they become due.

(3) A net operating surplus or a financial plan for maintaining solvency that is satisfactory to HCFA and the State administering agency.

(b) *Insolvency plan.* The organization must have a documented plan in the event of insolvency, approved by HCFA and the State administering agency, which provides for the following:

(1) Continuation of benefits for the duration of the period for which capitation payment has been made.

(2) Continuation of benefits to participants who are confined in a hospital on the date of insolvency until their discharge.

(3) Protection of participants from liability for payment of fees that are the legal obligation of the PACE organization.

(c) *Arrangements to cover expenses.*

(1) A PACE organization must demonstrate that it has arrangements to cover expenses in the amount of at least the sum of the following in the event it becomes insolvent:

(i) One month's total capitation revenue to cover expenses the month before insolvency.

(ii) One month's average payment to all contractors, based on the prior quarter's average payment, to cover expenses the month after the date it declares insolvency or ceases operations.

(2) Arrangements to cover expenses may include, but are not limited to, the following:

(i) Insolvency insurance or reinsurance.

(ii) Hold harmless arrangement.

(iii) Letters of credit, guarantees, net worth, restricted State reserves, or State law provisions.

§ 460.82 Marketing.

(a) *Information that a PACE organization must include in its marketing materials.* (1) A PACE organization must inform the public about its program and give prospective participants the following written information:

(i) An adequate description of the PACE organization's enrollment and disenrollment policies and requirements.

(ii) PACE enrollment procedures.

(iii) Description of benefits and services.

(iv) Premiums.

(v) Other information necessary for prospective participants to make an informed decision about enrollment.

(2) Marketing information must be free of material inaccuracies, misleading information, or misrepresentations.

(b) *Approval of marketing information.* (1) HCFA must approve all marketing information before distribution by the PACE organization, including any revised or updated material.

(2) HCFA reviews initial marketing information as part of an entity's application for approval as a PACE organization, and approval of the application includes approval of marketing information.

(3) Once a PACE organization is under a PACE program agreement, any revisions to existing marketing information and new information are subject to the following:

(i) *Time period for approval.* HCFA approves or disapproves marketing information within 45 days after HCFA receives the information from the organization.

(ii) *Deemed approval.* Marketing information is deemed approved, and the organization can distribute it, if HCFA and the State administering agency do not disapprove the marketing material within the 45-day review period.

(c) *Special language requirements.* A PACE organization must furnish printed marketing materials to prospective and current participants as specified below:

(1) In English and in any other principal languages of the community.

(2) In Braille, if necessary.

(d) *Information on restriction of services.* (1) Marketing materials must inform a potential participant that he or she must receive all needed health care, including primary care and specialist physician services (other than emergency services), from the PACE organization or from an entity authorized by the PACE organization.

(2) 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.

(e) *Prohibited marketing practices.* A PACE organization must ensure that its employees or its agents do not use prohibited marketing practices which includes the following:

(1) Discrimination of any kind, except that marketing may be directed to individuals eligible for PACE by reason of their age.

(2) Activities that could mislead or confuse potential participants, or misrepresent the PACE organization, HCFA, or the State administering agency.

(3) Gifts or payments to induce enrollment.

(4) Contracting outreach efforts to individuals or organizations whose sole responsibility involves direct contact with the elderly to solicit enrollment.

(5) Unsolicited door-to-door marketing.

(f) *Marketing Plan.* A PACE organization must establish, implement, and maintain a documented marketing plan with measurable enrollment objectives and a system for tracking its effectiveness.

Subpart F—PACE Services

§ 460.90 PACE benefits under Medicare and Medicaid.

If a Medicare beneficiary or Medicaid recipient chooses to enroll in a PACE program, the following conditions apply:

(a) Medicare and Medicaid benefit limitations and conditions relating to amount, duration, scope of services, deductibles, copayments, coinsurance, or other cost-sharing do not apply.

(b) The participant, while enrolled in a PACE program, must receive Medicare and Medicaid benefits solely through the PACE organization.

§ 460.92 Required services.

The PACE benefit package for all participants, regardless of the source of payment, must include the following:

(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 multidisciplinary team to improve and maintain the participant's overall health status.

§ 460.94 Required services for Medicare participants.

(a) Except for Medicare requirements that are waived for the PACE program, as specified in paragraph (b) of this section, the PACE benefit package for Medicare participants must include the following services:

(1) The scope of hospital insurance benefits described in part 409 of this chapter.
 (2) The scope of supplemental medical insurance benefits described in part 410 of this chapter.
 (b) *Waivers of Medicare coverage requirements.* The following Medicare requirements are waived for purposes of the PACE program and do not apply:
 (1) The provisions of subpart F of part 409 of this chapter that limit coverage of institutional services.
 (2) The provisions of subparts G and H of part 409 of this chapter, and parts 412 through 414 of this chapter that relate to payment for benefits.
 (3) The provisions of subparts D and E of part 409 of this chapter that limit coverage of extended care services or home health services.
 (4) The provisions of subpart D of part 409 of this chapter that impose a 3-day prior hospitalization requirement for coverage of extended care services.
 (5) Sections 411.15(g) and (k) of this chapter that may prevent payment for PACE program services to PACE participants.

§ 460.96 Excluded services.

The following services are excluded from coverage under PACE:

(a) Any service that is not authorized by the multidisciplinary team, even if it is a required service, unless it is an emergency service.
 (b) In an inpatient facility, private room and private duty nursing services (unless medically necessary), and nonmedical items for personal convenience such as telephone charges and radio or television rental (unless specifically authorized by the multidisciplinary team as part of the participant's plan of care).
 (c) Cosmetic surgery, which does not include surgery that is required for improved functioning of a malformed part of the body resulting from an accidental injury or for reconstruction following mastectomy.
 (d) Experimental medical, surgical, or other health procedures.

(e) Services furnished outside of the United States, except as follows:

(1) In accordance with §§ 424.122 through 424.124 of this chapter.

(2) As permitted under the State's approved Medicaid plan.

§ 460.98 Service delivery.

(a) *Plan.* 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.

(b) *Provision of services.* (1) The PACE organization must furnish comprehensive medical, health, and social services that integrate acute and long-term care.

(2) These services must be furnished in at least the PACE center, the home, and inpatient facilities.

(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, mental or physical disability, or source of payment.

(c) *Minimum services furnished at each PACE center.* At a minimum, the following services must be furnished at each PACE center:

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

(2) Social services.

(3) Restorative therapies, including physical therapy and occupational therapy.

(4) Personal care and supportive services.

(5) Nutritional counseling.

(6) Recreational therapy.

(7) Meals.

(d) *Center operation.* (1) A PACE organization must operate at least one PACE center either in, or contiguous to, its defined service area with sufficient capacity to allow routine attendance by participants.

(2) A PACE organization must ensure accessible and adequate services to meet the needs of its participants. If necessary, a PACE organization must increase the number of PACE centers, staff, or other PACE services.

(3) If a PACE organization operates more than one center, each center must offer the full range of services and have sufficient staff to meet the needs of participants.

(e) *Center attendance.* The frequency of a participant's attendance at a center is determined by the multidisciplinary team, based on the needs and preferences of each participant.

§ 460.100 Emergency care.

(a) *Written plan.* A PACE organization must establish and maintain a written plan to handle emergency care. The

plan must ensure that HCFA, the State, and PACE participants are held harmless if the PACE organization does not pay for emergency services.

(b) *Emergency care.* Emergency care is appropriate when services are needed immediately because of an injury or sudden illness and the time required to reach the PACE organization or one of its contract providers, would cause risk of permanent damage to the participant's health. Emergency services include inpatient and outpatient services that meet the following requirements:

(1) Are furnished by a qualified emergency services provider, other than the PACE organization or one of its contract providers, either in or out of the PACE organization's service area.

(2) Are needed to evaluate or stabilize an emergency medical condition.

(c) 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 the following:

(1) Serious jeopardy to the health of the participant.

(2) Serious impairment to bodily functions.

(3) Serious dysfunction of any bodily organ or part.

(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.

(e) *On-call providers.* The plan must provide for the following:

(1) An on-call provider, available 24-hours per day to address participant questions about emergency services and respond to requests for authorization of urgently needed out-of-network services and post stabilization care services following emergency services.

(2) Coverage of urgently needed out-of-network and post-stabilization care services when either of the following conditions are met:

(i) The services are preapproved by the PACE organization.

(ii) The services are not preapproved by the PACE organization because the PACE organization did not respond to a request for approval within 1 hour after being contacted or cannot be contacted for approval.

§ 460.102 Multidisciplinary team.

(a) *Basic requirement.* A PACE organization must meet the following requirements:

(1) Establish a multidisciplinary team at each center to comprehensively

assess and meet the individual needs of each participant.

(2) Assign each participant to a multidisciplinary team functioning at the PACE center that the participant attends.

(b) *Composition of multidisciplinary team.* The multidisciplinary team must be composed of at least the following members:

(1) Primary care physician.

(2) Registered nurse.

(3) Social worker.

(4) Physical therapist.

(5) Occupational therapist.

(6) Recreational therapist or activity coordinator.

(7) Dietitian.

(8) PACE center manager.

(9) Home care coordinator.

(10) Personal care attendant or his or her representative.

(11) Driver or his or her representative.

(c) *Primary care physician.* (1)

Primary medical care must be furnished to a participant by a PACE primary care physician.

(2) Each primary care physician is responsible for the following:

(i) Managing a participant's medical situations.

(ii) Overseeing a participant's use of medical specialists and inpatient care.

(d) *Responsibilities of multidisciplinary team.* (1) The multidisciplinary team is responsible for the initial assessment, periodic reassessments, plan of care, and coordination of 24 hour care delivery.

(2) Each team member is responsible for the following:

(i) Regularly informing the multidisciplinary team of the medical, functional, and psychosocial condition of each participant.

(ii) Remaining alert to pertinent input from other team members, participants, and caregivers.

(iii) Documenting changes in a participant's condition in the participant's medical record.

(3) Except as specified in paragraph (g) of this section, the members of the multidisciplinary team must serve primarily PACE participants.

(e) *Exchange of information between team members.* The PACE organization must establish, implement, and maintain documented internal procedures governing the exchange of information between team members, contractors, and participants and their caregivers consistent with the requirements for confidentiality in § 460.200(e).

(f) *Organization employees.* Except as specified in paragraph (g) of this section, at least the following members

of the multidisciplinary team must be employees of the PACE organization:

(1) Primary care physician.

(2) Registered nurse.

(3) Social worker.

(4) Recreational therapist or activity coordinator.

(5) PACE center manager.

(6) Home care coordinator.

(7) PACE center personal care attendant.

(g) *Waivers.* (1) HCFA and the State administering agency may waive either or both of the following:

(i) The requirement in paragraph (d)(3) of this section that members of the multidisciplinary team must serve primarily PACE participants.

(ii) The requirement in paragraph (f)(1) of this section that the primary care physician must be an employee of the PACE organization.

(2) If an applicant seeking approval as a PACE organization believes a waiver under this paragraph is warranted, it must include a request for the waiver in its application and describe in detail the circumstances supporting the request.

(3) HCFA and the State administering agency may grant a waiver if they determine the following:

(i) There is insufficient availability in the PACE organization's service area of individuals who meet the requirements, or State licensing laws make it inappropriate for the organization to employ physicians.

(ii) The proposed alternative does not adversely affect the availability of care or the quality of care that is furnished to participants.

§ 460.104 Participant assessment.

(a) *Initial comprehensive assessment—*(1) *Basic requirement.* The multidisciplinary team must conduct an initial comprehensive assessment on each participant. The assessment must be completed promptly following enrollment.

(2) As part of the initial comprehensive assessment, each of the following members of the multidisciplinary 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) Social worker.

(iv) Physical therapist or occupational therapist, or both.

(v) Recreational therapist or activity coordinator.

(vi) Dietitian.

(vii) Home care coordinator.

(3) At the recommendation of individual team members, other

professional disciplines (for example, speech-language pathology, dentistry, or audiology) may be included in the comprehensive assessment process.

(4) *Comprehensive assessment criteria.* The comprehensive assessment must include, but is not limited to, the following:

(i) Physical and cognitive function and ability.

(ii) Medication use.

(iii) Participant and caregiver preferences for care.

(iv) Socialization and availability of family support.

(v) Current health status and treatment needs.

(vi) Nutritional status.

(vii) Home environment, including home access and egress.

(viii) Participant behavior.

(ix) Psychosocial status.

(x) Medical and dental status.

(xi) Participant language.

(b) *Development of plan of care.* The multidisciplinary team must promptly consolidate discipline-specific assessments into a single plan of care for each participant through discussion in team meetings and consensus of the entire multidisciplinary team. In developing the plan of care, female participants must be informed that they are entitled to choose a qualified specialist for women's health services from the PACE organization's network to furnish routine or preventive women's health services.

(c) *Periodic reassessment—(1) Semiannual reassessment.* On at least a semiannual basis, or more often if a participant's condition dictates, the following members of the multidisciplinary team must conduct an in-person reassessment:

(i) Primary care physician.

(ii) Registered nurse.

(iii) Social worker.

(iv) Recreational therapist or activity coordinator.

(v) 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.

(2) *Annual reassessment.* On at least an annual basis, the following members of the multidisciplinary team must conduct an in-person reassessment:

(i) Physical therapist or occupational therapist, or both.

(ii) Dietitian.

(iii) Home care coordinator.

(3) *Reassessment based on change in participant status or at the request of the participant or designated representative.* If the health or psychosocial status of a participant

changes or if a participant (or his or her designated representative) believes that the participant needs to initiate, eliminate, or continue a particular service, the members of the multidisciplinary team, listed in paragraph (a)(2) of this section, 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 (c)(3)(iii) of this section, the multidisciplinary 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 multidisciplinary team receives the request for reassessment.

(iii) The multidisciplinary 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.

(v) If the participant or designated representative is dissatisfied with the decision on the request, 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).

(D) If the multidisciplinary 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.

(d) *Changes to plan of care.* Team members who conduct a reassessment must meet the following requirements:

(1) Reevaluate the participant's plan of care.

(2) Discuss any changes in the plan with the multidisciplinary team.

(3) Obtain approval of the revised plan from the multidisciplinary team and the participant (or designated representative).

(4) Furnish any services included in the revised plan of care as a result of a reassessment to the participant as expeditiously as the participant's health condition requires.

(e) *Documentation.* Multidisciplinary team members must document all assessment and reassessment information in the participant's medical record.

§ 460.106 Plan of care.

(a) *Basic requirement.* The multidisciplinary team must promptly develop a comprehensive plan of care for each participant.

(b) *Content of plan of care.* The plan of care must meet the following requirements:

(1) Specify the care needed to meet the participant's medical, physical, emotional, and social needs, as identified in the initial comprehensive assessment.

(2) Identify measurable outcomes to be achieved.

(c) *Implementation of the plan of care.* (1) The team must implement, coordinate, and monitor the plan of care whether the services are furnished by PACE employees or contractors.

(2) The team must continuously monitor the participant's health and psychosocial status, as well as the effectiveness of the plan of care, through the provision of services, informal observation, input from participants or caregivers, and communications among members of the multidisciplinary team and other providers.

(d) *Evaluation of plan of care.* On at least a semi-annual basis, the multidisciplinary team must reevaluate the plan of care, including defined outcomes, and make changes as necessary.

(e) *Participant and caregiver involvement in plan of care.* The team must develop, review, and reevaluate the plan of care in collaboration with the participant or caregiver, or both, to ensure that there is agreement with the

plan of care and that the participant's concerns are addressed.

(f) *Documentation.* The team must document the plan of care, and any changes made to it, in the participant's medical record.

Subpart G—Participant Rights

§ 460.110 Bill of rights.

(a) *Written bill of rights.* A PACE organization must have a written participant bill of rights designed to protect and promote the rights of each participant. Those rights include, at a minimum, the ones specified in § 460.112.

(b) *Explanation of rights.* The organization must inform a participant upon enrollment, in writing, of his or her rights and responsibilities, and all rules and regulations governing participation.

(c) *Protection of rights.* The organization must protect and provide for the exercise of the participant's rights.

§ 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, mental or physical disability, or source of payment. Specifically, each participant has the right to the following:

(1) To receive comprehensive health care in a safe and clean environment and in an accessible manner.

(2) To be treated with dignity and respect, be afforded privacy and confidentiality in all aspects of care, and be provided humane care.

(3) Not to be required to perform services for the PACE organization.

(4) To have reasonable access to a telephone.

(5) To be free from harm, including physical or mental abuse, neglect, corporal punishment, involuntary seclusion, excessive medication, and any physical or chemical restraint imposed for purposes of discipline or convenience and not required to treat the participant's medical symptoms.

(6) To be encouraged and assisted to exercise rights as a participant, including the Medicare and Medicaid appeals processes as well as civil and other legal rights.

(7) To be encouraged and assisted to recommend changes in policies and services to PACE staff.

(b) *Information disclosure.* Each PACE participant has the right to receive accurate, easily understood information and to receive assistance in making informed health care decisions. Specifically, each participant has the following rights:

(1) To be fully informed in writing of the services available from the PACE organization, including identification of all services that are delivered through contracts, rather than furnished directly by the PACE organization at the following times:

(i) Before enrollment.

(ii) At enrollment.

(iii) When there is a change in services.

(2) To have the enrollment agreement, described in § 460.154, fully explained in a manner understood by the participant.

(3) To examine, or upon reasonable request, to be assisted to examine the results of the most recent review of the PACE organization conducted by HCFA or the State administering agency and any plan of correction in effect.

(c) *Choice of providers.* Each participant has the right to a choice of health care providers, within the PACE organization's network, that is sufficient to ensure access to appropriate high-quality health care. Specifically, each participant has the right to the following:

(1) To choose his or her primary care physician and specialists from within the PACE network.

(2) To request that a qualified specialist for women's health services furnish routine or preventive women's health services.

(3) To disenroll from the program at any time.

(d) *Access to emergency services.* Each participant has the right to access emergency health care services when and where the need arises without prior authorization by the PACE multidisciplinary team.

(e) *Participation in treatment decisions.* Each participant has the right to participate fully in all decisions related to his or her treatment. A participant who is unable to participate fully in treatment decisions has the right to designate a representative. Specifically, each participant has the following rights:

(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 PACE organization 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 multidisciplinary team.

(4) To participate in the development and implementation of the plan of care.

(5) To request a reassessment by the multidisciplinary team.

(6) To be given reasonable advance notice, in writing, of any transfer to another treatment setting and the justification for the transfer (that is, 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.

(f) *Confidentiality of health information.* 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 information protected. Each participant also has the right to review and copy his or her own medical records and request amendments to those records. Specifically, each participant has the following rights:

(1) To be assured of confidential treatment of all information contained in the health record, including information contained in an automated data bank.

(2) To be assured that his or her written consent will be obtained for the release of information to persons not otherwise authorized under law to receive it.

(3) To provide written consent that limits the degree of information and the persons to whom information may be given.

(g) *Complaints and appeals.* Each participant has the right to a fair and efficient process for resolving differences with the PACE organization, including a rigorous system for internal review by the organization and an independent system of external review. Specifically, each participant has the following rights:

(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 PACE organization, its employees, or contractors through the process described in § 460.122.

§ 460.114 Restraints.

(a) The PACE organization must limit use of restraints to the least restrictive and most effective method available. The term restraint includes either a

physical restraint or a chemical restraint.

(1) A physical restraint is any manual method or physical or mechanical device, materials, or equipment attached or adjacent to the participant's body that he or she cannot easily remove that restricts freedom of movement or normal access to one's body.

(2) A chemical restraint is a medication used to control behavior or to restrict the participant's freedom of movement and is not a standard treatment for the participant's medical or psychiatric condition.

(b) If the multidisciplinary team determines that a restraint is needed to ensure the participant's physical safety or the safety of others, the use must meet the following conditions:

(1) Be imposed for a defined, limited period of time, based upon the assessed needs of the participant.

(2) Be imposed in accordance with safe and appropriate restraining techniques.

(3) Be imposed only when other less restrictive measures have been found to be ineffective to protect the participant or others from harm.

(4) Be removed or ended at the earliest possible time.

(c) The condition of the restrained participant must be continually assessed, monitored, and reevaluated.

§ 460.116 Explanation of rights.

(a) *Written policies.* 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.

(b) *Explanation of rights.* The PACE organization must fully explain the rights to the participant and his or her representative, if any, at the time of enrollment in a manner understood by the participant.

(c) *Display.* The PACE organization must meet the following requirements:

(1) Write the participant rights in English and in any other principal languages of the community.

(2) Display the participant rights in a prominent place in the PACE center.

§ 460.118 Violation of rights.

The PACE organization must have established documented procedures to respond to and rectify a violation of a participant's rights.

§ 460.120 Grievance process.

For purposes of this part, a grievance is a complaint, either written or oral, expressing dissatisfaction with service delivery or the quality of care furnished.

(a) *Process to resolve grievances.* A PACE organization must have a formal

written process to evaluate and resolve medical and nonmedical grievances by participants, their family members, or representatives.

(b) *Notification to participants.* Upon enrollment, and at least annually thereafter, the PACE organization must give a participant written information on the grievance process.

(c) *Minimum requirements.* At a minimum, the PACE organization's grievance process must include written procedures for the following:

(1) How a participant files a grievance.

(2) Documentation of a participant's grievance.

(3) Response to, and resolution of, grievances in a timely manner.

(4) Maintenance of confidentiality of a participant's grievance.

(d) *Continuing care during grievance process.* The PACE organization must continue to furnish all required services to the participant during the grievance process.

(e) *Explaining the grievance process.* The PACE organization must discuss with and provide to the participant in writing the specific steps, including timeframes for response, that will be taken to resolve the participant's grievance.

(f) *Analyzing grievance information.* The PACE organization must maintain, aggregate, and analyze information on grievance proceedings. This information must be used in the PACE organization's internal quality assessment and performance improvement program.

§ 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.

(a) *PACE organization's written appeals process.* The PACE organization must have a formal written appeals process, with specified timeframes for response, to address noncoverage or nonpayment of a service.

(b) *Notification of participants.* Upon enrollment, at least annually thereafter, and whenever the multidisciplinary team denies a request for services or payment, the PACE organization must give a participant written information on the appeals process.

(c) *Minimum requirements.* At a minimum, the PACE organization's appeals process must include written procedures for the following:

(1) Timely preparation and processing of a written denial of coverage or payment as provided in § 460.104(c)(3).

(2) How a participant files an appeal.

(3) Documentation of a participant's appeal.

(4) Appointment of an appropriately credentialed and impartial third party who was not involved in the original action and who does not have a stake in the outcome of the appeal to review the participant's appeal.

(5) Responses to, and resolution of, appeals as expeditiously as the participant's health condition requires, but no later than 30 calendar days after the organization receives an appeal.

(6) Maintenance of confidentiality of appeals.

(d) *Notification.* A PACE organization must give all parties involved in the appeal the following:

(1) Appropriate written notification.

(2) A reasonable opportunity to present evidence related to the dispute, in person, as well as in writing.

(e) *Services furnished during appeals process.* During the appeals process, the PACE organization must meet the following requirements:

(1) For a Medicaid participant, continue to furnish the disputed services until issuance of the final determination if the following conditions are met:

(i) The PACE organization is proposing to terminate or reduce services currently being furnished to the participant.

(ii) The participant requests continuation with the understanding that he or she may be liable for the costs of the contested services if the determination is not made in his or her favor.

(2) Continue to furnish to the participant all other required services, as specified in subpart F of this part.

(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 maximum function would be seriously jeopardized, absent provision of the service in dispute.

(2) Except as provided in paragraph (f)(3) of this section, the PACE organization 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.

(3) The PACE organization may extend the 72-hour timeframe by up to 14 calendar days for either of the following reasons:

(i) The participant requests the extension.

(ii) The organization justifies to the State administering agency the need for additional information and how the delay is in the interest of the participant.

(g) Determination in favor of participant. A PACE organization must furnish the disputed service as expeditiously as the participant's health condition requires if a determination is made in favor of the participant on appeal.

(h) Determination adverse to participant. For a determination that is wholly or partially adverse to a participant, at the same time the decision is made, the PACE organization must notify the following:

- (1) HCFA.
- (2) The State administering agency.
- (3) The participant.

(i) *Analyzing appeals information.* A PACE organization must maintain, aggregate, and analyze information on appeal proceedings and use this information in the organization's internal quality assessment and performance improvement program.

§ 460.124 Additional appeal rights under Medicare or Medicaid.

A PACE organization must inform a participant in writing of his or her appeal rights under Medicare or Medicaid managed care, or both, assist the participant in choosing which to pursue if both are applicable, and forward the appeal to the appropriate external entity.

Subpart H—Quality Assessment and Performance Improvement

§ 460.130 General rule.

(a) A PACE organization must develop, implement, maintain, and evaluate an effective, data-driven quality assessment and performance improvement program.

(b) The program must reflect the full range of services furnished by the PACE organization.

(c) A PACE organization must take actions that result in improvements in its performance in all types of care.

§ 460.132 Quality assessment and performance improvement plan.

(a) *Basic rule.* A PACE organization must have a written quality assessment and performance improvement plan.

(b) *Annual review.* The PACE governing body must review the plan annually and revise it, if necessary.

(c) *Minimum plan requirements.* At a minimum, the plan must specify how the PACE organization proposes to meet the following requirements:

- (1) Identify areas 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.

(3) Document and disseminate to PACE staff and contractors the results from the quality assessment and performance improvement activities.

§ 460.134 Minimum requirements for quality assessment and performance improvement program.

(a) *Minimum program requirements.* A PACE organization's quality assessment and performance improvement program must include, but is not limited to, the use of objective measures to demonstrate improved performance with regard to the following:

(1) Utilization of PACE services, such as decreased inpatient hospitalizations and emergency room visits.

(2) Caregiver and participant satisfaction.

(3) Outcome measures that are derived from data collected during assessments, including data on the following:

- (i) Physiological well being.
 - (ii) Functional status.
 - (iii) Cognitive ability.
 - (iv) Social/behavioral functioning.
 - (v) Quality of life of participants.
- (4) Effectiveness and safety of staff-provided and contracted services, including the following:
- (i) Competency of clinical staff.
 - (ii) Promptness of service delivery.
 - (iii) Achievement of treatment goals and measurable outcomes.

(5) Nonclinical areas, such as grievances and appeals, transportation services, meals, life safety, and environmental issues.

(b) *Basis for outcome measures.* Outcome measures must be based on current clinical practice guidelines and professional practice standards applicable to the care of PACE participants.

(c) *Minimum levels of performance.* The PACE organization must meet or exceed minimum levels of performance, established by HCFA and the State administering agency, on standardized quality measures, such as influenza immunization rates, which are specified in the PACE program agreement.

(d) *Accuracy of data.* The PACE organization must ensure that all data used for outcome monitoring are accurate and complete.

§ 460.136 Internal quality assessment and performance improvement activities.

(a) *Quality assessment and performance improvement requirements.* A PACE organization must do the following:

- (1) Use a set of outcome measures to identify areas of good or problematic performance.

(2) Take actions targeted at maintaining or improving care based on outcome measures.

(3) Incorporate actions resulting in performance improvement into standards of practice for the delivery of care and periodically track performance to ensure that any performance improvements are sustained over time.

(4) Set priorities for performance improvement, considering prevalence and severity of identified problems, and give priority to improvement activities that affect clinical outcomes.

(5) Immediately correct any identified problem that directly or potentially threatens the health and safety of a PACE participant.

(b) *Quality assessment and performance improvement coordinator.* A PACE organization must designate an individual to coordinate and oversee implementation of quality assessment and performance improvement activities.

(c) *Involvement in quality assessment and performance improvement activities.* (1) A PACE organization must ensure that all multidisciplinary team members, PACE staff, and contract providers are involved in the development and implementation of quality assessment and performance improvement activities and are aware of the results of these activities.

(2) The quality improvement coordinator must encourage a PACE participant and his or her caregivers to be involved in quality assessment and performance improvement activities, including providing information about their satisfaction with services.

§ 460.138 Committees with community input.

A PACE organization must establish one or more committees, with community input, to do the following:

(a) Evaluate data collected pertaining to quality outcome measures.

(b) Address the implementation of, and results from, the quality assessment and performance improvement plan.

(c) Provide input related to ethical decisionmaking, including end-of-life issues and implementation of the Patient Self-Determination Act.

§ 460.140 Additional quality assessment activities.

A PACE organization must meet external quality assessment and reporting requirements, as specified by HCFA or the State administering agency, in accordance with § 460.202.

Subpart I—Participant Enrollment and Disenrollment**§ 460.150 Eligibility to enroll in a PACE program.**

(a) *General rule.* To enroll in a PACE program, an individual must meet eligibility requirements specified in this section. To continue to be eligible for PACE, an individual must meet the annual recertification requirements specified in § 460.160.

(b) *Basic eligibility requirements.* To be eligible to enroll in PACE, an individual must meet the following requirements:

(1) Be 55 years of age or older.
 (2) Be determined by the State administering agency to need the level of care required under the State Medicaid plan for coverage of nursing facility services, which indicates that the individual's health status is comparable to the health status of individuals who have participated in the PACE demonstration waiver programs.

(3) Reside in the service area of the PACE organization.

(4) Meet any additional program specific eligibility conditions imposed under the PACE program agreement. These additional conditions may not modify the requirements of paragraph (b)(1) through (b)(3) of this section.

(c) *Other eligibility requirements.* (1) At the time of enrollment, an individual must be able to live in a community setting without jeopardizing his or her health or safety.

(2) The criteria used to determine if an individual's health or safety would be jeopardized by living in a community setting must be specified in the program agreement.

(d) *Eligibility under Medicare and Medicaid.* Eligibility to enroll in a PACE program is not restricted to an individual who is either a Medicare beneficiary or Medicaid recipient. A potential PACE enrollee may be, but is not required to be, any or all of the following:

- (1) Entitled to Medicare Part A.
- (2) Enrolled under Medicare Part B.
- (3) Eligible for Medicaid.

§ 460.152 Enrollment process.

(a) *Intake process.* Intake is an intensive process during which PACE staff members make one or more visits to a potential participant's place of residence and the potential participant makes one or more visits to the PACE center. At a minimum, the intake process must include the following activities:

(1) The PACE staff must explain to the potential participant and his or her

representative or caregiver the following information:

(i) The PACE program, using a copy of the enrollment agreement described in § 460.154, specifically references the elements of the agreement including but not limited to § 460.154(e), (i) through (m), and (r).

(ii) The requirement that the PACE organization would be the participant's sole service provider and clarification that the PACE organization guarantees access to services, but not to a specific provider.

(iii) A list of the employees of the PACE organization who furnish care and the most current list of contracted health care providers under § 460.70(c).

(iv) Monthly premiums, if any.

(v) Any Medicaid spenddown obligations.

(2) 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.

(3) The State administering agency must assess the potential participant, including any individual who is not eligible for Medicaid, to ensure that he or she needs the level of care required under the State Medicaid plan for coverage of nursing facility services, which indicates that the individual's health status is comparable to the health status of individuals who have participated in the PACE demonstration waiver programs.

(4) PACE staff must assess the potential participant to ensure that he or she can be cared for appropriately in a community setting and that he or she meets all requirements for PACE eligibility specified in this part.

(b) *Denial of Enrollment.* 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 meet the following requirements:

(1) Notify the individual in writing of the reason for the denial.

(2) Refer the individual to alternative services, as appropriate.

(3) Maintain supporting documentation of the reason for the denial.

(4) Notify HCFA and the State administering agency and make the documentation available for review.

§ 460.154 Enrollment agreement.

If the potential participant meets the eligibility requirements and wants to enroll, he or she must sign an enrollment agreement which contains, at a minimum, the following information:

(a) Applicant's name, sex, and date of birth.

(b) Medicare beneficiary status (Part A, Part B, or both) and number, if applicable.

(c) Medicaid recipient status and number, if applicable.

(d) Other health insurance information, if applicable.

(e) Conditions for enrollment and disenrollment in PACE.

(f) Description of participant premiums, if any, and procedures for payment of premiums.

(g) Notification that a Medicaid participant and a participant who is eligible for both Medicare and Medicaid are not liable for any premiums, but may be liable for any applicable spenddown liability under §§ 435.121 and 435.831 of this chapter and any amounts due under the post-eligibility treatment of income process under § 460.184.

(h) Notification that a Medicare participant may not disenroll from PACE at a social security office.

(i) Notification that enrollment in PACE results in disenrollment from any other Medicare or Medicaid prepayment plan or optional benefit. Electing enrollment in any other Medicare or Medicaid prepayment plan or optional benefit, including the hospice benefit, after enrolling as a PACE participant is considered a voluntary disenrollment from PACE.

(j) Information on the consequences of subsequent enrollment in other optional Medicare or Medicaid programs following disenrollment from PACE.

(k) Description of PACE services available, including all Medicare and Medicaid covered services, and how services are obtained from the PACE organization.

(l) Description of the procedures for obtaining emergency and urgently needed out-of-network services.

(m) The participant bill of rights.

(n) Information on the process for grievances and appeals and Medicare/Medicaid phone numbers for use in appeals.

(o) Notification of a participant's obligation to inform the PACE organization of a move or lengthy absence from the organization's service area.

(p) An acknowledgment by the applicant or representative that he or she understands the requirement that the PACE organization must be the applicant's sole service provider.

(q) A statement that the PACE organization has an agreement with HCFA and the State administering agency that is subject to renewal on a periodic basis and, if the agreement is

not renewed, the program will be terminated.

(r) The applicant's authorization for disclosure and exchange of personal information between HCFA, its agents, the State administering agency, and the PACE organization.

(s) The effective date of enrollment.

(t) The applicant's signature and the date.

§ 460.156 Other enrollment procedures.

(a) *Items a PACE organization must give a participant upon enrollment.*

After the participant signs the enrollment agreement, the PACE organization must give the participant the following:

(1) A copy of the enrollment agreement.

(2) A PACE membership card.

(3) Emergency information to be posted in his or her home identifying the individual as a PACE participant and explaining how to access emergency services.

(4) Stickers for the participant's Medicare and Medicaid cards, as applicable, which indicate that he or she is a PACE participant and include the phone number of the PACE organization.

(b) *Submittal of participant information to HCFA and the State.* The PACE organization must submit participant information to HCFA and the State administering agency, in accordance with established procedures.

(c) *Changes in enrollment agreement information.* If there are changes in the enrollment agreement information at any time during the participant's enrollment, the PACE organization must meet the following requirements:

(1) Give an updated copy of the information to the participant.

(2) Explain the changes to the participant and his or her representative or caregiver in a manner they understand.

§ 460.158 Effective date of enrollment.

A participant's enrollment in the program is effective on the first day of the calendar month following the date the PACE organization receives the signed enrollment agreement.

§ 460.160 Continuation of enrollment.

(a) *Duration of enrollment.*

Enrollment continues until the participant's death, regardless of changes in health status, unless either of the following actions occur:

(1) The participant voluntarily disenrolls.

(2) The participant is involuntarily disenrolled, as described in § 460.164.

(b) *Annual recertification requirement.* At least annually, the State

administering agency must reevaluate whether a participant needs the level of care required under the State Medicaid plan for coverage of nursing facility services.

(1) *Waiver of annual requirement.* (i) The State administering agency may permanently waive the annual recertification requirement for a participant if it determines that there is no reasonable expectation of improvement or significant change in the participant's condition because of the severity of a chronic condition or the degree of impairment of functional capacity.

(ii) The PACE organization must retain in the participant's medical record the documentation of the reason for waiving the annual recertification requirement.

(2) *Deemed continued eligibility.* If the State administering agency determines that a PACE participant no longer meets the State Medicaid nursing facility level of care requirements, the participant may be deemed to continue to be eligible for the PACE program until the next annual reevaluation, if, in the absence of continued coverage under this program, the participant reasonably would be expected to meet the nursing facility level of care requirement within the next 6 months.

(3) *Continued eligibility criteria.* (i) The State administering agency, in consultation with the PACE organization, makes a determination of continued eligibility based on a review of the participant's medical record and plan of care.

(ii) The criteria used to make the determination of continued eligibility must be specified in the program agreement.

§ 460.162 Voluntary disenrollment.

A PACE participant may voluntarily disenroll from the program without cause at any time.

§ 460.164 Involuntary disenrollment.

(a) *Reasons for involuntary disenrollment.* A participant may be involuntarily disenrolled for any of the following reasons:

(1) The participant fails to pay, or to make satisfactory arrangements to pay, any premium due the PACE organization after a 30-day grace period.

(2) The participant engages in disruptive or threatening behavior, as described in paragraph (b) of this section.

(3) The participant moves out of the PACE program service area or is out of the service area for more than 30 consecutive days, unless the PACE

organization agrees to a longer absence due to extenuating circumstances.

(4) The participant is determined to no longer meet the State Medicaid nursing facility level of care requirements and is not deemed eligible.

(5) The PACE program agreement with HCFA and the State administering agency is not renewed or is terminated.

(6) The PACE organization is unable to offer health care services due to the loss of State licenses or contracts with outside providers.

(b) *Disruptive or threatening behavior.* For purposes of this section, a participant who engages in disruptive or threatening behavior refers to a participant who exhibits either of the following:

(1) A participant whose behavior jeopardizes his or her health or safety, or the safety of others; or

(2) A participant with decision-making capacity who consistently refuses to comply with his or her individual plan of care or the terms of the PACE enrollment agreement.

(c) *Documentation of disruptive or threatening behavior.* If a PACE organization proposes to disenroll a participant who is disruptive or threatening, the organization must document the following information in the participant's medical record:

(1) The reasons for proposing to disenroll the participant.

(2) All efforts to remedy the situation.

(d) *Noncompliant behavior.* (1) A PACE organization may not disenroll a PACE participant on the grounds that the participant has engaged in noncompliant behavior if the behavior is related to a mental or physical condition of the participant, unless the participant's behavior jeopardizes his or her health or safety, or the safety of others.

(2) For purposes of this section, noncompliant behavior includes repeated noncompliance with medical advice and repeated failure to keep appointments.

(e) *State administering agency review and final determination.* Before an involuntary disenrollment is effective, the State administering agency must review it and determine in a timely manner that the PACE organization has adequately documented acceptable grounds for disenrollment.

§ 460.166 Effective date of disenrollment.

(a) In disenrolling a participant, the PACE organization must take the following actions:

(1) Use the most expedient process allowed under Medicare and Medicaid procedures, as set forth in the PACE program agreement.

(2) Coordinate the disenrollment date between Medicare and Medicaid (for a participant who is eligible for both Medicare and Medicaid).

(3) Give reasonable advance notice to the participant.

(b) Until the date enrollment is terminated, the following requirements must be met:

(1) PACE participants must continue to use PACE organization services and remain liable for any premiums.

(2) The PACE organization must continue to furnish all needed services.

§ 460.168 Reinstatement in other Medicare and Medicaid programs.

To facilitate a participant's reinstatement in other Medicare and Medicaid programs after disenrollment, the PACE organization must do the following:

(a) Make appropriate referrals and ensure medical records are made available to new providers in a timely manner.

(b) Work with HCFA and the State administering agency to reinstate the participant in other Medicare and Medicaid programs for which the participant is eligible.

§ 460.170 Reinstatement in PACE.

(a) A previously disenrolled participant may be reinstated in a PACE program.

(b) If the reason for disenrollment is failure to pay the premium and the participant pays the premium before the effective date of disenrollment, the participant is reinstated in the PACE program with no break in coverage.

§ 460.172 Documentation of disenrollment.

A PACE organization must meet the following requirements:

(a) Have a procedure in place to document the reasons for all voluntary and involuntary disenrollments.

(b) Make documentation available for review by HCFA and the State administering agency.

(c) Use the information on voluntary disenrollments in the PACE organization's internal quality assessment and performance improvement program.

Subpart J—Payment

§ 460.180 Medicare payment to PACE organizations.

(a) *Principle of payment.* Under a PACE program agreement, HCFA 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+Choice organization.

(b) *Determination of rate.* (1) The PACE program agreement specifies the

monthly capitation amount for each year applicable to a PACE organization.

(2) Except as specified in paragraph (b)(4) of this section, the monthly capitation amount is based on the aged Part A and Part B payment rates established for purposes of payment to Medicare+Choice organizations. As used in this section, "Medicare+Choice rates" means the Part A and Part B rates calculated by HCFA for making payment to Medicare+Choice organizations under section 1853 of the Act.

(3) The rates specified in paragraph (b)(2) of this section are adjusted by a frailty factor necessary to ensure comparability between PACE participants and the reference population in the Medicare system. The factor is specified in the PACE program agreement.

(4) For Medicare participants who require ESRD services, the monthly capitation amount is based on the Medicare+Choice State ESRD rate. The monthly rate is adjusted by a factor to recognize the frailer and older ESRD population being served by the PACE organization. The PACE program agreement specifies this factor.

(5) HCFA may adjust the monthly capitation amount to take into account other factors HCFA determines to be appropriate.

(6) The monthly capitation payment is a fixed amount, regardless of changes in the participant's health status.

(7) The monthly capitation payment amount is an all-inclusive payment for Medicare benefits provided to participants. A PACE organization must not seek any additional payment from Medicare. The only additional payment that a PACE organization may collect from, or on behalf of, a Medicare participant for PACE services is the following:

(i) Any applicable premium amount specified in § 460.186.

(ii) Any charge permitted under paragraph (d) of this section when Medicare is not the primary payer.

(iii) Any payment from the State, as specified in § 460.182, for a participant who is eligible for both Medicare and Medicaid.

(iv) Payment with respect to any applicable spenddown liability under §§ 435.121 and 435.831 of this chapter and any amount due under the post-eligibility treatment of income process under § 460.184 for a participant who is eligible for both Medicare and Medicaid.

(8) HCFA computes the Medicare monthly capitation payment amount under a PACE program agreement so that the total payment level for all

participants is less than the projected payment under Medicare for a comparable population not enrolled under a PACE program.

(c) *Adjustments to payments.* If the actual number of Medicare participants differs from the estimated number of participants on which the amount of the prospective monthly payment was based, HCFA adjusts subsequent monthly payments to account for the difference.

(d) *Application of Medicare secondary payer provisions.* (1) *Basic rule.* HCFA does not pay for services to the extent that Medicare is not the primary payer under part 411 of this chapter.

(2) *Responsibilities of the PACE organization.* The PACE organization must do the following:

(i) Identify payers that are primary to Medicare under part 411 of this chapter.

(ii) Determine the amounts payable by those payers.

(iii) Coordinate benefits to Medicare participants with the benefits of the primary payers.

(3) *Charges to other entities.* The PACE organization may charge other individuals or entities for PACE services covered under Medicare for which Medicare is not the primary payer, as specified in paragraphs (d)(4) and (5) of this section.

(4) *Charge to other insurers or the participant.* If a Medicare participant receives from a PACE organization covered services that are also covered under State or Federal workers' compensation, any no-fault insurance, or any liability insurance policy or plan, including a self-insured plan, the PACE organization may charge any of the following:

(i) The insurance carrier, the employer, or any other entity that is liable for payment for the services under part 411 of this chapter.

(ii) The Medicare participant, to the extent that he or she has been paid by the carrier, employer, or other entity.

(5) *Charge to group health plan (GHP) or large group health plan (LGHP).* If Medicare is not the primary payer for services that a PACE organization furnished to a Medicare participant who is covered under a GHP or LGHP, the organization may charge the following:

(i) GHP or LGHP for those services.

(ii) Medicare participant to the extent that he or she has been paid by the GHP or LGHP for those services.

§ 460.182 Medicaid payment.

(a) Under a PACE program agreement, the State administering agency makes a prospective monthly payment to the PACE organization of a capitation amount for each Medicaid participant.

(b) The monthly capitation payment amount is negotiated between the PACE organization and the State administering agency, and specified in the PACE program agreement. The amount represents the following:

(1) Is less than the amount that would otherwise have been paid under the State plan if the participants were not enrolled under the PACE program.

(2) Takes into account the comparative frailty of PACE participants.

(3) Is a fixed amount regardless of changes in the participant's health status.

(4) Can be renegotiated on an annual basis.

(c) The PACE organization must accept the capitation payment amount as payment in full for Medicaid participants and may not bill, charge, collect, or receive any other form of payment from the State administering agency or from, or on behalf of, the participant, except as follows:

(1) Payment with respect to any applicable spenddown liability under §§ 435.121 and 435.831 of this chapter and any amounts due under the post-eligibility treatment of income process under § 460.184.

(2) Medicare payment received from HCFA or from other payers, in accordance with § 460.180(d).

(d) State procedures for the enrollment and disenrollment of participants in the State's system, including procedures for any adjustment to account for the difference between the estimated number of participants on which the prospective monthly payment was based and the actual number of participants in that month, are included in the PACE program agreement.

§ 460.184 Post-eligibility treatment of income.

(a) A State may provide for post-eligibility treatment of income for Medicaid participants in the same manner as a State treats post-eligibility income for individuals receiving services under a waiver under section 1915(c) of the Act.

(b) Post-eligibility treatment of income is applied as it is under a waiver of section 1915(c) of the Act, as specified in §§ 435.726 and 435.735 of this chapter, and section 1924 of the Act.

§ 460.186 PACE premiums.

The amount that a PACE organization can charge a participant as a monthly premium depends on the participant's eligibility under Medicare and Medicaid, as follows:

(a) *Medicare Parts A and B.* For a participant who is entitled to Medicare Part A, enrolled under Medicare Part B, but not eligible for Medicaid, the premium equals the Medicaid capitation amount.

(b) *Medicare Part A only.* For a participant who is entitled to Medicare Part A, not enrolled under Medicare Part B, and not eligible for Medicaid, the premium equals the Medicaid capitation amount plus the Medicare Part B capitation rate.

(c) *Medicare Part B only.* For a participant who is enrolled only under Medicare Part B and not eligible for Medicaid, the premium equals the Medicaid capitation amount plus the Medicare Part A capitation rate.

(d) *Medicaid, with or without Medicare.* A PACE organization may not charge a premium to a participant who is eligible for both Medicare and Medicaid, or who is only eligible for Medicaid.

Subpart K—Federal/State Monitoring

§ 460.190 Monitoring during trial period.

(a) *Trial period review.* During the trial period, HCFA, in cooperation with the State administering agency, conducts comprehensive annual reviews of the operations of a PACE organization to ensure compliance with the requirements of this part.

(b) *Scope of review.* The review includes the following:

(1) An onsite visit to the PACE organization, which may include, but is not limited to, the following:

(i) Review of participants' charts.

(ii) Interviews with staff.

(iii) Interviews with participants and caregivers.

(iv) Interviews with contractors.

(v) Observation of program operations, including marketing, participant services, enrollment and disenrollment procedures, grievances, and appeals.

(2) A comprehensive assessment of an organization's fiscal soundness.

(3) A comprehensive assessment of the organization's capacity to furnish all PACE services to all participants.

(4) Any other elements that HCFA or the State administering agency find necessary.

§ 460.192 Ongoing monitoring after trial period.

(a) At the conclusion of the trial period, HCFA, in cooperation with the State administering agency, continues to conduct reviews of a PACE organization, as appropriate, taking into account the quality of care furnished and the organization's compliance with all of the requirements of this part.

(b) Reviews include an on-site visit at least every 2 years.

§ 460.194 Corrective action.

(a) A PACE organization must take action to correct deficiencies identified during reviews.

(b) HCFA or the State administering agency monitors the effectiveness of corrective actions.

(c) Failure to correct deficiencies may result in sanctions or termination, as specified in subpart D of this part.

§ 460.196 Disclosure of review results.

(a) HCFA and the State administering agency promptly report the results of reviews under §§ 460.190 and 460.192 to the PACE organization, along with any recommendations for changes to the organization's program.

(b) HCFA and the State administering agency make the results of reviews available to the public upon request.

(c) The PACE organization must post a notice of the availability of the results of the most recent review and any plans of correction or responses related to the most recent review.

(d) The PACE organization must make the review results available for examination in a place readily accessible to participants.

Subpart L—Data Collection, Record Maintenance, and Reporting

§ 460.200 Maintenance of records and reporting of data.

(a) *General rule.* A PACE organization must collect data, maintain records, and submit reports as required by HCFA and the State administering agency.

(b) *Access to data and records.* A PACE organization must allow HCFA and the State administering agency access to data and records including, but not limited to, the following:

(1) Participant health outcomes data.

(2) Financial books and records.

(3) Medical records.

(4) Personnel records.

(c) *Reporting.* A PACE organization must submit to HCFA and the State administering agency all reports that HCFA and the State administering agency require to monitor the operation, cost, quality, and effectiveness of the program and establish payment rates.

(d) *Safeguarding data and records.* A PACE organization must establish written policies and implement procedures to safeguard all data, books, and records against loss, destruction, unauthorized use, or inappropriate alteration.

(e) *Confidentiality of health information.* A PACE organization must establish written policies and

implement procedures to do the following:

(1) Safeguard the privacy of any information that identifies a particular participant. Information from, or copies of, records may be released only to authorized individuals. Original medical records are released only in accordance with Federal or State laws, court orders, or subpoenas.

(2) Maintain complete records and relevant information in an accurate and timely manner.

(3) Grant each participant timely access, upon request, to review and copy his or her own medical records and to request amendments to those records.

(4) Abide by all Federal and State laws regarding confidentiality and disclosure for mental health records, medical records, and other participant health information.

(f) *Retention of records.* (1) A PACE organization must retain records for the longest of the following periods:

(i) The period of time specified in State law.

(ii) Six years from the last entry date.

(iii) For medical records of disenrolled participants, 6 years after the date of disenrollment.

(2) 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.

§ 460.202 Participant health outcomes data.

(a) A PACE organization must establish and maintain a health information system that collects, analyzes, integrates, and reports data necessary to measure the organization's performance, including outcomes of care furnished to participants.

(b) A PACE organization must furnish data and information pertaining to its provision of participant care in the manner, and at the time intervals, specified by HCFA and the State administering agency. The items collected are specified in the PACE program agreement.

§ 460.204 Financial recordkeeping and reporting requirements.

(a) *Accurate reports.* A PACE organization must provide HCFA and the State administering agency with accurate financial reports that are—

(1) Prepared using an accrual basis of accounting; and

(2) Verifiable by qualified auditors.

(b) *Accrual accounting.* A PACE organization must maintain an accrual accounting recordkeeping system that does the following:

(1) Accurately documents all financial transactions.

(2) Provides an audit trail to source documents.

(3) Generates financial statements.

(c) *Accepted reporting practices.* Except as specified under Medicare principles of reimbursement, as defined in part 413 of this chapter, a PACE organization must follow standardized definitions, accounting, statistical, and reporting practices that are widely accepted in the health care industry.

(d) *Audit or inspection.* A PACE organization must permit HCFA and the State administering agency to audit or inspect any books and records of original entry that pertain to the following:

(1) Any aspect of services furnished.

(2) Reconciliation of participants' benefit liabilities.

(3) Determination of Medicare and Medicaid amounts payable.

§ 460.208 Financial statements.

(a) *General rule.* (1) Not later than 180 days after the organization's fiscal year ends, a PACE organization must submit a certified financial statement that includes appropriate footnotes.

(2) The financial statement must be certified by an independent certified public accountant.

(b) *Contents.* At a minimum, the certified financial statement must consist of the following:

(1) A certification statement.

(2) A balance sheet.

(3) A statement of revenues and expenses.

(4) A source and use of funds statement.

(c) *Quarterly financial statement*—(1) *During trial period.* A PACE organization must submit a quarterly financial statement throughout the trial period within 45 days after the last day of each quarter of the PACE organization's fiscal year.

(2) *After trial period.* If HCFA or the State administering agency determines that an organization's performance requires more frequent monitoring and oversight due to concerns about fiscal soundness, HCFA or the State administering agency may require a PACE organization to submit monthly or quarterly financial statements, or both.

§ 460.210 Medical records.

(a) *Maintenance of medical records.*

(1) A PACE organization must maintain a single, comprehensive medical record

for each participant, in accordance with accepted professional standards.

(2) The medical record for each participant must meet the following requirements:

(i) Be complete.

(ii) Accurately documented.

(iii) Readily accessible.

(iv) Systematically organized.

(v) Available to all staff.

(vi) Maintained and housed at the PACE center where the participant receives services.

(b) *Content of medical records.* At a minimum, the medical record must contain the following:

(1) Appropriate identifying information.

(2) Documentation of all services furnished, including the following:

(i) A summary of emergency care and other inpatient or long-term care services.

(ii) Services furnished by employees of the PACE center.

(iii) Services furnished by contractors and their reports.

(3) Multidisciplinary assessments, reassessments, plans of care, treatment, and progress notes that include the participant's response to treatment.

(4) Laboratory, radiological and other test reports.

(5) Medication records.

(6) Hospital discharge summaries, if applicable.

(7) Reports of contact with informal support (for example, caregiver, legal guardian, or next of kin).

(8) Enrollment Agreement.

(9) Physician orders.

(10) Discharge summary and disenrollment justification, if applicable.

(11) Advance directives, if applicable.

(12) A signed release permitting disclosure of personal information.

(13) Accident and incident reports.

(c) *Transfer of medical records.* The organization must promptly transfer copies of medical record information between treatment facilities.

(d) *Authentication of medical records.* (1) All entries must be legible, clear, complete, and appropriately authenticated and dated.

(2) Authentication must include signatures or a secured computer entry by a unique identifier of the primary author who has reviewed and approved the entry.

(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: May 6, 1999.

Nancy-Ann DeParle,
Administrator, Health Care Financing
Administration.

Approved: July 8, 1999.

Donna E. Shalala,
Secretary.

Note: This Addendum A will not appear in the Code of Federal Regulations.

Addendum A

PACE Protocol

Overview

The following document describes the minimum requirements for PACE (Program of All-inclusive Care for the Elderly) providers as well as core operational procedures and processes. This definition document, the PACE Protocol, was first developed in 1990 as part of a cooperative effort involving staff from Health Care Financing Administration's (HCFA) Office of Research and Demonstrations, states participating in the PACE replication, and PACE sites, including On Lok Senior Health Services.

Originally authorized by Congress in 1986, the PACE demonstration was designed to determine if the community-based long term care model developed by On Lok Senior Health Services in San Francisco, California could be replicated. Since 1990, ten sites have successfully implemented PACE. For those sites, the protocol served as the specific legal instrument for implementation of the demonstration and the regulatory framework for operations in the absence of formal regulation.

In preparation for moving PACE beyond demonstration status, a work group comprised of PACE site representatives began the process of updating the protocol in December 1993 to incorporate the experience existing PACE providers have had in implementation. With comments from HCFA and State Medicaid agency representatives, the document has now been finalized and is intended to serve as the basic standard for PACE providers.

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Introduction

This document describes the minimum requirements for PACE (Program of All-inclusive Care for the Elderly) providers as well as core operational procedures and processes. The requirements outlined are applicable to PACE providers in varying degree depending upon whether the provider is in its initial trial period, as defined below, or if it has completed that period and attained permanent provider status. It is intended that this document outline the basic standards for PACE providers except as may be subsequently modified by law or regulation.

Definitions

1. *PACE provider:* In this document, the term "PACE provider" means a private not-for-profit or public entity (or a distinct part of such an entity) which:

(a) is primarily engaged in providing participants a comprehensive range of acute and long-term care services as described in Part IV. of this document; and

(b) meets the requirements defined in this document and includes PACE providers with permanent status and PACE providers in the trial period.

2. *Trial Period:* A period of up to three years in length during which the PACE provider meets all the requirements in operating a PACE program except that financial risk is shared between the provider and the federal and state governments based on the arrangement developed by HCFA. At the conclusion of this period, providers may opt for permanent provider status under Medicare and Medicaid.

3. *Participant:* An individual who meets the eligibility requirements outlined in Part II and enrolls in a PACE program as described. This individual may also be called an enrollee.

4. *Contract:* In this document, contract, when referring to the contract between the PACE provider and the federal and state governments, may be in the form of a cooperative agreement or a contract.

Part I. Organization

A. Philosophy Statement

The PACE provider must include in its mission statement or philosophy statement the following values:

1. To enhance the quality of life and autonomy for frail, older adults;
2. To maximize dignity and respect of older adults;
3. To enable frail, older adults to live in their homes and in the community as long as medically and socially feasible; and
4. To preserve and support the older adult's family unit.

B. Organizational Structure

1. The PACE provider must be a public or private not-for-profit 501(c)(3) organization and may meet this requirement in any of the following ways:

- a. A free-standing 501(c)(3) corporation;
- b. A 501(c)(3) subsidiary of a larger organization;
- c. A department of a 501(c)(3) corporation;

or

d. Governmental entities at the city, county, or state level.

2. As a community-based model of care, the PACE provider must ensure that community representation is provided on issues of program management and participant care. This representation may be achieved through participation on the board of the PACE provider or through advisory committees.

3. The PACE provider must make available a current organizational chart displaying corporate officers and relationships to any parent or other corporate subsidiaries or affiliates, and indicating the PACE provider's relationship to the corporate board. A PACE provider considering a change in organizational structure must notify HCFA and the State Medicaid agency at least 60 days before the anticipated change. Changes must be approved by Health Care Financing Administration (HCFA) and the State Medicaid agency.

C. Organizational Requirements

The PACE provider shall have the organizational, administrative and service delivery ability to effectively organize and guide operations and meet the contractual obligations which include, but are not limited to:

1. A policymaking body which oversees operations and devotes resources sufficient to effectively plan, organize, administer and evaluate the PACE provider's operation;
2. Ability to provide the complete PACE service package, including the full scope of Medicare and Medicaid benefits on a capitation basis regardless of the frequency, extent, or level of services provided to any participant;
3. Project Director whose responsibilities and duties are described in writing;
4. Medical Director whose responsibilities and duties are defined in writing;
5. Staff to directly provide PACE Center services, including primary medical care;
6. A standing multidisciplinary team based in the PACE Center composed of medical and health-related professionals and para-professionals, all of whom meet applicable

state licensing and certification requirements and who provide direct care and services appropriate to participant need;

7. Demonstrated separation of medical, social and supportive services from fiscal and administrative management sufficient to assure that medical decisions will not be unduly influenced by fiscal and administrative management;

8. Staff to maintain financial records and books of accounts on an accrual basis;

9. Staff to report data required for management, as well as the Federal and State governments;

10. Facilities and equipment that meet applicable State requirements;

11. A system for informing employees and contract providers about all relevant provider requirements including coverage and appeal procedures.

D. Service Area

The PACE provider must serve a defined service area identified by county, zip code and street boundaries. Changes in the service area must be pre-approved by HCFA and the State Medicaid Agency.

E. Conflict of Interest

1. The PACE provider must not have any agents or management staff who have been convicted of criminal offenses related to their involvement in Medicaid, Medicare and/or other health insurance and health care programs.

2. No member of the PACE provider's policymaking body or any immediate family member thereof shall have any direct or indirect interest in any contract for supplying service or materials to the PACE provider.

F. Fiscal Soundness

1. During the trial period, the PACE provider must prepare an annual budget by month or by quarter that is acceptable to HCFA and the State Medicaid agency. The budget shall be based on the cost center accounting structure provided by HCFA and the State Medicaid agency.

The provider must have an insolvency plan approved by HCFA and the State Medicaid agency, which in the event of insolvency, provides for:

a. The continuation of benefits for the duration of the contract period for which capitation payment has been made;

b. The continuation of benefits to participants who are confined in a hospital on the date of insolvency until their discharge; and

c. Arrangements to protect participants from incurring liability for payment of any fees which are the legal obligation of the PACE provider.

2. By the end of the trial period, each PACE provider shall 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, a net operating surplus and a plan for handling insolvency that includes the provisions listed as 1.a-c. above.

Furthermore, the PACE program must demonstrate that it has arrangements in place in the amount of at least the sum of the following to cover expenses in the event it becomes insolvent:

a. One month's total capitation revenue to cover expenses the month prior to insolvency; and

b. One month's average payment to subcontractors, including providers of emergency services, to cover potential expenses the month after the date insolvency has been declared or operations cease.

Arrangements to cover expenses may include but are not limited to: Insolvency insurance, hold harmless arrangement, continuation of benefits provisions, letters of credit, guarantees, net worth, restricted state reserves, state law provisions.

3. Providers are required to submit financial reports as specified in their contracts with HCFA and the State Medicaid agency.

Part II: Participant Rights

A. Participant Bill of Rights

The PACE provider has a formal Participant Bill of Rights designed to protect and promote the rights of each participant to be treated with dignity and respect.

1. These rights, which may be exercised by the participant or his/her representative, if necessary, include the rights:

a. To have the "Enrollment Agreement" fully discussed and explained;

b. To be fully informed in writing prior to and at the time of enrollment (as well as during participation) of the services available from the PACE provider;

c. To be fully informed of rights and responsibilities as a participant and/or all rules and regulations governing participation;

d. To be encouraged and assisted to exercise rights as a participant, as well as civil and legal rights.

e. To be encouraged and assisted to voice grievances and recommend changes in policies and services to PACE staff and outside representatives of his/her choice.

There will be no restraint, interference, coercion, discrimination or reprisal by the PACE staff towards participants exercising this right;

f. To be fully informed by the multidisciplinary team of health and functional status;

g. To participate in the development and implementation of the treatment plan designed to promote functional ability to the optimal level and to encourage independence;

h. To receive treatment and rehabilitative services;

i. To have dignity, privacy, and humane care;

j. To be free from harm, including unnecessary physical restraint or isolation, excessive medication, physical or mental abuse or neglect;

k. To be free from hazardous procedures;

l. Not to be required to perform services for the provider that are not included for therapeutic purposes in the individual treatment plan;

m. To be given reasonable advance notice of any transfer to another part of the program for medical reasons or for the participant's welfare or that of other participants. Such actions will be documented in the health record;

n. To have reasonable access to telephones;

o. To be assured of confidential treatment of all information contained in the health record, including information contained in any automated data bank. Written consent is required for the release of information to persons not otherwise authorized under law to receive it. Participants may provide written consent which limits the degree of information and the persons to whom information may be given;

p. To refuse treatment and be informed of the consequences of such refusal;

q. To disenroll from the program at any time subject to the terms of this agreement; and

r. To establish advance directives and make health care decisions.

2. Written policies or established procedures identify mechanisms for ensuring that the participant and family members understand their rights including items listed above.

a. Staff must orally review the Participant Bill of Rights with the participant and family at enrollment in a language understood by the participant. A copy of the Bill of Rights is included in the member handbook given to participants at enrollment.

b. Participant rights must be posted in a prominent place in the PACE center in English and any other predominant language of the community.

B. Complaints, Grievances and Appeals

The PACE provider must have internal procedures, approved by HCFA and the State Medicaid agency, which provide participants and their family members a process for expressing dissatisfaction with the services provided by PACE, whether medical or non-medical in nature, and which allow for orderly resolution of any complaint or grievance. Furthermore, all involuntary disenrollments, other than those resulting from participants moving out of the PACE provider's geographic catchment area, are considered participant grievances and are subject to these procedures.

1. The PACE provider must have written internal grievance procedures which describe the process by which participants can make appeals, and give the time frames for the PACE provider's response to participants.

2. The PACE provider must inform all participants of the grievance procedures in writing (i.e., in member handbooks).

3. In cases where grievances are not resolved to the participant's satisfaction (e.g., denial of payment for claim or refusal of services), the PACE provider must state the specific reasons for its determination and inform the participant of his/her right to appeal. The PACE provider must process grievances in a timely manner.

4. Reconsideration of grievances must be made by a person or persons who were not involved in making the initial determination. The PACE provider must give the parties to the reconsideration reasonable opportunity to present evidence related to the issue in dispute, in person as well as in writing.

5. All determinations that are wholly or partially adverse to the participant must be forwarded to HCFA and the State Medicaid agency. If on appeal a judgment is made in favor of the participant, the PACE provider

must take appropriate action in a timely manner.

Part III: Eligibility, Enrollment, Disenrollment

A. Eligibility

1. To be eligible for enrollment in PACE, an individual must be:

- a. At least fifty-five years of age;
- b. A resident in the PACE provider's service area;
- c. Assessed by the PACE provider's multidisciplinary team; and
- d. Certified by the State Medicaid Agency as eligible for nursing home level of care.

2. The contracts between the PACE provider, HCFA and the State Medicaid agency will include site-specific eligibility criteria including minimum age limit, service area and health status requirements of the State Medicaid agency for nursing home level of care.

3. The PACE provider may choose not to enroll participants whose condition is such at the point of enrollment that their health and safety would be jeopardized by remaining in their home and community.

B. Marketing

1. *Marketing Activities.* The PACE provider may inform the general public of its program through appropriate activities and media. The PACE provider must ensure that prohibited marketing activities are not conducted by its employees or its agents. Prohibited practices are:

- a. Discrimination of any kind aside from PACE eligibility requirements;
- b. Activities that could mislead or confuse potential participants, or misrepresent the PACE provider, HCFA or the State Medicaid agency;
- c. Gifts or payments to induce enrollment; and
- d. Subcontracting outreach efforts to individuals or organizations whose sole responsibility involves direct contact with elderly to solicit enrollment.

2. *Marketing Materials.* a. The PACE provider must provide prospective participants adequate written descriptions of the PACE provider's enrollment requirements, procedures, benefits, fees and other charges, services and other information necessary for prospective participants to make an informed decision about enrollment.

b. All written marketing information distributed to PACE participants to encourage or prolong enrollment must be approved by HCFA, the State Medicaid agency, and other agencies, if required. Approval or denial shall be granted in 30 days. No response in 30 days constitutes approval.

Distribution of marketing materials before HCFA and the State Medicaid agency approval or expiration of the 30 day period is prohibited.

c. Marketing and enrollment materials which must be approved include, but are not limited to, marketing brochures, enrollment agreement, member handbook, and disenrollment forms.

3. *Marketing Plan.* The PACE provider shall have an active marketing plan, with measurable enrollment objectives and a system for tracking its effectiveness.

C. Enrollment

1. Participants enrolled in PACE must accept PACE as his/her sole service provider and its multidisciplinary team as his/her sole case manager (the "lock-in" provision).

2. Following referral to the program, PACE provider staff schedule a screening visit with the potential participant and/or his/her significant others or legal guardians to explain:

- a. PACE;
 - b. the "lock-in" provision; and
 - c. monthly fees, if any.
3. Following this explanation, the potential participant must sign a release of his/her medical and financial information.

4. The potential participant is assessed by the PACE provider to determine eligibility.

5. All participants, including Medicare-only eligibles, shall be reviewed by the State Medicaid agency for a one-time only certification at enrollment that the participant meets State Medicaid health status requirements for nursing home level of care. Procedures for enrollment, including level of care certification, shall be included in the contract between HCFA and the State Medicaid agency.

6. If the potential participant is certified as nursing home eligible and is willing to join PACE, he/she must sign an Enrollment Agreement which contains the following information:

- a. Applicant's name, sex, date of birth, health insurance claim numbers, Medicare eligibility status (Part A and/or Part B) and number, Medicaid number or none;
- b. Description of benefits available, including all Medicare and Medicaid covered services, and how services are allocated or can be obtained from the PACE provider;
- c. Explanation of participant premiums and procedures for payment, if any;
- d. Effective date of enrollment;
- e. Explanation of participant rights, grievance procedures, conditions for enrollment and disenrollment and Medicare and Medicaid contacts in appeal situations;
- f. Notification of participant's obligation to notify PACE provider of a move or absence from the provider's service area;
- g. Explanation of the "lock-in" requirement and an acknowledgment on the part of the applicant that he/she understands that all services must be received through the PACE provider;
- h. Explanation of procedures for obtaining emergency services and urgent care;
- i. Requirement to maintain their own Medicare and Medicaid eligibility including Medicare Part B eligibility through the payment of required premiums;
- j. Statement that the private premium can only be raised once a year;
- k. Statement that PACE provider has a contract with HCFA and the State Medicaid agency which is subject to renewal on a periodic basis and failure of the PACE provider to renew the contract will result in termination of enrollment in the program;
- l. Explanation that the Medicare member may not disenroll from PACE at a social security office; and
- m. Explanation that enrollment in PACE will result in automatic disenrollment from any other Medicare or Medicaid prepayment health plan;

n. Applicant's authorization for the disclosure and exchange of information between HCFA, its agent, the State Medicaid agency and the PACE provider;

o. Applicant's signature and date.

7. The participant's enrollment in the program is effective the first day of the calendar month following the signing date of the Enrollment Agreement.

8. Once the participant signs the Enrollment Agreement, he/she is given:

- a. A copy of the Enrollment Agreement;
- b. The Member Handbook (Combined Contract and Evidence of Coverage), if different from the Enrollment Agreement;
- c. A PACE membership card;
- d. An emergency sticker to be posted in his/her home in case of emergency; and
- e. A sticker for his/her Medicare card and, if applicable, a Medicaid card which indicates that he/she is a PACE participant.

9. The PACE provider will submit enrollment documents to HCFA and the State Medicaid agency in accordance with established procedures.

10. Enrollment continues as long as desired by the participant, regardless of changes in health status, until death, voluntary disenrollment, or involuntary disenrollment as described in Section D.

11. If, after complete assessment by the multidisciplinary team, a prospective participant is denied enrollment based on Part III, Section A.3., the PACE provider shall provide written notification explaining the reason for denial and refer the individual to alternative services as appropriate.

D. Disenrollment Process

1. A PACE participant may either voluntarily or involuntarily disenroll from the program. A participant may be involuntarily disenrolled if he/she:

- a. Moves out of the PACE program service area;
- b. Is a person with decision making capacity who consistently does not comply with his/her individual plan of care and poses a significant risk to him/herself or others;
- c. Experiences a breakdown in the physician and/or team-participant relationship such that the PACE provider's ability to furnish services to either the participant or other participants is seriously impaired;
- d. Refuses services and/or is unwilling to meet conditions of participation as they appear in the Enrollment Agreement;
- e. Refuses to provide accurate financial information, provides false information or illegally transfers assets;
- f. Fails to pay or to make satisfactory arrangements to pay any amount due the PACE provider after a 30-day grace period;
- g. Is out of the PACE provider service area for more than 30 days (unless other arrangements have been made); or
- h. Is enrolled in a PACE program that loses its contracts and/or licenses enabling it to offer health care services.

2. For voluntary disenrollments, the PACE provider shall use the most expedient process allowed for by Medicare and Medicaid procedures while ensuring a coordinated disenrollment date. The PACE provider disenrollment procedures shall be

included in the contracts with HCFA and the State Medicaid agency. Until enrollment is terminated, PACE participants are required to continue using the PACE provider services and remain liable for any premiums. The PACE provider shall continue to provide all needed services until the date of termination.

3. To facilitate a participant's reinstatement in the fee-for-service system, the PACE provider must:

a. Assist a participant who wishes to return to the fee-for-service system by making appropriate referrals and by making medical records available to new providers; and

b. Work with HCFA and the State Medicaid agency to reinstate his/her benefits in the fee-for-service system.

4. Renewal provisions. a. If the reason for disenrollment is due to failure to pay, payment of the monthly fee before the end of the month of disenrollment will result in reinstatement as of the first day of succeeding month. b. In the case of a voluntary disenrollment, a one time only reinstatement will be allowed if the participant meets eligibility criteria.

5. All voluntary and involuntary disenrollments must be documented and available for review by HCFA and the State Medicaid agency.

Part IV: Service Coverage and Arrangement

A. Service Coverage

1. The PACE service package includes, but is not limited to, all current Medicare and Medicaid services. All usual limitations and conditions for covered services are waived.

2. The PACE provider must provide its participants with access to medical care and other services, as applicable, 24 hours per day, 7 days a week, 365 days per year.

3. At a minimum each PACE provider shall provide the following services:

a. Multidisciplinary assessment and treatment planning;

b. Primary care services including physician and nursing services;

c. Social work services;

d. Restorative therapies, including physical therapy, occupational therapy and speech therapy;

e. Personal care and supportive services;

f. Nutritional counseling;

g. Recreational therapy;

h. Transportation;

i. Meals;

j. Medical specialty services including, but not limited to: anesthesiology, audiology, cardiology, dentistry, dermatology, gastroenterology, gynecology, internal medicine, nephrology, neurosurgery, oncology, ophthalmology, oral surgery, orthopedic surgery, otorhinolaryngology, plastic surgery, pharmacy consulting services, podiatry, psychiatry, pulmonary disease, radiology, rheumatology, surgery, thoracic and vascular surgery, urology;

k. Laboratory tests, x-rays and other diagnostic procedures;

l. Drugs and biologicals;

m. Prosthetics and durable medical equipment, corrective vision devices such as eyeglasses and lenses, hearing aids, dentures, and repairs and maintenance for these items;

n. Acute inpatient care:

i. Ambulance;

ii. Emergency room care and treatment room services;

iii. Semi-private room and board;

iv. General medical and nursing services;

v. Medical surgical/intensive care/coronary care unit, as necessary;

vi. Laboratory tests, x-rays and other diagnostic procedures;

vii. Drugs and biologicals;

viii. Blood and blood derivatives;

ix. Surgical care, including the use of anesthesia;

x. Use of oxygen;

xi. Physical, speech, occupational, and respiratory therapies; and

xii. Social services.

o. Nursing facility care:

i. Semi-private room and board;

ii. Physician and skilled nursing services;

iii. Custodial care;

iv. Personal care and assistance;

v. Drugs and biologicals;

vi. Physical, speech, occupational, and recreational therapies, if necessary;

vii. Social services; and

viii. Medical supplies and appliances.

p. Additional services determined necessary by the multidisciplinary team.

4. Emergency Care. Emergency services are defined as covered inpatient or outpatient services that are furnished in or out of the PACE provider's service area by a source other than the PACE provider or its contract providers and:

a. Are needed immediately because of an injury or sudden illness; and

b. The time required to reach the PACE provider staff and/or contract providers would have meant risk of permanent damage to the participant's health.

5. Urgent Care. Urgently needed services are covered services required in order to prevent a serious deterioration of a participant's health that results from an unforeseen illness or injury if:

a. The participant is temporarily absent from the provider's service area; and

b. The receipt of health care services cannot be delayed until the participant returns to the provider's service area.

6. Excluded services are:

a. Any service which has not been authorized by the multidisciplinary team, even if it is listed as a covered benefit;

b. Services rendered in a non-emergency setting or for a non-emergency reason without authorization;

c. Prescription and over-the-counter drugs not prescribed by the PACE provider physician;

d. In inpatient facilities, private room and private duty nursing, unless medically necessary, and non-medical items for personal convenience such as telephone charges, radio or television rental;

e. Cosmetic surgery unless required for improved functioning of a malformed part of the body resulting from an accidental injury or for reconstruction following mastectomy;

f. Experimental medical, surgical or other health procedures or procedures not generally available;

g. Care in a government hospital (VA, federal/State hospital) unless authorized;

h. Service in any county hospital for the treatment of tuberculosis or chronic,

medically uncomplicated drug dependency or alcoholism; and

i. Any services rendered outside of the United States.

B. Service Arrangement

1. PACE is a comprehensive health and social services delivery system which integrates acute and long-term care services. The PACE staff provides these services in all settings which may include, but are not limited to, the PACE Center, the home, and inpatient facilities.

2. 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.

a. At a minimum, the following services are provided in the PACE Center:

i. Primary care services including physician and nursing services;

ii. Social services;

iii. Restorative therapies, including physical therapy and occupational therapy;

iv. Personal care and supportive services;

v. Nutritional counseling;

vi. Recreational therapy; and

vii. Meals.

b. The PACE provider must operate at least one PACE Center in its defined service area with sufficient capacity to allow routine attendance by its enrolled population.

c. The frequency of attendance is determined by the multidisciplinary team based on each participant's needs.

d. 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.

3. Each participant is assigned a multidisciplinary team based at the PACE Center. Responsibility for assessment, treatment planning and care delivery rests with the multidisciplinary team which coordinates and delivers care on a 24-hour basis. The multidisciplinary team is composed of at least the following members:

a. Primary care physician;

b. Nurse;

c. Social worker;

d. Physical therapist;

e. Occupational therapist;

f. Recreational therapist or activity coordinator;

g. Dietitian;

h. PACE Center supervisor;

i. Home care liaison;

j. Health workers/aides or their representatives; and

k. Drivers or their representatives.

4. The multidisciplinary team authorizes PACE covered services which meet the specific needs of the participant.

5. As part of the initial assessment process, the following members of the multidisciplinary team conduct individual, in-person assessments of the participant's health and social status and develop discipline specific treatment plans which are documented in the participant's medical record:

a. Primary care physician;

b. Nurse;

c. Social worker;

d. Physical therapist and/or occupational therapist;

e. Recreational therapist or activity coordinator;

f. Dietitian; and

g. Home care liaison.

6. On at least a semi-annual basis, the following members of the multidisciplinary team conduct individual, in-person assessments of the participant's health and social status and develop discipline specific treatment plans which are documented in the participant's medical record:

a. Primary care physician;

b. Nurse;

c. Social worker;

d. Recreational therapist or activity coordinator; and

e. Team members actively involved in the plan of care, *i.e.*, home care liaison, physical therapist, occupational therapist, dietitian.

7. On at least an annual basis, the following members of the multidisciplinary team conduct individual, in-person assessments of the participant's health and social status and develop discipline specific treatment plans which are documented in the participant's medical record:

a. Physical therapist and/or occupational therapist;

b. Dietitian; and

c. Home care liaison.

8. The treatment planning process consists of the following:

a. On at least a semi-annual basis, the discipline specific plans are consolidated into a single plan of care for the participant through discussion and consensus of the entire multidisciplinary team, including members (e.g., health workers/aides, drivers, PACE Center supervisor) who are not required to conduct quarterly assessments. The treatment plan is then discussed and finalized with the participant and/or his/her significant others.

b. At the recommendation of individual team members, other professional disciplines (e.g., speech therapy, dentistry, audiology, *etc.*) can be included in the assessment and treatment planning process.

9. When the health status or psycho-social situation of a participant changes, he/she is reassessed by the team or by selected members of the team to develop a new treatment plan. Changes in the treatment plan during the quarter are discussed and approved by the multidisciplinary team.

10. Ultimate responsibility for management of medical situations rests with the PACE primary care physician. The physician keeps the multidisciplinary team informed of the medical condition of each participant and remains alert to pertinent input from other team members.

11. The team implements the treatment plan by providing services directly and supervising the delivery of services provided by contract providers.

12. The participant's health status and psycho-social conditions as well as the effectiveness of the treatment plan are monitored continuously through direct provision of services, informal observation, input from participants and their significant others, and communications among members of the multidisciplinary team and other providers.

13. The multidisciplinary team is instrumental in controlling the delivery, quality and continuity of care.

a. The following members of the team must be employees of the PACE provider or PACE Center:

i. Primary care physician;

ii. Nurse;

iii. Social worker;

iv. Recreational therapist or activity coordinator;

v. PACE Center supervisor;

vi. Home care liaison; and

vii. PACE Center health workers/aides.

b. The members of the multidisciplinary team must serve primarily PACE participants.

c. The effective delivery of services depends on a consistent multidisciplinary team whose members are knowledgeable of individual participant's needs.

14. The PACE provider must ensure accessible and adequate service capacity to meet the needs of the enrolled population. As enrollment increases, the number of PACE Centers, multidisciplinary teams and other PACE services must increase accordingly.

15. Primary medical care is provided by the PACE primary care physician(s) to all participants. The primary care physician is the gatekeeper to the participant's use of medical specialists and inpatient care and is an integral member of the multidisciplinary team.

16. Since PACE services may be provided in the home, the coordination of in-home services with PACE Center and primary care services is critical to effective service delivery. The PACE provider shall designate a home care liaison to supervise and coordinate home care services whether these services are provided directly by the PACE provider or through a contract vendor.

17. All other PACE covered services can be provided either directly or on a contractual basis with related or unrelated organizations, agencies, or providers.

18. Medical Records. a. To facilitate continuity of care, the PACE provider must maintain a single comprehensive medical record for each participant at the PACE Center which contains:

i. Appropriate identifying information

ii. Documentation of all services provided;

iii. Multidisciplinary assessments, reassessments, plans of care, treatment and progress notes, signed and dated;

iv. Lab reports;

v. Medications record;

vi. Hospital discharge summaries;

vii. Reports from contracted providers;

viii. Contacts with informal support;

ix. Enrollment Agreements;

x. Physician orders.

xi. Discharge summary and disenrollment agreement, if applicable;

xii. Information on advance directives; and

xiii. Disclosure of release of information.

b. Chart organization and documentation shall meet professional and other applicable requirements.

c. Policies to ensure confidentiality, storage and retention must be in place in accordance with professional and other applicable requirements.

19. Program Flexibility. At the request of a PACE provider, HCFA and the State

Medicaid agency shall have the authority to waive specific requirements in this Section provided that in their judgment, the intent of the requirement is met by the proposed alternative, and safe and quality care will be provided. Such requests must be submitted in writing by the PACE provider and be approved by HCFA and the State Medicaid agency prior to implementation of the proposed alternative.

Part V: Quality Assurance

A. The PACE multidisciplinary team is a critical element of quality assurance. The process of service delivery in this model requires the team to identify participant problems, determine appropriate treatment objectives, select interventions and evaluate efficiencies of care on an individual participant basis. This activity becomes the foundation for all subsequent quality assurance activities.

B. The PACE provider must have a written plan of Quality Assurance and Improvement which provides for a system of ongoing assessment, implementation, evaluation, and revision of activities related to overall program administration and services. The plan should include, at the minimum, the following essential elements:

1. Standards that are performance benchmarks, established by the provider, and are incorporated into the provider Policy and Procedure Manual. The provider standards must be based on the PACE protocol, applicable PACE standards and applicable licensing and certification criteria.

2. Goals and objectives that provide a framework for quality improvement activities, evaluation and corrective action. These goals and objectives will be reviewed periodically.

3. Quality indicators that are objective and measurable variables related to the entire range of services provided by the PACE provider. The methodology should assure that all demographic groups, all care settings (e.g., inpatient, PACE Center and in-home) will be included in the scope of the quality assurance review.

Quality indicators should be selected for review on the basis of high volume, high risk diagnosis or procedure, adverse outcomes, or some other problem-focused method consistent with the state of the art.

4. Process to review the effectiveness of the PACE multidisciplinary team in its ability to assess participant's care needs, identify the participant's treatment goals, assess effectiveness of interventions, evaluate adequacy and appropriateness of service utilization and reorganize plan as necessary.

5. Policies and procedures related to establishing committees with community input to (1) evaluate data collected pertaining to quality indicators, (2) address the process and outcomes of the quality improvement plan, and (3) provide input related to ethical decision making including end-of-life issues and implementation of the Patient Self-Determination Act (PSDA).

a. These procedures will define a process for taking appropriate action to resolve problems identified as part the quality assurance activities.

b. Policies will be established that define professional qualifications of individuals participating on these committees.

6. Participant involvement in program QA plan and evaluation of satisfaction with services.

7. Board level accountability for overall oversight of program activities and review of the QA plan, annual review and approval of the quality assurance plan by the program board with periodic feedback to Board on review process by oversight committees.

8. The PACE provider shall designate an individual to coordinate and oversee implementation of quality assurance activities.

Part VI: Reimbursement

A. PACE Reimbursement Overview

PACE is not limited to individuals on the basis of their eligibility for Medicare and/or Medicaid. The majority of PACE participants are eligible for Medicare, however, because PACE enrolls an elderly population. Medicaid eligibility is also common just as it is in a nursing home population. As financing for long-term care services becomes more widely available, PACE providers will negotiate capitation payments from payers of those services.

B. Medicare Payment

1. For a Medicare entitled participant, the monthly capitation rate paid by HCFA to the PACE provider equals the Adjusted Average Per Capita Cost (AAPCC) as calculated by HCFA for HMO reimbursement with adjustment for frailty factors necessary to ensure comparability between PACE participants and the reference population in the Medicare fee-for-service system.

2. The capitation payment is fixed, regardless of changes in the participant's health status.

3. The PACE provider shall accept the capitation payments as payment in full and shall not bill, charge, collect or receive any form of payment from HCFA and the participant (with the exception of the ESRD participants) except as provided in Section VI, D.

4. HCFA procedures for accretions and deletions, payment mechanism, cost finding and risk sharing are included in the contract between the PACE provider and HCFA.

C. Medicaid Payment

1. The monthly capitation payment from Medicaid is negotiated between the PACE provider and the State Medicaid agency and is specified in the contract between them. The Medicaid rate is renegotiated on an annual basis.

2. The capitation payment is fixed, regardless of changes in the participant's health status.

3. The PACE provider shall accept the capitation payments as payment in full and shall not bill, charge, collect or receive any other form of payment from State Medicaid agency and the participant except as provided in Section VI, D.

4. State procedures for enrollment and disenrollment in the state system and capitation payment mechanism as well as any variations to HCFA's cost finding and risk sharing are included in the contract

between the PACE provider and the State Medicaid agency.

D. Private Pay Premiums

1. Participant's premium responsibility depends upon his/her eligibility for Medicare and Medicaid (cash grant and share of cost).

a. Medicare Only—premium equal to Medicaid capitation. (This premium is determined on an annual basis.)

b. Medicare and Medicaid with share of cost—premium equal to share of cost requirement.

c. Medicare and Medicaid—no participant premium.

d. Medicaid Only—no participant premium.

2. The private pay premium is fixed, regardless of changes in the participant's health status.

3. The PACE provider shall accept the private pay premium as payment in full and shall not bill, charge, collect or receive any other form of payment from the participants.

4. Participants with private co-payment are to be billed monthly.

5. If participants have long-term care insurance policies that cover PACE services, these benefits can be applied to participants' premium responsibility.

Part VII: Provider Administration

A. Contracting Requirements

1. Subcontracts between the PACE provider and contract providers shall be established for services not delivered directly by the PACE provider.

a. The PACE provider may contract only with qualified or licensed providers, who meet Federal and State requirements as applicable;

b. Contract providers must be accessible to participants, located either within or near the PACE provider's geographic catchment area;

c. The format of subcontracts must be approved by HCFA and the State Medicaid agency;

d. A list of subcontractors must be on file at the State Medicaid agency and updated as it changes; and

e. Copies of signed contracts for inpatient care are included in the contract between the PACE provider, HCFA and the State Medicaid agency.

2. Each subcontract shall contain:

a. Name of subcontractor;

b. Specification of the services provided;

c. Specification of reimbursement rate and payment method;

d. Specification of the terms of the subcontract, including the beginning and ending dates, as well as methods of extension, re-negotiation and termination;

e. Subcontractor agreement to provide services in accordance with the services authorized by the PACE multidisciplinary team;

f. Specification that the subcontract shall be governed by and construed in accordance with all laws, regulations and contractual obligations incumbent upon the PACE provider;

g. Subcontractor agreement to accept the PACE provider's payment as payment in full and not to bill participants, HCFA, the State Medicaid agency or private insurers;

h. Subcontractor's agreement to hold harmless HCFA, the State and PACE participants in the event that the PACE provider cannot or will not pay for services performed by the subcontractor pursuant to the subcontract;

i. Subcontractor's agreement that assignment or delegation of the subcontract is prohibited unless prior written approval is obtained from the PACE provider;

j. Subcontractor's agreement to submit reports as required by the PACE provider; and

k. Subcontractor's agreement to make all books and records, pertaining to the goods and services furnished under the terms of the subcontract, available for inspection, examination or copying by the State Medicaid agency and/or HCFA.

B. Data Collection and Reporting

1. During the trial period, the PACE provider shall meet the following data collection and reporting requirements.

a. The PACE provider is required to collect a standardized set of data which includes the following:

i. Participant-specific intake, assessment and service utilization data, coded according to the guidelines in the PACE Data Collection Manual. The definition of data and the manner in which it is collected may be changed to meet changes in HCFA and State Medicaid agency reporting requirements, in response to requests from PACE providers and others. Any changes made in data collection will incorporate sufficient lead time necessary to minimize transition difficulty. Data uniformity shall be maintained across all PACE providers.

ii. Fiscal data based on cost center accounting structure provided by HCFA and the State Medicaid agency. At the twelfth month, the year-to-date summary will provide the necessary annual data.

b. At a minimum, the provider must maintain complete participant-specific utilization data on-site updated to one month prior to the present. Data shall be transmitted to HCFA or its agent.

c. To ensure the quality of the data, HCFA or its agent, may provide the PACE provider with training in the use of data collection tools and may conduct ongoing monitoring to determine data completeness and reliability. Data collection problems that are identified must be reported to HCFA and the State Medicaid agency. If HCFA and the State Medicaid agency determine that problems require correction, the PACE provider will be required to resolve them.

d. HCFA, or its agent, reserve the right to review and assure the reliability and completeness of data and may obtain all provider data for the purposes of program monitoring.

e. The PACE provider will submit to HCFA and State Medicaid agency, 45 days after the end of each quarter, the following quarterly reports:

i. Quarterly narrative progress report; and

ii. Quarterly program statistical reports—Program Status Report, Sociodemographic Characteristics of Participants, Health and Functional Status of Participants, and Service Utilization Summary. The contents of these reports may be changed to meet changes in

Federal and State reporting requirements or for the purpose of program monitoring.

2. For providers that have completed the trial period, HCFA and its agent will work with PACE providers and their respective State Medicaid agencies to develop a standardized set of data to be collected by PACE providers and a standardized reporting processes. To assure the quality of the data, requirements 1.,c-d described above will apply.

C. Financial Reporting

1. For sites in the trial period, the following financial reports are required:

a. The PACE provider will submit a Budgeted versus Actual Financial Report for the current and year-to-date periods to HCFA, its agent, and the State Medicaid agency.

During the first year of operation, this report will be submitted on a monthly basis 45 days after the end of each month. Thereafter, this report will be submitted on a quarterly basis 45 days after the end of each quarter. HCFA and the State Medicaid agency reserve the right to extend the submission of this report on a monthly basis should provider performance indicate a need for more frequent monitoring.

b. The PACE provider must submit a cumulative cost report in the form and detail prescribed by HCFA. The interim cost report is due 45 days after the end of each provider's fiscal quarter and covers the period from the beginning of the fiscal year through the respective quarter.

c. The PACE provider must submit to HCFA and the State Medicaid agency an independently certified cost report in the form and detail prescribed by HCFA, no later than 180 days after the end of the provider's fiscal year.

d. PACE providers which are separate corporate entities must submit to HCFA and the State Medicaid agency a quarterly balance sheet.

2. For providers that have completed the trial period, HCFA and its agent will work with PACE providers and their respective State Medicaid agencies to develop a standardized financial reporting process.

D. Maintenance of Books and Records

1. The PACE provider must establish policies and procedures for maintaining all books and records necessary to determine whether contractual obligations are met. Books include, but are not limited to:

- a. Financial records;
- b. Medical records; and
- c. Personnel records;

2. Books and records must be made available to HCFA and the State Medicaid agency upon request.

3. Records must be stored so as to be protected against loss, destruction or unauthorized use.

Part VIII: External Oversight

A. General

It is the duty and responsibility of the Secretary to assure that requirements which govern the provision of care by PACE providers, and the enforcement of such requirements, are adequate to protect the health, safety, welfare, and rights of participants and to promote the effective and efficient use of public moneys. External oversight activities will include:

1. Periodic review of the financial status of the PACE provider to ensure its solvency and continuing viability; and

2. A periodic on-site survey, as described below, to determine the quality of care provided by the PACE provider and adherence to requirements defined in the contracts between the PACE provider, HCFA and the State Medicaid agency.

B. National Standards and Surveys

The National PACE Association (NPA) recommends that national standards for PACE be developed and an on-site survey process established for determining the quality of care provided by the PACE provider and the provider's adherence to contract requirements. To facilitate this process, NPA intends to develop model standards for use by HCFA and States. NPA urges HCFA and States to ensure that PACE providers are in accordance with these standards. NPA recommends that the survey process provides for surveys to be conducted at least once every two years by the State or through an accreditation organization or other entity. In addition, the Secretary would have the authority to conduct additional surveys, independent or in conjunction with the State, if there is reason to question the compliance of the PACE provider with any applicable requirements. Additional recommended provisions are:

1. The survey shall consist of an on-site visit which includes review of participant charts, interviews with staff and participants and observation of program operations including multidisciplinary team processes.

2. The survey shall be performed by a team composed of individuals who are experienced in providing care to the frail elderly and are knowledgeable about the PACE service delivery system. At a minimum, the team shall include a physician, nurse, social worker and a peer reviewer. The physician, nurse and social worker shall have experience in community-based care and should have recent clinical experience. The peer reviewer shall be from a PACE provider operating at full risk.

3. Procedures will be established to determine whether corrective action has been taken by the PACE provider to resolve deficiencies identified during the survey.

Part IX: Provider Termination

A. The PACE provider can be terminated for any one of the following four reasons and in each case must comply with HCFA and the State Medicaid agency guidelines for provider termination:

1. Either HCFA and/or the State Medicaid agency determine the provider cannot insure the health and safety of its participants. This determination may result from a medical survey or audit revealing provider deficiencies which HCFA and/or the State determine cannot be corrected.

2. The PACE provider chooses to discontinue providing services. In such event, a minimum of 90 days notice must be given to HCFA, its agent, and the State Medicaid agency regarding the provider's intent. Providers must give participants a minimum of 60 days notice.

3. Either HCFA and/or the State Medicaid agency can terminate the PACE provider's contract in response to large losses for which corrective action is unsuccessful. In response to financial audits which show a loss, the provider must develop a plan which is designed to prevent future losses. If the plan is developed by the PACE provider and is determined to be unacceptable to HCFA and the State Medicaid agency, the provider's contract may be terminated.

4. The provider may be terminated should it deviate from, violate or fail to comply with the contractual agreements of HCFA and the State Medicaid agency.

B. The PACE provider is required to develop a detailed provider termination plan included in which are the following: the process of informing participants, the community, HCFA and State Medicaid agency; and steps that will be taken to reinstate participants' Medicare and Medicaid benefits through the fee-for-service system, transition their care to other providers, and terminate the referral and intake process.

Part X: Medicare and Medicaid Contracts Requirements

A. General

The PACE provider should have formal contracts in place with the responsible federal and state agencies, which incorporate the requirements defining and applicable to PACE providers. These legal requirements would be based upon the PACE Protocol. Absent such formal contracts the PACE Protocol and other requirements, if any, which the responsible agencies deem appropriate, would govern. Critical elements of the formal contract should include, but not be limited to, requirements related to:

1. organization of the PACE provider
2. participant rights
3. eligibility, enrollment and disenrollment policies
4. service definition, coverage and arrangement
5. quality assurance
6. reimbursement
7. PACE provider administration
8. PACE provider termination

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