DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare and Medicaid Services

42 CFR Part 413

Principles of Reasonable Cost Reimbursement; Payment for End-Stage Renal Disease Services; Prospectively Determined Payment Rates for Skilled Nursing Facilities

CFR Correction

In Title 42 of the Code of Federal Regulations, Parts 400 to 429, revised as of October 1, 2001, § 413.86 is corrected, on page 525, by revising the designation (e)(4)(ii)(C)(*2*)(iii) to read (e)(4)(ii)(C)(*2*)(*iii*) and by adding (e)(4)(ii)(C)(*2*) introductory text, (*i*), and (*ii*) to read as follows:

§ 413.86 Direct graduate medical education payments.

* * * * *

(e)* * *

(4)* * *

(ii)* * *

(C)* * *

(*2*) *Ceiling.* If the hospital's per resident amount is greater than 140 percent of the locality-adjusted national average per resident amount, the per resident amount is adjusted as follows for FY 2001 through FY 2005:

(*i*) *FY 2001.* For cost reporting periods beginning on or after October 1, 2000 and on or before September 30, 2001, if the hospital's FY 2000 per resident amount exceeds 140 percent of the FY 2001 locality-adjusted national average per resident amount (as calculated under paragraph (e)(4)(ii)(B) of this section), then, subject to the provision stated in paragraph (e)(4)(ii)(C)(*2*)(*iv*) of this section, the hospital's per resident amount is frozen at the FY 2000 per resident amount and is not updated for FY 2001 by the CPI–U factor.

(*ii*) *FY 2002.* For cost reporting periods beginning on or after October 1, 2001 and on or before September 30, 2002, if the hospital's FY 2001 per resident amount exceeds 140 percent of the FY 2002 locality-adjusted national average per resident amount, then, subject to the provision stated in paragraph (e)(4)(ii)(C)(*2*)(*iv*) of this section, the hospital's per resident amount is frozen at the FY 2001 per resident amount and is not updated for FY 2002 by the CPI–U factor.

* * * * *

[FR Doc. 02–55519 Filed 9–30–02; 8:45 am]

BILLING CODE 1505–01–D

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

42 CFR Part 460

[CMS–1201–IFC]

RIN 0938–AL59

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

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

ACTION: Interim final rule with comment period.

SUMMARY: This rule revises the interim final rule with comment period that established requirements for Program of All-inclusive Care for the Elderly (PACE) under the Medicare and Medicaid programs. The revisions in this rule will implement section 903 of the Medicare, Medicaid, and SCHIP Benefits Improvement and Protection Act of 2000 (Pub. L. 106–554) by establishing a process through which PACE organizations may request waiver of certain Medicare and Medicaid regulatory requirements.

DATES: *Effective date:* These regulations are effective on October 31, 2002.

Comment date: Comments will be considered if we receive them at the appropriate address, as provided below, no later than 5 p.m. on December 2, 2002.

ADDRESSES: In commenting, please refer to file code CMS–1201–IFC. Because of staff and resource limitations, we cannot accept comments by facsimile (FAX) transmission.

Mail written comments (one original and three copies) to the following address ONLY: Centers for Medicare & Medicaid Services, Department of Health and Human Services, Attention: CMS–1201–IFC, P.O. Box 8017, Baltimore, MD 21244–8017.

Please allow sufficient time for mailed comments to be timely received in the event of delivery delays.

If you prefer, you may deliver (by hand or courier) your written comments (one original and three copies) to one of the following addresses:

Room 445–G, Hubert H. Humphrey Building, 200 Independence Avenue, SW., Washington, DC 20201, or

Room C5–14–03, 7500 Security Boulevard, Baltimore, MD 21244–1850.

(Because access to the interior of the HHH Building is not readily available to persons without Federal Government identification, commenters are encouraged to leave their comments in the CMS drop slots located in the main lobby of the building. A stamp-in clock is available for commenters wishing to retain a proof of filing by stamping in and retaining an extra copy of the comments being filed.)

Comments mailed to the addresses indicated as appropriate for hand or courier delivery may be delayed and could be considered late.

For information on viewing public comments, see the beginning of the **SUPPLEMENTARY INFORMATION** section.

FOR FURTHER INFORMATION CONTACT: Janet Samen, (410) 786–4533; or Sue Davison, for State technical assistance, (410) 786–5831.

SUPPLEMENTARY INFORMATION: *Inspection of Public Comments:* Comments received timely will be available for public inspection as they are received, generally beginning approximately 3 weeks after publication of a document, at the headquarters of the Centers for Medicare & Medicaid Services, 7500 Security Boulevard, Baltimore, Maryland 21244, Monday through Friday of each week from 8:30 a.m. to 4 p.m. To schedule an appointment to view public comments, call (410) 786–7195.

I. Background

A. Legislative History

Section 4801 of Public Law 105–33, the Balanced Budget Act of 1997 (BBA), authorized coverage of the Program of All-inclusive Care for the Elderly (PACE) under the Medicare program. It amended title XVIII of the Social Security Act (the Act) by adding section 1894, which addresses Medicare payments and coverage of benefits under PACE. Section 4802 of the BBA authorized the establishment of PACE as a State option under Medicaid. It amended title XIX of the Act by adding section 1934, which directly parallels the provisions of section 1894.

B. Demonstration Project History

The BBA built on the success of the PACE demonstration program. Section 603(c) of the Social Security Amendments of 1983 (Pub. L. 98–21), as extended by section 9220 of the Consolidated Omnibus Budget Reconciliation Act of 1985 (Pub. L. 99–272) authorized the original demonstration waiver for On Lok Senior Health Services in San Francisco. Section 9412(b) of Public Law 99–509, the Omnibus Budget Reconciliation Act of 1986, authorized us to conduct a demonstration project to determine

whether the model of care developed by On Lok may be replicated across the country. The number of sites was originally limited to 10, but the Omnibus Budget Reconciliation Act of 1990 (Pub. L. 101–508) authorized an increase to 15 demonstration sites.

The PACE demonstration program replicated a unique model of managed care service delivery for a group of very frail community-dwelling elderly, most of whom were dually eligible for Medicare and Medicaid benefits, and all of whom were assessed as being eligible for nursing home placement according to the standards established by their respective States. The PACE model of care includes as core services the provision of adult day health care and interdisciplinary team case management, through which access to and allocation of all health services is managed. Physician, therapeutic, ancillary, and social support services are furnished in the participant's residence or on-site at a PACE center. Hospital, nursing home, home health, and other specialized services are generally furnished under contract. Financing of the PACE model is accomplished through prospective capitation of both Medicare and Medicaid payments, and under the demonstration, programs gradually assumed full financial risk for all care provided to their enrolled participants.

The PACE demonstration program was operated under a Protocol published by On Lok, Inc., on April 14, 1995. A copy of the Protocol was included as an attachment to the interim final rule with comment period that was published in the **Federal Register** on November 24, 1999, to implement the PACE program (64 FR 66234.) As directed by sections 1894(f)(2) and 1934(f)(2) of the Act, we incorporated the requirements under the Protocol in the PACE regulation, to the extent consistent with the BBA provisions described throughout sections 1894 and 1934 of the Act. The November 24, 1999 PACE regulation was a comprehensive rule that addressed eligibility, administrative requirements, application procedures, services, payment, participant rights, and quality assurance. There are currently 24 approved PACE demonstration programs and two programs that have been approved as permanent PACE organizations. In accordance with section 901 of BIPA, all PACE demonstration programs must transition to permanent provider status by November 2003.

C. Flexibility

As noted above, the PACE demonstration program was operated pursuant to a Protocol developed by On Lok. The PACE Protocol provided authority for CMS and the State Agency to waive specific requirements of the Protocol, if, in their judgment, the intent of the requirements was met by the proposed alternative and safe and quality care would be provided. Written requests for waivers were required to be approved by CMS and the State before implementation of the proposed alternative. Flexibility was limited to the requirements in the section on service coverage and arrangement. That section includes: A requirement that the PACE organization provide all Medicare and Medicaid services and provide care 7 days per week, 365 days per year; a listing of required and excluded services; minimum services provided at the PACE Center; a requirement that each participant be assigned to a multidisciplinary team, as well as the composition and duties of the multidisciplinary team; and assessment and reassessment requirements. Flexibility was not authorized for other sections of the PACE Protocol, such as participant rights, enrollment and disenrollment, and administration.

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

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

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

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

In the November 24, 1999 interim final rule, we identified, as specific waivers that were intended to encourage development of PACE programs in rural and Tribal areas, waivers of the following three requirements:

- A prohibition on members of the governing body and their family members from having a direct or indirect interest in contracts with the organization (see § 460.68(c));
- A requirement that members of the multidisciplinary team primarily serve PACE participants (see § 460.102(g)); and
- A requirement that the primary care physician must be employed by the PACE organization (see § 460.102(g)).

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

Our rationale for this rather limited view of the flexibility provision was based on our belief that all PACE demonstration programs were in compliance with the PACE Protocol and, therefore, would need to make only minor changes in their operations to meet the PACE regulatory requirements. Our intention was to allow some flexibility to promote PACE in rural and Tribal areas while maintaining consistency of requirements for other PACE programs. We intended to expand opportunities for flexibility to cover more requirements and provide more flexibility to all PACE organizations once we had gained sufficient experience with PACE and had implemented the program. In addition, we were guided by the fact that the Protocol, and thus the PACE regulation, had been proven effective for new organizations as they built their patient census and attained financial solvency.

We have since learned that although the early PACE demonstration programs initially complied with the Protocol, most of them modified the Protocol requirements as they expanded, using the flexibility provision. While many of these modifications were related to service coverage and arrangement provisions, many others were implemented that were not authorized by the flexibility clause in the Protocol. In addition, many of the later PACE demonstration programs exercised the flexibility clause in the Protocol in developing their programs, especially with regard to direct employment of staff. Finally, very few of the waivers

were requested in writing or approved by CMS or the State before implementation.

II. The Medicare, Medicaid, and SCHIP Benefits Improvement and Protection Act of 2000, (BIPA) (Pub. L. 106–554)

A. Background

BIPA modified the PACE program in the following three ways:

- Section 901 extended the transition period for the current PACE demonstration programs to allow an additional year for these organizations to transition to the permanent PACE program.
- Section 902 gave the Secretary the authority to grandfather in the modifications these programs had implemented as of July 1, 2000. This provision will allow the PACE demonstration programs to continue program modifications they have implemented and avoid disruptions in participant care where these modifications have been determined to be consistent with the PACE model. These sections are being implemented administratively.
- Section 903 specifically addressed flexibility in exercising the waiver authority provided under sections 1894(f)(2)(B) and 1934(f)(2)(B) of the Act. It allowed the Secretary to modify or waive PACE regulatory provisions in a manner that responds promptly to the needs of PACE organizations relating to the areas of employment and the use of community-based primary care physicians. Section 903 of BIPA also established a 90-day review period for waiver requests. Since the flexibility language is part of the statutory section dealing with regulations (sections 1894(f) and 1934(f) of the Act), we believe it was intended that waiver requirements be incorporated into the PACE regulations.

B. Contracting for Multidisciplinary Team Members and Administrative Staff

We note that although the PACE Protocol and the PACE regulation refer to a multidisciplinary team, it has become more common to regard the team in PACE as an interdisciplinary team to reflect the interactive and collaborative approach of the PACE care team. Therefore, we are amending the PACE regulation to replace the term multidisciplinary with interdisciplinary wherever it appears and will use that phrase in the preamble to describe the PACE team.

Section 460.102(f) of the PACE regulation requires that the following PACE interdisciplinary team members be employees of the PACE organization: primary care physician, registered nurse, social worker, recreational therapist or activity coordinator, PACE Center manager, home care coordinator, and PACE Center personal care attendants. This requirement is based on part IV.B.13.a. of the PACE Protocol that specifies that these team members must be employees of the PACE provider or PACE Center. (Employment of staff by the PACE Center is discussed in the next section of this preamble.) In addition, § 460.60 requires the PACE organization to employ the program director and the medical director.

We are no longer requiring that the PACE organization employ the interdisciplinary team, the program director or the medical director. Instead, the PACE organization may contract with these staff members, and we are expanding § 460.70 to include additional contract requirements. Finally, we are removing the specific waiver in § 460.102(g) for rural or Tribal organizations to contract for the primary care physicians.

The National PACE Association (NPA), an industry group representing the PACE demonstration programs and developing PACE programs, has indicated that the objectives of the Protocol with regard to employment are as follows:

- To assure that the same individuals provide care to the same participants over time (as opposed to a contractual relationship in which a different staff person may provide care from one month or even one day to the next); and
- To assure that the interdisciplinary team members are fully accountable to the PACE organization which has responsibility and is accountable for the entire range of PACE services.

NPA has indicated that contractual arrangements should be utilized only where it is consistent with continuity of care, and efficient and economical delivery of services. In addition, individual team members must be specified by name and work schedule.

We have become aware that most of the PACE demonstration programs have entered into contractual arrangements for interdisciplinary team members and key PACE staff such as the medical director. We have come to agree that there are reasonable circumstances where dedicated staff decide to contract rather than be employed by the PACE organization. For example, the medical director or primary care physicians may wish to maintain their employment with a hospital or academic institution while providing services to PACE participants. We believe that these arrangements may be done so as to be completely transparent to participants and have no impact on care coordination or service delivery.

Current requirements for contracted services are found in § 460.70. We are reorganizing and amending that section to include additional contract requirements for interdisciplinary team members or PACE administrative staff. Where these staff are not employed by the PACE organization, the contract must stipulate that the individuals: (1) Agree to perform all the duties related to their position in the PACE organization and specified in the PACE regulation; (2) participate in interdisciplinary team meetings as required; and (3) be accountable to the PACE organization.

Where the PACE organization contracts with another organization for interdisciplinary team staff, for example, with a rehabilitation agency that employs the physical therapist, the contract must also stipulate the name of the individual assigned to the PACE program and the schedule for attendance at the PACE Center. In this way, participants may be scheduled for attendance at the PACE Center to coincide with the schedule for the staff assigned to their care. Given the frailty of the population served by the PACE organization, we believe it is important that, where possible, services are provided to participants by the same core staff, whether employed directly by the PACE organization or provided via a contracting arrangement.

As mentioned above, our regulations currently require that the PACE program director and the medical director be employees of the PACE organization. In order to allow for contracting of the PACE program director and medical director, we are amending § 460.60(b) and (c) to require that the PACE organization employ these staff members directly or have contracts for these staff that meet the contracting requirements specified in § 460.70.

Finally, we are removing § 460.102(g), which allows CMS and the State administering agency to waive the employment requirement for the primary care physician and the requirement that the interdisciplinary team serve primarily PACE participants. Since the PACE organization may contract for primary care physicians in accordance with the requirements specified in § 460.70 as revised and other waivers are governed by § 460.26, these specific waiver provisions are no longer necessary.

C. Contracting With Another Entity to Furnish PACE Center Services

The PACE Protocol at section IV.B.13.a. provides that the interdisciplinary team may be employed by the PACE organization or the PACE Center. In developing the PACE regulation, we did not address this issue because we believed that in all cases the PACE organization and the PACE Center were the same organization. We have learned that this change was made in the PACE Protocol in 1995 to reflect an operating arrangement implemented by one of the PACE demonstration organizations, On Lok Senior Health Services. In this arrangement, On Lok entered into a contractual relationship with another organization to provide all PACE Center services under which the interdisciplinary team is employed and managed by the contracting organization. On Lok remains responsible for all care provided at the Center and remains at risk for the healthcare needs of the participants attending this center. In addition, On Lok has retained many of the administrative responsibilities associated with PACE, for example, marketing and enrollment. Through this contractual relationship, On Lok has been able to expand PACE services to a different part of their service area without disrupting the care that traditionally had been provided by the other organization.

Since this approach was reflected in the PACE Protocol, we are amending the PACE regulation to allow PACE organizations to provide PACE Center services through contractual arrangements. Although we do not view this approach as a waiver authorized by BIPA, we are establishing specific waiver requirements for this approach consistent with the On Lok arrangement. We are more likely to allow PACE organizations to contract out PACE Center services when they have attained sufficient experience in delivering services and managing the risk associated with the frail elderly.

We are adding a new § 460.70(f) to identify the criteria that a PACE organization must meet to contract out PACE Center services. We are not inclined to approve a waiver for a PACE organization unless it is financially stable and has demonstrated competence with the PACE model by successful CMS and State onsite reviews and monitoring efforts. We specifically invite public comments on the appropriateness of these criteria.

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

On Lok is able to monitor the care provided in the contracted PACE Center through the sharing of electronic medical records. While we are not requiring electronic medical records as a condition of our approval, it will be necessary for a PACE organization wishing to pursue this type of arrangement to describe how it will monitor the care provided and perform all the administrative duties required by the PACE regulation.

D. Oversight of Direct Patient Care Services

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

Currently, § 460.66 requires the PACE organization to provide training to maintain and improve the skills and knowledge of each staff member for the individual's specific duties that results in his or her continued ability to demonstrate the skills necessary for the performance of the position. We are expanding this requirement by creating a new § 460.71 to identify PACE organization oversight requirements for PACE employees and contractors with direct patient care responsibilities. These requirements fall into two categories, that is, competency evaluation and staff and contractor requirements, and are listed as follows:

- The PACE organization must ensure that employees and contracted staff providing care directly to participants demonstrate the skills necessary for performance of their position.
- The PACE organization must provide each employee and all contracted staff with an orientation. The orientation must include at a minimum the organization s mission, philosophy, policies on participant rights, emergency plan, ethics, the PACE benefit, and policies and procedures relevant to each individual's job duties.
- The PACE organization must develop a competency evaluation program that identifies those skills, knowledge, and abilities that must be demonstrated by direct participant care staff (employees and contractors). The program must be evidenced as completed prior to performing participant care and on an ongoing basis by qualified professionals. The PACE organization must designate a staff person to oversee these activities for employees and work with the PACE contractor liaison to ensure compliance by contracted staff.

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

The PACE organization must develop a program to ensure that all staff providing direct participant care services meet the requirements listed below. We revised § 460.70(e) to require contractors who furnish direct

participant care to meet the requirements of § 460.71 as well. The PACE organization will verify that direct participant care staff or contractors meet the following requirements:

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

E. Waiver Process

To implement section 903 of BIPA, we considered amending the November 24, 1999 PACE interim final regulations to identify each requirement that is eligible for waiver and provide separate waiver criteria for each requirement. However, we were concerned that amending the regulation for each waiver would: (1) Create a regulatory level of specificity that might make it difficult to apply to future requests for similar but not identical waivers; and (2) cause a significant delay between when the need for a waiver is identified and when it may be implemented.

As an alternative, we are amending the PACE regulation by adding §§ 460.26 and 460.28 to establish a process for a PACE organization to request waiver of regulatory requirements. As noted previously, the PACE Protocol and the November 24, 1999 PACE regulation have been proven effective as PACE organizations grow and reach financial solvency.

We have learned a great deal about variations in the model through the information we received in processing grandfathering requests under section 902 of BIPA and numerous discussions with the NPA, PACE organizations, and States. Allowing for waivers provides a unique opportunity for PACE organizations, the States, and CMS to experiment with new approaches within the structure of the PACE model. This process will allow for variations that achieve the intent of the regulatory provision while responding to the needs of PACE organizations to develop and expand within their States' long-term care delivery system. The PACE organizations will serve as an ongoing laboratory that over time will establish best practices that may ultimately replace the current regulatory requirements.

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

Based upon our experience and review of grandfathering requests under section 902 of BIPA, we realize we must consider two categories of waiver requests, that is, general waivers and conditional waivers subject to evaluation. They are discussed as follows:

1. General Waivers

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

2. Conditional Waivers

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

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

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

Each of the conditional waivers will be subject to periodic monitoring. A PACE organization approved for a conditional waiver would need to submit the prescribed data at specified intervals. CMS intends to establish elements for evaluating the conditional requests. This evaluation would serve a dual purpose. It would allow CMS to monitor the impact on participant care as well as enable us to determine if any permanent changes to PACE should be implemented through regulations. In addition, we may provide technical assistance to other PACE organizations requesting a similar waiver.

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

Consistent with the process developed for initial PACE provider applications, all waiver requests must be submitted to the State administering agency for initial review. The State administering agency would forward the waiver request to CMS along with any concerns or conditions they may have

regarding the waiver. We will not accept waiver requests directly from PACE organizations. Waiver requests submitted with an initial application process must be prepared as a separate document. These requests will be reviewed simultaneously and in conjunction with the application. Where an existing PACE organization is requesting a waiver, the request must be submitted through the State to the CMS address for PACE applications indicated on the PACE homepage *(www.cms.hhs.gov/PACE).* We intend to process waiver requests as expeditiously as possible in order to be responsive to the needs of new organizations to develop their programs and to the needs of mature organizations as they expand.

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

Consistent with sections 1894 and 1934 of the Act, we are specifying in § 460.26(c) the following requirements that must not be waived:

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

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

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

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

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

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

As noted previously, the November 24, 1999 PACE regulation was a comprehensive document that included many provisions that are not appropriate for waiver. For example, subpart B of the PACE regulation describes the types of entities that may submit PACE applications and the process for submission of applications. Since these requirements reflect statutory requirements and our application process, no waiver or modification is appropriate. Likewise, subpart C of the November 24, 1999 PACE regulation describes the terms and content of the PACE program agreement. Although we agree that it would be easier to manage PACE program agreements without the significant detail, the content of the PACE program agreement is specifically required by statute. Thus, no waiver or modification is appropriate.

Regarding other subparts of the PACE regulation, we view many, but not all, of the requirements as appropriate for waiver or modification. For example, while we may approve a waiver regarding the organization's structure or division of responsibilities amongst staff, we would not be inclined to waive infection control requirements that are standard precautions established by the Centers for Disease Control and Prevention.

We note that providing services through contracts rather than through direct employment of staff is the type of flexibility most often requested by PACE organizations and the NPA and will be permissible without waiver.

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

Two waiver issues specifically mentioned in section 903 of BIPA are requirements related to employment and the use of community-based primary care physicians. An example of this would be to allow a PACE organization to provide primary care through community physicians operating independent of the PACE program, that is, physicians who do not participate in interdisciplinary team meetings. This approach is part of our demonstration project currently underway in Wisconsin. The evaluation of the demonstration will not be completed until 2005. As this demonstration has developed, the sites have modified their use of community-based physicians over time. We believe that further testing and refinement of this approach is needed. We will follow the evaluation of this demonstration to determine the optimal policies and procedures to require for PACE organizations wishing to adopt this option.

Another example is the use of satellite locations, where required PACE Center services (and the interdisciplinary team services) are provided at various locations. Although services may be provided at various locations currently, we are concerned that routinely dispersing service delivery will fundamentally change the PACE model, especially the focus of services at the PACE Center and care management through the interdisciplinary team.

Since this rule will establish a process for submission and approval of waiver requests, we are removing the restrictive waiver provisions that were limited to rural and Tribal organizations, that is, § 460.68(c) regarding direct or indirect interest in contracts, and, as noted previously, the two waivers in § 460.102(g) related to employment of the primary care physician and the requirement that the interdisciplinary team primarily serve PACE participants. Although we are deleting the specific waivers that were intended to encourage development of PACE in rural or Tribal areas, we continue to recognize the special need for flexibility for these areas and remain committed to allowing waivers to promote PACE in medically underserved areas. Deletion of the specific waiver language is intended to provide greater flexibility within the overall PACE structure. We remain committed to working with rural and Tribal communities to help them

address the challenges of developing successful PACE programs. Organizations that seek waiver of these or any other regulatory requirements would follow the requirements specified in § 460.26.

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

III. Comments and Responses to the November 1999 Interim Final Regulation

We received a total of 27 comments on the November 1999 interim final regulation (64 FR 66234), many of them concerning the waiver provisions published at §§ 460.68 and 460.102.

Comment: Most of the commenters expressed concern that the regulation is too prescriptive and limits flexibility and innovation and that the waiver provisions in §§ 460.68 and 460.102 of the regulation were too restrictive. The commenters argued that developments during the PACE demonstration program had led to alternative practices (primarily associated with contracting flexibility) that were not reflected in the November 1999 interim final regulation. They urged CMS to allow alternative approaches to meeting the regulatory intent and specifically recommended that we broaden the limited waivers provided in the regulation targeted to rural and Tribal organizations to permit waiver of additional requirements by all PACE organizations. In addition, section 903 of BIPA provided us with additional guidance concerning both the practices of longstanding PACE demonstration programs (grandfathering) and new organizations which may apply to become PACE organizations.

Response: This interim final regulation is a response to the portion of the November 1999 regulation that dealt with waivers and flexibility. It responds to the concerns raised in the public comments by establishing a process through which approved PACE organizations, as well as applicants, may request a waiver of regulatory requirements (§ 460.26) and allow expanded contracting opportunities (§ 460.70). Through the waiver process, we hope to learn about any barriers the PACE requirements create in developing new organizations, especially those in medically underserved areas, and expanding existing PACE programs.

Once we have completed the transition of PACE demonstrations to permanent provider status and gained sufficient experience with the waiver process, we intend to develop a final rule to revise the PACE regulation and respond to all the public comments we received on the November 1999 interim final regulation as well as any public comments submitted in response to publication of this regulation.

IV. Provisions of the Interim Final Rule

The regulation amends part 460 by replacing the term ''multidisciplinary'' with ''interdisciplinary'' wherever it appears to reflect the interactive and collaborative approach of the PACE team.

Section 460.10 Purpose

We are amending this section to clarify that subpart B also establishes a process for a PACE organization to request a waiver of regulatory requirements in order to provide for reasonable flexibility in adapting the PACE service delivery model to the needs of particular organizations (such as those in rural areas).

Section 460.12 Application Requirements

We are removing and reserving paragraph (a)(2) to clarify that, although CMS may begin review of PACE organization applications, we may sign a program agreement only with a PACE organization located in a State with an approved State plan amendment electing PACE as an optional benefit under its Medicaid State plan.

Section 460.26 CMS Evaluation of Waiver Requests

In accordance with the requirements in section 903 of BIPA, we are adding this section to subpart B to establish a process for a PACE organization to request waiver of regulatory requirements and to list provisions that are statutorily excluded. This process is described in section II.E. of this preamble.

Section 460.28 Notice of CMS Determination on Waiver Requests

As required by section 903 of BIPA, we are adding this section to subpart B to specify the time limit for notification to PACE organizations of our decisions on waiver requests and to state that we may withdraw approval of a waiver for good cause. This process is described in section II.E. of this preamble.

Section 460.30 Program Agreement Requirements

We are revising paragraph (b) to reflect that the PACE program agreement is a 3-party agreement that is signed by CMS, the State administering agency, and the PACE organization. Also, we are adding a new paragraph (c) to clarify that we may sign a program agreement only with a PACE organization that is located in a State with an approved State plan amendment electing PACE as an optional benefit under its State plan.

Section 460.60 PACE Organizational Structure

In order to allow for contracting of a PACE program director and medical director described in section II.B. of this preamble, we are amending paragraphs (b) and (c) to require that the PACE organization employ these staff members directly or have contracts for these staff that meet the contracting requirements specified in § 460.70.

Section 460.68 Program Integrity

As discussed in section II.E. of this preamble, we are removing paragraph (c) and amending paragraph (b) by removing the cross reference to paragraph (c).

Section 460.70 Contracted Services

As described in section II.B. of this preamble, we are amending paragraph (e) to include additional contract requirements where the PACE organization chooses to contract for interdisciplinary team members or key administrative staff. In addition, we are adding a new paragraph (f) to include specific contract requirements where the PACE organization chooses to contract for PACE Center services. These changes are described in section II.C. of this preamble. Finally, we are amending paragraph (b)(1)(i) to clarify that an institutional contractor, such as a hospital or skilled nursing facility, must meet the Medicare or Medicaid participation requirements. However, where the PACE organization is supplementing its own staff to provide services in the home or at the PACE Center, certain staffing agencies that may not be Medicare certified providers may be used as long as the staff and the agency meet applicable State licensure requirements.

Section 460.71 Oversight of Direct Participant Care

In consideration of the vulnerable population served by PACE, we are adding this section to identify PACE organization oversight requirements for PACE employees and contractors with

direct patient care responsibilities. These requirements are described in section II.D. of this preamble.

Section 460.102 Interdisciplinary Team

We are amending paragraph (d)(2)(iii) to clarify that interdisciplinary team members must document changes of a participant's condition in a participant's medical record consistent with the PACE organization's documentation policies. This will ensure that only designated team members have access to patients records. Also, in consideration of the expanded contracting opportunities described in section II.B. of this preamble, we are removing paragraph (f) that requires members of the PACE interdisciplinary team to be employed by the PACE organization. Finally, we are removing paragraph (g) that allows CMS and the State administering agency to waive the employment requirement for the primary care physician and the requirement that the interdisciplinary team serve primarily PACE participants. Since the PACE organization may contract for primary care physicians in accordance with the requirements specified in § 460.70 (described in section II.B. of this preamble) and other waivers are governed by § 460.26 (described in section II.E. of this preamble), these specific waiver provisions are no longer necessary. We are amending paragraph (d)(3) by removing the cross reference to paragraph (g).

V. 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.

VI. Waiver of Proposed Rulemaking

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. However, section 1894(f)(1) if the Act specifically permits the Secretary to issue interim final or final regulations to carry out sections 1894 and 1934 of the Act. Therefore, we are issuing this final rule on an interim basis with a 60-day comment period.

VII. 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 these issues for the following sections of this document that contain information collection requirements:

Section 460.26 CMS Evaluation of Waiver Requests

Section 460.26(b) requires a PACE organization or prospective PACE organization to submit a written request to obtain CMS approval of its request for waiver or modification of a PACE regulatory requirement. Section 460.26(a) requires that the request be submitted through the State administering agency.

The burden associated with this requirement is the time and effort to develop and submit a waiver request to CMS. We estimate that 25 entities will apply per year and that each entity will take 3 hours to complete the requirements of this section for a total annual burden of 50 hours.

In addition, § 460.26(a) requires that a waiver request must be submitted to the State administering agency of the State in which the program is located for review prior to submittal to CMS.

The burden associated with this requirement is the time and effort for a State to review and submit waiver requests to CMS indicating that it approves the waiver requests. We estimate that 25 States will each take 1 hour to complete these requirements for a total annual burden of 25 hours.

Section 460.71 Oversight of Direct Participant Care

In summary, § 460.71(a) requires a PACE organization to develop a competency evaluation program to ensure that direct participant care staff (employees and contractors) have the skills, knowledge, and ability to perform the duties associated with their positions.

The burden associated with this requirement is the time and effort to develop and maintain a competency evaluation program, perform evaluations including evaluation of all current staff, and document the results. We estimate that each organization will spend 3 hours developing the program, 50 hours implementing the program for all current staff, and 50 hours maintaining the program and verifying the qualifications and competency of new staff and contractors. There will be approximately 54 PACE organizations with approximately 100 contracted staff for a total annual burden of 2700 hours.

Section 460.102 Multidisciplinary Team

Section 460.102(d)(2)(iii) requires the documention of any changes in a participant's condition in the participant's medical record consistent with documentation polices established by the medical director.

We believe that the burden associated with this ICR 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 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 these information collection and recordkeeping requirements, please mail copies directly to the following: Centers for Medicare and Medicaid Services, Office of Information Services, Security and Standards Group, Division of CMS Enterprise Standards, Room C2–26–17, 7500 Security Boulevard, Baltimore, MD 21244–1850, Attn: John Burke, CMS–1201–IFC, and Office of Information and Regulatory Affairs, Office of Management and Budget, Room 10235, New Executive Office Building, Washington, DC 20503, Attn: Brenda Aguilar, HCFA Desk Officer.

VIII. Regulatory Impact Statement

We have examined the impacts of this rule as required by Executive Order 12866 (September 1993, Regulatory Planning and Review), the Regulatory Flexibility Act (RFA) (September 16, 1980, Pub. L. 96–354), section 1102(b) of the Social Security Act, the Unfunded Mandates Reform Act of 1995 (Pub. L. 104–4), and Executive Order 13132.

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). A regulatory impact analysis (RIA) must be prepared for major rules with economically significant effects ($100 million or more in any 1 year).

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 $6 to $29 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 100 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 and request waiver of regulatory requirements for startup or expansion. The rule will indirectly affect Medicare beneficiaries and Medicaid recipients who may qualify for a PACE program and who might wish to enroll in one in their geographic area, because it may affect the availability of those programs. A typical mature PACE program maintains an enrollment of about 200 to 300 individuals.

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. Payment rates for PACE 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 effect of the PACE program should be a slight savings for this small population. Approved PACE organizations that request waivers to support expansion activities or prospective organizations that request waivers to support start up may incur a minimal cost and burden associated with waiver requests.

If this rule were not issued, PACE programs would be unable to implement modifications to PACE regulatory requirements, potentially impeding their ability to start up or expand their programs.

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.

Section 202 of the Unfunded Mandates Reform Act of 1995 also requires that agencies anticipate costs and benefits before issuing any rule that may result in expenditure in any 1 year by State, local, or tribal governments, in the aggregate, or by the private sector, of $110 million. This interim final rule will not mandate any requirements for State, local, or tribal governments nor would it result in expenditures by the private sector of $110 million or more in any 1 year.

Under Executive Order 13132, this regulation will not significantly affect the States beyond what is required and provided for under the BBA. It follows the intent and letter of the law and does not usurp State authority beyond what the BBA requires. This regulation describes the processes that must be undertaken by CMS, the States, and PACE organizations in order to implement the flexibility afforded by section 903 of BIPA.

As we explained in the November 1999 interim final regulation (64 FR 66235), 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 BIPA amendments reflect this partnership between CMS and the State administering agency. However, section 903 of BIPA does not specifically provide for consultation or agreement by the States in making waiver determinations. Nonetheless, it is our intention to engage the State in discussion regarding waiver requests and to require the PACE organization to submit a waiver request through the State administering agency.

In addition, we continue to obtain State input in the early stages of policy development through conference calls with State Medicaid Agency representatives. The calls, which began after enactment of the BBA, have been very productive in understanding the variety of State concerns inherent in implementing the PACE program. We are committed to continuing this dialogue with States after publication of this regulation to ensure this cooperative atmosphere continues as we complete the transition of the current PACE demonstration sites to full provider status and expand access to the PACE benefit.

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

List of Subjects in 42 CFR Part 460

Aged, Health facilities, Medicare, Medicaid, Reporting and recordkeeping requirements.

For the reasons set forth in the preamble, the Centers for Medicare & Medicaid Services amends 42 CFR Chapter IV as set forth below:

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

1. The authority citation for part 460 continues to read as follows:

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

2. In part 460, revise all references to ''multidisciplinary'' to read ''interdisciplinary'.

Subpart B—PACE Organization Application and Waiver Process

3. The heading for subpart B is revised as set forth above.

4. Section 460.10 is revised to read as follows:

§ 460.10 Purpose.

This subpart sets forth the application requirements for an entity that seeks approval from CMS as a PACE organization and the process by which a PACE organization may request waiver of certain regulatory requirements. The

purpose of the waivers is to provide for reasonable flexibility in adapting the PACE model to the needs of particular organizations (such as those in rural areas).

§ 460.12 [Amended]

5. Section 460.12 is amended by removing and reserving paragraph (a)(2).

6. Sections 460.26 and 460.28 are added to subpart B to read as follows:

§ 460.26 Submission and evaluation of waiver requests.

(a) A PACE organization must submit its waiver request through the State administering agency for initial review. The State administering agency forwards waiver requests to CMS along with any concerns or conditions regarding the waiver.

(b) CMS evaluates a waiver request from a PACE organization on the basis of the following information:

(1) The adequacy of the description and rationale for the waiver provided by the PACE organization, including any additional information requested by CMS.

(1) Information obtained by CMS and the State administering agency in on-site reviews and monitoring of the PACE organization.

(c) Requirements related to the following principles may not be waived:

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

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

(3) An interdisciplinary team approach to care management and service delivery.

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

(5) The assumption by the provider of full financial risk.

§ 460.28 Notice of CMS determination on waiver requests.

(a) *Time limit for notification of determination.* Within 90 days after receipt of a waiver request, CMS takes one of the following actions:

(1) Approves the request.

(2) Denies the request and notifies the PACE organization in writing of the basis for the denial.

(b) *Date of receipt.* For purposes of the 90-day time limit described in this section, the date that a waiver request is received by CMS from the State administering agency is the date on which the request is delivered to the address designated by CMS.

(c) *Waiver approval.* (1) A waiver request is deemed approved if CMS fails to act on the request within 90 days after the date the waiver request is received by CMS.

(2) CMS may withdraw approval of a waiver for good cause.

Subpart C—PACE Program Agreement

7. Section 460.30 is amended by revising paragraph (b) and adding paragraph (c) to read as follows:

§ 460.30 Program agreement requirement.

* * * * *

(b) The agreement must be signed by an authorized official of CMS, the PACE organization and the State administering agency.

(c) CMS may only sign program agreements with PACE organizations that are located in States with approved State plan amendments electing PACE as an optional benefit under their Medicaid State plan.

Subpart E—PACE Administrative Requirements

8. In § 460.60, paragraphs (b) and (c) are revised to read as follows:

§ 460.60 PACE organizational structure.

* * * * *

(b) *Program director.* The organization must employ, or contract with in accordance with § 460.70, a program director who is responsible for oversight and administration of the entity.

(c) *Medical director.* The organization must employ, or contract with in accordance with § 460.70, 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.

* * * * *

9. In § 460.68 the following changes are made:

a. Paragraph (b) is revised.

b. Paragraph (c) is removed and reserved.

The revision reads as follows:

§ 460.68 Program integrity.

* * * * *

(b) *Direct or indirect interest in contracts.* 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.

* * * * *

10. In § 460.70, the following changes are made:

a. Paragraph (b) introductory text is republished and (b)(1)(i) is revised.

b. Paragraph (e) introductory text is republished and (e)(2) is revised.

c. Paragraph (e)(5) introductory text is republished and paragraphs (e)(5)(vi) through (ix) and (f) are added.

The revisions and additions read as follows:

§ 460.70 Contracted services.

* * * * *

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

(1) * * *

(i) An institutional contractor, such as a hospital or skilled nursing facility, must meet Medicare or Medicaid participation requirements.

* * * * *

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

(1) * * *

(2) Services furnished (including work schedule if appropriate).

* * * * *

(5) Contractor agreement to do the following:

* * * * *

(vi) Agree to perform all the duties related to its position as specified in this part.

(vii) Participate in interdisciplinary team meeting as required.

(viii) Agree to be accountable to the PACE organization.

(ix) Cooperate with the competency evaluation program and direct participant care requirements specified in § 460.71.

(f) *Contracting with another entity to furnish PACE Center services.* (1) A PACE organization may only contract for PACE Center services if it is fiscally sound as defined in § 460.80(a) of this part and has demonstrated competence with the PACE model as evidenced by successful monitoring by CMS and the State administering agency.

(2) The PACE organization retains responsibility for all participants and may only contract for the PACE Center services identified in § 460.98(d).

11. Section 460.71 is added to subpart E to read as follows:

§ 460.71 Oversight of direct participant care.

(a) The PACE organization must ensure that all employees and contracted staff furnishing care directly to participants demonstrate the skills necessary for performance of their position.

(1) The PACE organization must provide each employee and all contracted staff with an orientation. The orientation must include at a minimum

the organization's mission, philosophy, policies on participant rights, emergency plan, ethics, the PACE benefit, and any policies related to the job duties of specific staff.

(2) The PACE organization must develop a competency evaluation program that identifies those skills, knowledge, and abilities that must be demonstrated by direct participant care staff (employees and contractors).

(3) The competency program must be evidenced as completed before performing participant care and on an ongoing basis by qualified professionals.

(4) The PACE organization must designate a staff member to oversee these activities for employees and work with the PACE contractor liaison to ensure compliance by contracted staff.

(b) The PACE organization must develop a program to ensure that all staff furnishing direct participant care services meet the following requirements:

(1) Comply with any State or Federal requirements for direct patient care staff in their respective settings.

(2) Comply with the requirements of § 460.68(a) regarding persons with criminal convictions.

(3) Have verified current certifications or licenses for their respective positions.

(4) Are free of communicable diseases.

(5) Have been oriented to the PACE program.

(6) Agree to abide by the philosophy, practices, and protocols of the PACE organiztion.

Subpart F—PACE Services

12. In § 460.102, the following changes are made: a. Paragraph (d)(2) introductory text is republished and (d)(2)(iii) is revised.

b. Paragraph (d)(3) is amended by removing ''Except as specified in paragraph (g) of this section''.

c. Paragraphs (f) and (g) are removed.

The revisions read as follows:

§ 460.102 Interdisciplinary team.

* * * * *

(d) * * *

(2) Each team member is responsible for the following:

* * * * *

(iii) Documenting changes of a participant's condition in the participant's medical record consistent with documentation polices established by the medical director.

* * * * *

(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: July 17, 2002.

Thomas A. Scully,

Administrator, Centers for Medicare & Medicaid Services.

Approved: September 16, 2002.

Tommy G. Thompson,

Secretary.

[FR Doc. 02–24858 Filed 9–27–02; 8:45 am]

BILLING CODE 4120–01–P

DEPARTMENT OF THE INTERIOR

Office of Hearings and Appeals

43 CFR Part 4

RIN 1090–AA82

Special Rules Applicable to Surface Coal Mining Hearings and Appeals

AGENCY: Office of Hearings and Appeals, Interior.

ACTION: Final rule.

SUMMARY: The Office of Hearings and Appeals is publishing final rules to update addresses and telephone numbers and to conform cross-references and language in existing rules with rules of the Office of Surface Mining Reclamation and Enforcement.

DATES: Effective Date: October 1, 2002.

FOR FURTHER INFORMATION CONTACT: Will A. Irwin, Administrative Judge, Interior Board of Land Appeals, 801 N. Quincy Street, Suite 300, Arlington, Virginia 22203. Phone 703–235–3750.

SUPPLEMENTARY INFORMATION:

I. Background

The rules governing procedures for hearings and appeals under the Surface Mining Control and Reclamation Act of 1977 (SMCRA), 30 U.S.C. 1201–1328 (2000), that appear in Title 43, Part 4, Subpart L, of the Code of Federal Regulations (CFR) have been adopted by the Office of Hearings and Appeals (OHA) at various times since that statute was enacted. Over the years some of the addresses, phone numbers, cross references, and language of those rules have become out of date. For example, the Office of Surface Mining Reclamation and Enforcement (OSM) adopted final rules in December 2000, 65 FR 79582 (Dec. 19, 2000) in Title 30 CFR. The result is that the language and section numbers in OHA's existing rules in 43 CFR part 4, subpart L, that refer to OSM's rules do not correspond to the language and section numbers in OSM's recent rules. The final rules OHA adopts today are intended only to make technical amendments to the rules in Subpart L so that they will conform to the rules in 30 CFR and otherwise be up to date.

Definitions

Some rules in 43 CFR, Part 4, Subpart L, use the abbreviation ''OSM'' for the Office of Surface Mining Reclamation and Enforcement and some rules use ''OSMRE.'' As OSM's definition in 30 CFR 700.5 makes clear, the two abbreviations have the same meaning. The definition in 43 CFR 4.1100(e) is revised to correspond to OSM's definition.

Jurisdiction of the Board

The cross reference in 43 CFR 4.1101(a) to the jurisdiction of the Board, ''as set forth in 43 CFR 4.1(4),'' is out of date. In 1982, the Interior Board of Surface Mining and Reclamation Appeals (IBSMA) was abolished and jurisdiction over appeals under SMCRA was transferred to the Interior Board of Land Appeals (IBLA). *See* 49 FR 7564–7565 (March 1, 1984); 48 FR 22370 (May 18, 1983). IBLA's jurisdiction is now set forth in 4.1(b)(3), so 4.1101(a) is amended to read ''as set forth in 43 CFR 4.1(b)(3).''

In addition, the reference in 4.1101(a) to 43 CFR 4.21(c) is out of date. When 4.1101 was adopted in 1978, 4.21(c) dealt with requests for reconsideration. 43 CFR 4.21 was amended in 1993, however, and 4.21(c) became 4.21(d). 58 FR 4939, 4941 (Jan. 19, 1993). The reference in 4.1101(a) is revised to conform to the 1993 amendment of 4.21.

Several rules have been added to Subpart L since that subpart was originally promulgated in August 1978, *i.e.*, sections 4.1350–4.1356, 4.1360–4.1369, 4.1370–4.1377, 4.1380–4.1387, and 4.1390–4.1394. Some subjects covered in the rules that have been added are not specifically included in the list of subjects under the Board's jurisdiction in 4.1101(a)(1)–(7). The subjects not included by the rules that have been added to Subpart L are therefore added to the list in 4.1101(a) as (8)–(11) and previous sections (8) and (9) are renumbered (12) and (13).

Service

Some of the jurisdictions, addresses, and telephone numbers of the offices of the Office of the Solicitor that are to receive service of a document under 43 CFR 4.1109(a)(1) and (a)(3) have changed. 4.1109(a)(2) is amended to reflect these changes.